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CONSUMER-PATIENT RADIATION SAFETY AND
HEALTH ACT OF 1979

GOVERNMENT

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HEARING

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BEFORE THE

SUBCOMMITTEE ON

HEALTH AND SCIENTIFIC RESEARCH

OF THE

COMMITTEE ON

LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

NINETY-SIXTH CONGRESS

SECOND SESSION

ON

S. 500

TO PROVIDE FOR THE PROTECTION OF THE PUBLIC HEALTH
(INCLUDING CONSUMER PATIENTS) FROM UNNECESSARY
EXPOSURE TO RADIATION

APRIL 3, 1980



Printed for the use of the Committee on Labor and Human Resources

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CONSUMER-PATIENT RADIATION SAFETY AND HEALTH ACT OF 1979

THURSDAY, APRIL 3, 1980

U.S. SENATE,
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, D. C.

The subcommittee met, pursuant to notice, at 9:35 a.m., in room 4232, Dirksen Senate Office Building, Senator Jennings Randolph presiding pro tempore.

Present: Senator Randolph.

OPENING STATEMENT BY SENATOR RANDOLPH

Senator RANDOLPH. Good morning, ladies and gentlemen.

Today's hearing is very important. This subject matter continues with us. Individuals associated with this study have felt that the need for positive action in our effort to probe radiation and public exposure for some time.

I am not sure how many members of our Committee on Labor and Human Resources will be here. It is a very difficult day.

Public exposure to radiation in the healing arts professions accounts for 90 percent of the annual population dose in the United States from manmade sources. By comparison, annual exposure from nuclear facilities accounts for less than 1 percent.

It is estimated that 30 percent of that exposure is unnecessary. The annual direct cost of this unnecessary exposure to our health care system may be \$1½ to \$2 billion. The long-term cost to our health care systems for treatment of illnesses resulting from unnecessary exposure, although not quantifiable, is no doubt substantially more.

The reasons for unnecessary exposure are several—they have been stated in the past—faulty equipment, improper use of X-ray equipment, defensive medicine, economic incentives, and unnecessary screening. This morning, we will focus on the use of radiation in the healing arts.

Although the essential and beneficial role of radiologic services in the diagnosis and treatment of injuries and illness is well recognized and accepted, there is evidence that current procedures result in a greater risk to consumer-patients than is necessary.

In spite of the risk to individuals from radiation exposure and the known adverse health effects that may result, in 40 of our States, any individual may operate X-ray equipment, regardless of training or qualifications.

There are indications, as we study this question, of what I listed as one of the problems, and that is the lack of training, expertise, knowledge in the use of equipment.

Of the estimated 130,000 to 170,000 persons who operate the Nation's 250,000 pieces of medical X-ray equipment, only 80,000 have demonstrated their competence in voluntary certification or State licensing examinations. Seventy-five percent of all nonhospital radiologic procedures in the United States are performed by noncredentialed radiologists.

For over 10 years I, and other colleagues who have joined me, have sought to address this seeming paradox. On two occasions the Senate has passed legislation to provide for licensure of operators, the measure, however, was dropped in conference.

Unfortunately, in the interim, the need for such legislation has not diminished. If anything, with the growing use of radiation in the healing arts, it has increased. Over 300 million X-rays will be taken nationally this year.

The legislation we will discuss today has two principal thrusts:

One, to require the establishment of minimum Federal standards for the licensure of persons who operate machines used for diagnostic or therapeutic purposes which emit ionizing radiation; and

Two, to provide for accrediting educational institutions which conduct training programs for such persons.

[The text of S. 500 follows:]

96TH CONGRESS
1ST SESSION

\$ 500

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

IN THE SENATE OF THE UNITED STATES

FEBRUARY 26 (legislative day, FEBRUARY 22), 1979

Mr. RANDOLPH introduced the following bill; which was read twice and referred to the Committee on Human Resources

A BILL

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

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

SHORT TITLE

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

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FINDINGS

SEC. 102. The Congress finds that—

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

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

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

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

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

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

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

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

1 ations in Medical Diagnostic Radiology in October
2 1967;

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

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

10 (6) the Conference of Radiation Control Pro-
11 gram Directors in May 1974.

12 (e) that the protection of the public health and
13 safety from unnecessary consumer-patient exposure to
14 potentially hazardous radiation from all sources is the
15 primary responsibility of State and local government;
16 and

17 (f) any person who prescribes or administers ra-
18 diologic procedures to consumer-patients, including at
19 Federal facilities, should be required to demonstrate
20 competence by reason of education, experience, and ex-
21 amination.

22 STATEMENT OF PURPOSES

23 SEC. 103. The purposes of this Act, which shall be car-
24 ried out consistent with the maximum protection of public

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

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

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

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

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

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

21 DEFINITIONS

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

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

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

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

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

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

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

PART II—FEDERAL RADIATION PROTECTION

GUIDELINES

PROMULGATION OF RADIATION PROTECTION GUIDELINES

SEC. 121. (a)(1) The Administrator shall, in accordance with Executive Order 10831 and Public Law 86-373 (42 U.S.C. 2021(h)), promulgate Federal radiation guidance with respect to consumer-patient radiation matters directly or indirectly affecting public health. Such guidance shall contain information regarding (A) the sources of consumer-patient radiation exposure and (B) techniques, procedures and methods to minimize unnecessary and nonefficacious consumer-patient radiation exposure.

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

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

1 (1) the application of diagnostic X-rays to con-
2 sumer-patients;

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

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

8 (c) The Administrator shall review and, as appropriate,
9 revise guidelines promulgated by him pursuant to this
10 section.

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

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

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

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

8 (c) The Secretary shall review and, as appropriate,
9 revise the standards promulgated by him pursuant to this
10 section.

11 RECOMMENDED MINIMUM STANDARDS FOR LICENSURE

12 FOR RADIOLOGIC TECHNOLOGISTS

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

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

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

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

12 (c) The Secretary shall review and, as appropriate,
13 revise the standards promulgated by him pursuant to this
14 section.

15

STATE ASSISTANCE

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

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

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

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

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

16 GRANTS TO EDUCATIONAL INSTITUTIONS

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

21 GRANTS TO CERTIFICATION ORGANIZATIONS

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

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

4 STATE PROGRAM GRANTS

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

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

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

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

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

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

4 PART IV—FEDERAL ACTIVITIES

5 FEDERAL AGENCY COMPLIANCE

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

10 FEDERAL ASSISTANCE PROGRAMS

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

20 (b) The President may by order exempt any specific
21 grant, loan, contract, or other form of financial assistance
22 from the requirements of this subsection if he determines
23 such exemption is in the national interest. The President
24 shall notify the Congress in writing of such exemption at
25 least 90 days before it is effective.

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Senator RANDOLPH. Our first witness this morning is Mr. John Villforth, Director of the Bureau of Radiological Health of the Food and Drug Administration.

STATEMENT OF JOHN C. VILLFORTH, DIRECTOR, BUREAU OF RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY MARK BARNETT, ASSISTANT DIRECTOR FOR EDUCATIONAL AND COMMUNICATIONS PROJECTS; AND ROBERT ECCLESTON, SPECIAL ASSISTANT FOR LIAISON

Mr. VILLFORTH. Thank you, Mr. Chairman.

With your permission, I would like to introduce Mr. Mark Barnett and Mr. Robert Eccleston. They are both assistants in my office who have had a long history of association with the area of training and medical radiation.

Mr. Eccleston is a registered radiologic technologist and Mr. Barnett is a pharmacist who has had a long involvement in our training activities; I would appreciate it if they could accompany me.

Senator RANDOLPH. Off the record.

[Discussion off the record.]

Senator RANDOLPH. Will you please proceed.

Mr. VILLFORTH. I am pleased to appear before you to discuss the administration's position on S. 500, the "Consumer-Patient Radiation Health and Safety Act of 1979," its relationship to the Food and Drug Administration's efforts to reduce medical and dental radiation exposure, and the administration's recent initiatives to curtail unnecessary diagnostic X-ray exposure.

S. 500 would require the Department of Health, Education, and Welfare to promulgate voluntary State minimum standards for licensure of radiologic personnel and for accreditation for educational programs preparing radiologic technologists and medical and dental practitioners in the area of X-ray services. The bill would also authorize Federal technical and financial assistance as an inducement for States to adopt these standards.

The Department fully supports the goal of assuring optimum quality in all phases of health care and also endorses the objectives of insuring that diagnostic X-rays are administered with a minimum amount of exposure by competent radiologic personnel.

However, the Department opposes enactment of S. 500, primarily because it duplicates authority already vested in HEW, under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act.

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

In addition, the legislation would give the Environmental Protection Agency responsibilities respecting the establishment of radiation guidance for the healing arts currently exercised by the Secretary of HEW.

On February 21, 1980, following a year-long interagency analysis of Federal ionizing radiation protection and research programs, the

President issued an executive order establishing the Radiation Policy Council. This interagency effort was a result of the Interagency Task Force on the Health Effects of Ionizing Radiation, which was established in May of 1978, and has been referred to as the "Libassi Report."

The Council, chaired by EPA, will be comprised of all agencies concerned with radiation control, and will be responsible for advising on the formulation of broad radiation policies; monitoring implementation of Federal radiation protection strategies; resolving jurisdictional problems among Federal agencies; recommending needed legislation, insuring effective liaison with the States and the Congress; and providing a forum for public input. A companion committee has also been created to address radiation research needs and to develop a comprehensive Federal research strategy.

The President, in a February 21, 1980, letter to the Chairman of the Radiation Policy Council, indicated that the number of opportunities for radiation exposure that were identified by the Interagency Task Force on the Health Effects of Ionizing Radiation—but these had not received a detailed analysis of their risks, benefits, or cost effectiveness. He pointed out that the task force had made a series of recommendations, including a concerted program to reduce exposure in the healing arts, the most significant source of manmade radiation.

One of the tasks of the Council will be to oversee the implementation of a series of recommendations on diagnostic X-ray exposure reduction that was made by the interagency task force.

The task force specifically addressed the problem of training and credentialing of diagnostic X-ray personnel. In addition, the President directed the Council to coordinate for radiation exposure reduction and recommended that the Council should "oversee a broad and effective program to reduce diagnostic radiation exposure from medical and dental sources."

The President, in another memorandum, directed the Council to undertake a comprehensive review of EPA's Federal radiation protection guidance function and other Federal statutory authorities bearing on radiation protection.

In view of these mandates by the President, I believe that legislation at this time would be premature.

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

FDA has also produced educational materials, such as multimedia training package series showing X-ray technologists how to protect their patients and themselves from unnecessary radiation exposure. Over 2,000 of these training packages have been sold, and we estimate that about 25,000 persons view them annually.

To reach those operators who may not have access to formal educational programs, FDA is also working with the Health Resources Administration (HRA), and the American Society of Radiologic Technologists (ASRT), to provide a system through which credentialed and noncredentialed radiologic personnel can assess

their competence and strengthen their areas of weakness. This system will be integrated into the ASRT's nationwide Evidence of Continuing Education (ECE), program.

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

We announced this endeavor in a March 13, 1979, Federal Register notice of intent, a copy of which I would like to submit for the record. To date, we have received over 600 responses from professional organizations, State agencies, and the public sector. These are more comments than we usually get from Federal Register publications, indicating a very keen interest in this problem. We are in the final stages of analyzing these responses, and will publish the recommended standards in the near future.

Another economic and effective means of reducing patient exposure is through quality assurance programs.

Two examples of successful FDA efforts in this area are the "BENT"—Breast Exposure: Nationwide Trends—and "DENT"—Dental Exposure Normalization Technique—programs, which are aimed respectively at mammography and dental X-rays. Both of these programs enable States to identify quickly X-ray facilities where unusually high exposures are occurring.

This is accomplished by mailing specific cards containing radiation measurement devices to hospitals and clinics. The instructions tell the technologist to expose the card as would normally be done in an actual X-ray procedure.

The cards are mailed back to the State agency and "read." Followup visits by State personnel are made to facilities where high exposures are identified in order to pinpoint the problem and to suggest remedial action.

DENT, which is now used in 40 States and local agencies, has succeeded in reducing average dental X-ray exposures by 40 percent. Comparable reductions, perhaps 28 percent, have been achieved among the 46 States now participating in BENT. I just learned all of the Provinces in Canada are using this program and many of our sister Federal agencies are using it in their activities.

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

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

However, other indicators reveal that even with 24 months of education, technologists perform well below their potential. Other factors, not related to credentialing, such as work environment and supervision, also affect technologist performance.

Because noncredentialed X-ray machine operators are today responsible for only about 10 percent of the population dose, we question whether a funding program that would award large sums

of money to the States to institute mandatory credentialing programs will be cost-effective. It is important to note that, although there are a large number of noncredentialed operators in the United States, perhaps 45,000 to 80,000 representing 35 to 50 percent of all operators they are actually responsible for only about 10 percent of the population dose. This is because these noncredentialed individuals tend to be employed in low workload facilities such as general practitioners' offices where they conduct mainly low-dose X-ray examinations such as extremities and chests.

Considering the relatively small percentage of the total radiation dose to the population contributed by noncredentialed operators, we question the cost-effectiveness of a funding program that would award large sums of money to States to institute mandatory credentialing programs, programs which will mainly affect the operators accountable for only 10 percent of the population dose.

I want to digress, if I may, and emphasize some additional information on this point regarding cost-effectiveness.

There are several past observations which I would like to call to your attention. One relates to the scores on a 1974 proficiency test that was conducted by the Department's Health Resources Administration in conjunction with the Educational Testing Service. It was tested on about 1,200 technologists, some of whom were credentialed, some of whom were not credentialed. The results of this 1974 test indicated that, in the category of radiation protection and safety, only 33 percent of the operators who were credentialed passed that portion of the test. It is true that of the noncredentialed operators who took the test, only 14 percent of those passed the radiation safety portion of the examination.

The concern here is not that credentialed operators were more proficient but that the credentialed operators did not in fact achieve a very high score on the radiation protection section of this examination.

Second, we have been collecting data from the States as a part of our Nationwide Evaluation of X-ray Trends (NEXT) program in which State people collect information on exposure and characteristics that contribute to the exposure in medical and dental facilities, and relate them to certain factors such as credentialing, workload, et cetera.

One of the things we observed from this study of several thousand observations has been that X-ray exposure, that is the exposure at the entrance of the skin from a variety of these procedures, differs significantly between the credentialed technologists and noncredentialed operators.

Third, this examination also looked at the question of collimation. This refers to the process whereby the X-ray beam is reduced or limited to the size of the X-ray film. We know that collimation is important because if the X-ray beam extends beyond the area of clinical interest to certain critical organs which should be irradiated, they do get exposed. If we look at the frequency with which the operators collimated adequately, it was only 53 percent of the time. Of course, noncredentialed operators collimated adequately only 28 percent of the time. But the credentialed operators did not perform to the level that one would expect from the training that they had received.

This analysis was supported in addition by the report entitled "The Survey of the Impact of State Licensure on Selected Aspects of Radiologic Technology." This study was conducted by a committee composed of representatives from the American Society of Radiologic Technologists and the American College of Radiology.

A more recent bit of information that I have is extremely important, and by "recent," I mean less than 24 hours old.

The early result is just coming off of our computers. The data were obtained through an FDA study called "Front-End Analysis." The Front-End Analysis project was conceived several years ago when we realized that there were probably other factors that influenced the technologist in the performance of their duties beyond just training and experience. We tried to relate job performance to such things as work environment, the attitudes at the facility, supervision, type of facility, salary, and so forth.

As part of this program, which examined some 2,500 X-ray machine operators, most of whom were credentialed, in about 26 States around the country, we looked at four elements of radiation protection practices that they, the operators, would be expected to employ in performing two types of examinations, the chest examination and a lumbosacral spine examination.

We looked at the following parameters: did they collimate the beam; did they use protective shielding on the reproductive organs; did they measure the patient and did they use technique charts? Those four elements were scored for the two procedures, the chest X-ray and the lumbosacral spine examination. If an operator were performing well in all of these four categories they would have gotten a score of 8.

Our concern is that when we looked at the credentialed operators in this example, their average score was 3.3. For the noncredentialed operators, their score was 2.8. While the credentialed operators did perform slightly better than the noncredentialed operators, but in these four very critical elements we were disappointed that the credentialed operators did not perform at a higher level.

Thus, the key questions relating to job performance are: Is it credentialing? Is it education? Are there environmental factors that influence operator performance?

It was interesting when we went back and looked at some of the other observations, such as, did the facility require the use of technique charts, which is an indication of the degree of supervision and concern about management on this particular situation. In those facilities that did require the use of technique charts, the operators, regardless of whether they were credentialed or not, achieved a mean score was 3.7. In those facilities that did not require a technique chart, the mean score was 2.9.

We also evaluated performance in relation to whether facilities enforced radiation safety rules. In those facilities where radiation safety rules were enforced operators regardless of whether the group was credentialed or not, had a mean score of 3.5 out of 8; while in facilities where safety rules were not enforced, the mean score was 3.

These results have to be looked at in more detail for a variety of other parameters.

I share this because it suggests to us that, one, the operators who are credentialed are not performing as well as we would expect, especially in these very important elements of radiation safety.

Second, there seem to be other factors besides credentialing that influence job performance; for example, the concern for radiation safety on the part of the institution and management.

We suggest that a more workable, cost-effective approach would be to conduct programs to improve the performance of all X-ray personnel and to strengthen entry-level and continuing education of those who are now delivering 90 percent of the population doses through the training package and self-assessment examination and the practitioner package that we are working on.

In addition, we feel that a program of consumer education will help because by informing the consumer of some of these areas and having the consumer interact with the technologist, the machine operators, it will also influence the performance of that operator.

Finally, we think we need to alert the profession to exercise a greater leadership in their institutions, to motivate the technologists in the area of radiation safety.

Mr. Chairman, there is unquestionably a need for assuring the competence of persons who administer radiation to patients, and the FDA is working to reduce medical radiation exposure through programs that involve both credentialed and non-credentialed technologists. The administration's opposition to S. 500 is based upon our belief that it duplicates existing authorities and that other means for exposure reduction may be more cost-effective.

The Federal Government should continue to work with the private sector in devising viable and uniform standards for State licensure agencies and the medical professions. The legitimate role for the Government, we believe, is to provide leadership in the development of such standards by continuing cooperation with States and professional organizations.

I would call your attention to the fact that we do have an appendix that is attached to the testimony and I hope that will be available for the record.

[The prepared statement of Mr. Villforth and the attached appendix referred to follow:]



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

STATEMENT

BY

JOHN C. VILLFORTH

DIRECTOR

BUREAU OF RADIOLOGICAL HEALTH

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

BEFORE THE

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

APRIL 3, 1980

FOR RELEASE ONLY UPON DELIVERY

Mr. Chairman:

I am pleased to appear before you to discuss the Administration's position on S. 500, the "Consumer-Patient Radiation Health and Safety Act of 1979," its relationship to the Food and Drug Administration's (FDA) efforts to reduce medical and dental radiation exposure, and the Administration's recent initiatives to curtail unnecessary diagnostic x-ray exposure.

S. 500

S. 500 would require the Department of Health, Education, and Welfare (DHEW) to promulgate voluntary State minimum standards for licensure of radiologic personnel and for accreditation of educational programs preparing radiologic technologists and medical and dental practitioners in the area of x-ray services. The bill would also authorize Federal technical and financial assistance as an inducement for States to adopt these standards.

The Department is committed to carrying out the responsibility in this area and note that the Administration has undertaken a number of initiatives, including the establishment of a Radiation Policy Council. In addition, we fully support the goal of assuring optimum quality in all phases of health care and also endorses the objective of insuring that diagnostic x-rays are administered with the minimum amount of exposure by competent radiologic personnel. However, the Department opposes enactment of S. 500, primarily because it duplicates authority already vested in HEW, under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. Under existing authority, FDA produces and distributes educational materials for x-ray technologists, provides a system through which radiologic personnel can assess their competence and strengthen their areas of weakness, assists States with licensure programs, and establishes quality assurance programs to help reduce patient exposure.

In addition, the legislation would give to the Environmental Protection Agency (EPA) responsibilities respecting the establishment of radiation guidance for the healing arts currently exercised by the Secretary of HEW.

On February 21, 1980, following a year-long interagency analysis of Federal ionizing radiation protection and research programs, the President issued an Executive Order establishing the Radiation Policy Council. The Council, chaired by EPA, will be comprised of all agencies concerned with radiation control, and will be responsible for advising on the formulation of broad radiation policies; monitoring implementation of Federal radiation protection strategies; resolving jurisdictional problems among Federal agencies; recommending needed legislation; ensuring effective liaison with the States and the Congress; and providing a forum for public input. A companion committee has also been created to address radiation research needs and to develop a comprehensive Federal research strategy.

One of the tasks of the Council will be to oversee the implementation of a series of recommendations on diagnostic x-ray exposure reduction that were made by the Interagency Task Force on the Health Effects of Ionizing Radiation. ^{The Task Force} ~~These tasks~~ specifically addressed the problem of training and credentialing of diagnostic x-ray personnel. In addition, the President directed the Council to undertake a comprehensive review of EPA's Federal radiation protection guidance function and other Federal statutory authorities bearing on radiation protection.

FDA PROGRAMS TO REDUCE RADIATION EXPOSURE

FDA has implemented a combination of cost/effective activities aimed at improving x-ray technologists' performance. To upgrade the education of operators, both in the schools and in continuing, on-the-job training, and to ensure that a proper emphasis is placed on radiation protection, the Agency has actively collaborated with professional organizations in designing educational curricula. FDA has also produced educational materials, such as a multi-media training package series showing x-ray technologists how to protect their patients and themselves from unnecessary radiation exposure. Over 2,000 of these training packages have been sold, and we estimate that about 25,000 persons view them annually.

To reach those operators who may not have access to formal educational programs, FDA is also working with the Health Resources Administration (HRA) and the American Society of Radiologic Technologists (ASRT) to provide a system through which credentialed and noncredentialed radiologic personnel can assess their competence and strengthen their areas of weakness. This system will be integrated into the ASRT's nationwide Evidence of Continuing Education (ECE) program.

FDA has also assisted States with licensure programs to assure that State requirements are consistent and uniform. Toward that end, FDA has proposed to develop, in cooperation with States and professional groups, recommendations on voluntary national standards for the qualifications of medical radiologic technologists. We announced this endeavor in a March 1979 Federal Register notice of intent, a copy of which I would like to submit for the record. To date, we have received over 600 responses from professional organizations, State agencies, and the public sector. We are in the final stages of analyzing these responses, and will publish the recommended standards in the near future.

Another economic and effective means of reducing patient exposure is through quality assurance programs. Two examples of successful FDA efforts in this area are the "BENT" (Breast Exposure: Nationwide Trends) and "DENT" (Dental Exposure Normalization Technique) programs, which are aimed respectively at mammography and dental x rays. Both of these programs enable States to identify quickly x-ray facilities where unusually high exposures are occurring. This is accomplished by mailing special cards containing radiation measurement devices to hospitals and clinics. The instructions tell the technologist to expose the card as would normally be done in an actual x-ray procedure. The cards are mailed back to the State agency and "read." Followup visits by State personnel are made to facilities where high exposures are identified in order to pinpoint the problem and to suggest remedial action. DENT, which is now used in 40 States and local agencies, has succeeded in reducing average dental x-ray exposures by 40 percent. Comparable reductions ^{perhaps 25-70} have been achieved among the 46 States now participating in BENT.

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

Mandatory credentialing assures that entry-level x-ray equipment operators possess at least minimal competence. In addition, recent data seem to indicate that training and education, which would be required by State licensure, improve technologist performance to some extent. However, other indicators reveal that even with 24 months of education, technologists perform well below their potential. Other factors, not related to credentialing, such as work environment and supervision also affect technologist performance.

Because noncredentialed x-ray machine operators are today responsible for only about 10 percent of the population dose, we question whether a funding program that would award large sums of money to the States to institute mandatory credentialing programs will be cost-effective. We suggest that a more workable, cost-effective approach would be to conduct programs to improve the performance of all x-ray personnel and to strengthen entry level and continuing education of those who are now delivering 90 percent of the population dose.

SUMMARY

Mr. Chairman, there is unquestionably a need for assuring the competence of persons who administer radiation to patients, and the FDA is working to reduce medical radiation exposure through programs that involve both credentialed and non-credentialed technologists. The Administration's opposition to S. 500 is based upon our belief that it duplicates existing authorities and that other means for exposure reduction may be more cost-effective.

The Federal Government should continue to work with the private sector in devising viable and uniform standards for State licensure agencies and the medical professions. The legitimate role for the Government, we believe, is to provide leadership in the development of such standards by continuing cooperation with States and professional organizations.

APPENDIX

GENERAL INFORMATION

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

Approximately 130,000 medical x-ray machines are used to conduct about 186 million x-ray examinations annually, and 172,000 dental x-ray units are employed in 92 million dental x-ray examinations each year. According to our estimate about 85,000 of the 130,000 to 170,000 persons now operating medical x-ray equipment are certified by either the American Registry of Radiologic Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT), or licensed by one of the eleven States and one territory (New York, New Jersey, California, Kentucky, West Virginia, Florida, Vermont, Arizona, Montana, Oregon, Hawaii, and Puerto Rico) administering such programs. This leaves approximately 45,000 to 85,000 non-credentialed individuals who perform x-ray examinations with training and job skills that can only be approximated.

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

about 200,000 dental hygienists and assistants currently conduct x ray examinations; about 145,000 of these (primarily dental assistants) are non-credentialed.

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

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

FDA PROGRAMS

A promising area for reducing the number of medically unnecessary x-ray examinations is in the development and dissemination of x-ray referral criteria--indications for x-ray procedures based on patient history, signs, and symptoms. This guidance-setting activity represents one of the

cornerstones of our efforts to assist clinicians in deciding when X rays are needed.

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

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

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

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

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

Because patients themselves sometimes request unnecessary x-ray examinations or resist appropriate procedures, the role of the patient should not be overlooked in seeking ways to reduce unnecessary exposure. Aware consumers can play an important role in helping to minimize exposure by requesting special shielding for the reproductive organs, alerting the physician about the possibility of pregnancy, or suggesting

the use of previous x-rays to avoid a repeat examination. The FDA has instituted a consumer-patient education program to relay basic messages and information about how consumers can avoid needless medical radiation exposure. We have, for example, distributed over 500,000 wallet size x-ray record cards which enable patients to keep track of their own examinations and to inform practitioners about previous exposures.

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

CURRENT HEW AUTHORITY RELATING TO PROVISIONS OF S. 500

Part III of S. 500 directs the Secretary to promulgate voluntary minimum standards for the accreditation of educational institutions conducting education programs in radiologic services and voluntary minimum standards for licensure of radiologic technologists. Recommendations on voluntary national standards for the qualifications of medical radiologic technologists are now being developed by FDA under authority, delegated to the Commissioner by the Secretary (21 CFR, Part 5, Subpart A), of section 356 of the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263d) and sections 301 and 311 of the Public Health Service Act (42 U.S.C. 241 and 243).

Section 356 of the Public Health Service Act provides for the establishment and conduct of programs designed to protect the public health and safety from electronic product radiation and authorizes making recommendations where appropriate. Section 301 and 311 provide the broad responsibility to advise and promote cooperation between the States on matters relating to protecting the public against specified radiation hazards.

Part III of S. 500 also authorizes the Secretary to make grants to State radiation protection agencies, professional organizations, and education programs, to carry out the purposes of the bill. Under section 796 of the Public Health Service Act, the Secretary has been directed to make grants to "eligible entities" (i.e., schools, States, and universities) for projects relating to training, credentialing, and continuing education of allied health personnel.

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

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

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

Senator RANDOLPH. Thank you very much, Mr. Villforth.

You will recall that I said I did not believe that credentialing was the entire problem here. There are also other factors we consider important.

Is it not true that in the early 1970's the Department of Health, Education, and Welfare instituted a moratorium on further credentialing of the allied health professionals?

Mr. VILLFORTH. Yes, sir; that is correct.

Senator RANDOLPH. And the moratorium, after extensions, has now expired?

Mr. VILLFORTH. That is correct.

Senator RANDOLPH. Is that to your liking?

Mr. VILLFORTH. That the moratorium has expired?

Senator RANDOLPH. Yes.

Mr. VILLFORTH. Yes, sir.

Senator RANDOLPH. What is the Department's current position on this subject?

Mr. VILLFORTH. I think the Department has endorsed the provisions of Recommendation No. 2 in the July 1977 report on "Credentialing Health Manpower". There are six recommendations altogether in that document.

Recommendation No. 2, if I may paraphrase, says, "National standards for credentialing selected health occupations should be developed and evaluated by professional organizations, other elements in the private sector and State governments, with the Federal Government acting as a convenor of the involved parties". I think that the Department feels strongly about this and supports this.

Senator RANDOLPH. On March 20, 1980, you testified before the Governmental Affairs Subcommittee on Energy, Nuclear Proliferation and Federal Services. At that time, you stated that several thousand deaths per year resulted from radiation exposure exclusive of radiation-induced cancer.

Are more specific approximations of the number of deaths and illnesses, both cancer-related and other, available?

Mr. VILLFORTH. May I amplify my comments at Senator Glenn's hearing?

The statement that several thousand cancer deaths might result annually from diagnostic radiation is a high estimate based on the 1972 report of the committee on the Biological Effects of Ionizing Radiation of the National Academy of Sciences. On page 91 of that report the committee, responding to the needs of the regulatory agencies for guidance in setting radiation protection standards for the general population, stated:

By extrapolation, it can be estimated that the number of deaths per 0.17 rem/yr. in the entire U.S. population might range roughly from 3,000 to 15,000, with the most likely value falling in the range of 5,000 to 7,000 (or 3,500/0.1 rem per year).

Applying these risk figures to our estimate that the maximum annual per capital dose to active bone marrow from diagnostic X-rays in the United States may be as much as 0.077 rem per year,¹ we concluded that the risk estimate quoted above implied that, at equilibrium, diagnostic X-ray exposure might result in several

¹ Shleien, et. al., Health Physics, 34:587-601, June 1978.

cancer deaths in the U.S. population annually. To put this estimate in perspective, it should be noted that about 405,000 cancer deaths will occur in the U.S. population in 1980. Thus, on this basis X-ray-induced cancers might account for between 0.5 and 1 percent of the total cancer deaths in this country.

Any such estimate is attended by considerable uncertainty and imprecision. Among the problems that contribute to the uncertainty are the following:

One, the per capita population X-ray dose estimate is derived from 1970 data.

Two, the 0.077 rem per capita X-ray dose estimate is based on dose to the bone marrow.

Three, the estimate assumes that a state of equilibrium has been reached—that is, that roughly 0.077 rem year has been received by the population from medical X-rays for many years.

Four, the risk estimate quoted from the 1972 Academy report is based on the assumption of a linear relationship between radiation dose and excess cancer and on observations made at high doses and high dose rates for which we have reliable human data; to make any estimate at low doses we must extrapolate from the high-dose observations in some fashion. The limitations under which the Academy committee labored are expressed in the following quotation from page 88 of its 1972 report:

* * * expectations based on linear extrapolation from the known effects in man of larger doses delivered at high dose rates in the range of rising dose-incidence relationship may well over-estimate the risks of low-LET radiation at low dose rates and may, therefore, be regarded as upper limits of risk for low-LET irradiation. The lower limit, depending on the shape of the dose-incidence curve for low-LET radiation and the efficiency of repair processes in counteracting carcinogenic effects, could be appreciably smaller (the possibility of zero is not excluded by the data).

Low-LET, or sparsely ionizing, radiation includes X-rays.

Five, the estimate of cancer deaths attributable to diagnostic X-ray does not take full account of the age-specific variation in cancer incidence, in exposure to diagnostic X-ray, and in excess cancer risk per unit of radiation exposure.

In sum, then, although estimates can be made of the possible effect of diagnostic radiation on the mortality experience of the U.S. population, the underlying data and the assumptions upon which they must be based do not inspire great confidence in such estimates. Incidence of radiation-induced cancers is too low for direct observation and radiation carcinogenesis is too little understood to provide a secure basis for extrapolation from the fairly adequate human observations at high doses and high dose rates into the low-dose region of diagnostic X-ray. This uncertainty notwithstanding, agencies and organizations responsible for protecting the public health must make the prudent assumption that radiation of low doses can be carcinogenic in humans.

Senator RANDOLPH. This is very personal.

You expressed yourself using the words "exciting prospects."

Mr. Villforth, I am not sure that exciting is the right word; the word that I would use, in view of the tragedies that are involved with what we are discussing today, except that you do feel that there are some answers that you have not found. You are trying, and others, to secure those answers, even though you come in opposition to S. 500.

Mr. VILLFORTH. Yes, sir. By "exciting," I mean that the technology which we did not expect to be there several years ago is now emerging and will help achieve some very real solutions. It is exciting to me to think that in a very short time, in the next 10 years, that this technology will have a significant impact on reducing the doses. The technology I am talking about is hardware technology.

Senator RANDOLPH. You realize that in our legislation there are certain medical professionals, doctors, dentists, podiatrists, who are not covered; is that right?

Mr. VILLFORTH. Yes, sir.

Senator RANDOLPH. And, of course, they are licensed, are they not?

Mr. VILLFORTH. Yes.

Senator RANDOLPH. So that is the reason, basically, for what we are doing. Licensed professionals would be exempt from the provisions of the act.

Now, in your personal view, what is your feeling about this exemption? Is it justified, or should these professions be subject to provisions of S. 500?

Mr. VILLFORTH. I think again the answer has to do with cost-effectiveness. I think the answer has to do with getting those professionals more committed to the area of the proper selection of the patient, using what we refer to as referral criteria. Again, we have seen some successes by having physicians select those patients will be most likely to receive benefits from the radiation by using these screening procedures or selection procedures, and thereby reducing the dose considerably.

We think that our activities in a radiological health learning project that we have in the majority of the medical schools in this country to teach radiation protection, which includes documents like this, recently published documents, entitled "The Selection of Patients for X-Ray Examinations," covering many of the principles of radiation protection, and some of the principles of selection and the introduction of this material in the medical curriculum and into continuing education programs for dentists, physicians, chiropractors, et cetera will in fact have a greater impact from a cost-effective standpoint than would a formal credentialing program.

Senator RANDOLPH. I do not want to point to what we have tried to do here on the Hill because we are subject to error, but for 10 years we have been trying to move in the direction of this legislation, which is again put before us.

Would you care to say—and I am not asking for you to pat anyone on the shoulder here on the Hill, but the work we are doing, the work we are trying to accomplish, did it cause a stepped-up interest in your agency?

Mr. VILLFORTH. There is no question, absolutely no question. Whether it is the work of your past interest by the introduction of S. 500 in past years and your leadership in that area, whether it is the introduction of H.R. 5934, H.R. 5023 and former bills, when Congressman Koch was here—all of this reflects a sincere interest on the part of the Congress. Whether or not these bills are passed, the impact back on us as a regulatory agency is real. This is reflected, I think, very clearly in the results of the Interagency

Task Force recommendations, the so-called Libassi Report, in which the Intragency Task Force, chaired by Mr. Peter Libassi recommended specifically that some measures should be undertaken in cooperation with professional groups to improve the availability, training and credentialing of personnel who administer radiation-related procedures. This type of recommendation, I think, is clearly the reflection of the leadership of the Congress, which is a reflection of the concern of the public. This type of recommendation will be examined by the Radiation Policy Council from a cost-effective standpoint.

In the meantime, it has impacted on our programs. I think the type of materials—this brandnew document for professionals is a clear example. The front-end analysis which gives us the opportunity to examine more clearly whether credentialing or the leadership on the part of the profession has impacted more substantially on the way technologists have performed.

The fact that we published a notice of intent in March of last year following the Secretary's February 27, 1979 announcement in which the Commissioner of the Food and Drug Administration was directed to be more aggressive in following up the recommendations of the so-called Libassi Committee. All of these things, I believe, are reflections of the type of leadership you have shown.

Senator RANDOLPH. What you are saying, Mr. Villforth, you are indicating that the FDA promulgated the so-called model State law, in 1970. Is that correct?

Mr. VILLFORTH. Yes.

Senator RANDOLPH. Between then and now, there has been an effort to educate the public and the involved groups about the inherent dangers in the use of radiation. Is that correct?

Mr. VILLFORTH. Yes, sir.

Senator RANDOLPH. Do you believe that a constant flow of information is getting out?

Mr. VILLFORTH. Yes, sir.

Senator RANDOLPH. Including the necessity to reduce patient exposure to the minimum effective level.

What do you call the minimum effective level?

Mr. VILLFORTH. We always give an answer to this that is not satisfactory, and it is, that which is necessary for the clinician to make the diagnosis. That says that if a chest X-ray can be adequately done with an exposure of 10 to 15 milliroentgens of exposure at the surface of the skin, but the X-ray is clinically unnecessary then it is a wasted exposure, regardless of how low the level is. It has to be coupled with whether the X-ray is needed, and that is in the mind of the clinician, and his clear understanding of whether it is needed for the well-being of the patient.

Second, when it is needed, it has to be conducted in such a way that the exposure is at the very minimum. One of the things that I tried to illustrate with some of the examples we had from the front-end analysis, and from the nationwide evaluation of X-ray trends, is that we do not seem to observe that credentialed technologists are working at the level we would have expected. So we have to do more homework in those training and educational programs, more so than adding new credentialing programs.

Senator RANDOLPH. This effort goes on, as you have indicated.

What is your reply to the fact that only eight additional States during this 10-year period have established licensure for the front-line users of radiation?

Mr. VILLFORTH. I would say there are probably several reasons:

One is perhaps lack of clear leadership from our department as to exactly what has been expected by the States. Separate from that is this question of cost effectiveness. We understand from some informal discussions we recently had with people in the State of Kentucky—they have a good licensure program—that the cost of that program is about twice the revenue they bring in through the licensure fees. So any of the State programs examining this effort are going to ask whether it is going to be cost effective; whether it is going to put an unreasonable drain on the already scarce radiation-protection resources in the State agencies.

As you know, States like Pennsylvania that are forced to divert a considerable effort as a result of Three Mile Island, cost effectiveness and the maximum use of their personnel becomes a very real consideration. I think these concerns, plus a lack of leadership, are very real and reasons why the States have not rushed out to embrace the recommendations?

Senator RANDOLPH. They have not rushed, have they?

Mr. VILLFORTH. No, sir.

Senator RANDOLPH. Approximately 45,000 to 85,000 individuals operating as technologists remain noncredentialed.

Do you have any further comment on why that situation exists? It may be nothing beyond what you have said, but that is a rather startling number of people that are impacting the lives of others.

Mr. VILLFORTH. That is a large percentage, as I said earlier; up to 50 percent of all X-ray equipment operators. I suspect there is a large economic factor in that in that many of these people are working in facilities which are low workload, private practitioner facilities, maybe industrial clinics doing just X-rays. I am less concerned with the fact that that number is 50 percent or 37 percent, or whatever, because the actual impact of these people, as I said earlier, is only about 10 percent of the total dose. They work in low workload facilities. They perform the kinds of examinations that do not contribute as significantly to the dose of the patient and thus the risk, as do those credentialed operators who tend to perform in the bigger hospitals where sophisticated high dose procedures are done, such as gall bladder, fluoroscopy, and so forth. Although the numbers are startling in terms of the contribution of those people in terms of dose, if we are to look at it from a radiological standpoint, the contribution is not that great, and thus the question of cost effectiveness becomes predominant.

Senator RANDOLPH. I am sure you know that S. 500 provides for grants to States and national accrediting and certifying organizations to assist them in developing and implementing standards.

Does the Administration consider grants to be necessary, or should the legislation provide only for restrictions of States' participation in other Federal programs for failure to comply with S. 500's procedures?

Mr. VILLFORTH. I think, sir, that the need for grants to stimulate this type of program is—perhaps would be in evidence by the slow-

ness the program has taken in the past, presuming that one would take the direction of the bill S. 500.

Senator RANDOLPH. Possibly a more efficient approach would be to immediately order medicare and medicaid to pay for radiologic examinations or treatments only if standardized criteria are followed in ordering the treatment, the X-ray facility had certified equipment and an adequate quality assurance program and that the machine operator was properly licensed and trained.

Would that have any appeal?

Mr. VILLFORTH. That is the type of provision, I think, that needs to be examined with the Radiation Policy Council, again as to the cost effectiveness. I think that that is an alternative that certainly must be studied if one wants to implement the program. Again, one has to look at the cost effectiveness and the level of performance of the credentialed versus the noncredentialed operators and see if there are alternative ways of improving this performance.

Senator RANDOLPH. Mr. Villforth, in your testimony you said that HEW, under the Public Health Services Act and the Federal Food, Drug and Cosmetic Act, has authority to effectuate the purposes of S. 500, licensure and accreditation.

How long has HEW had this authority?

Mr. VILLFORTH. I think as far as the Radiation Control for Health and Safety Act, that goes back to 1968. As far as the Food, Drug and Cosmetic Act, that goes back way beyond that.

Senator RANDOLPH. I have a feeling that although HEW has had the authority, it has not and will not use that authority. The people will continue to be unnecessarily exposed to radiation in X-ray procedures.

Now, the Congress may in its judgment wish to assure that the public is only exposed to radiation by qualified technologists. Based on HEW's record to date, it would appear to me that the legislation we have introduced is required. I am not sure whether you agree with that personally.

One further observation, if I may.

Do you think that parts of S. 500, the thrust of S. 500, would it be helpful, would it stimulate, would it fill a void?

Mr. VILLFORTH. I want to make sure that my previous answer was correct. I want to make sure that I left you with the impression that the department, through its Radiation Control for Health and Safety Act, and the Food, Drug and Cosmetic Act has the authority for voluntary standards. We do not have specific statutory authority to mandatorily impose such standards on the States. We do not have that authority.

To answer your latter question, I think that——

Senator RANDOLPH. I think that clarification is helpful to me and is necessary for our record.

Mr. VILLFORTH. I do not think I was clear in my previous answer.

To your most recent question, I think cost-beneficial considerations must be weighed in determining whether S. 500 is the way to go, and again I would retreat back to the statement that the Radiation Policy Council, set up by the President, will address these types of issues including, as directed by the President, the healing arts radiation issue, I think that type of analysis will await the Radiation Policy Council.

Senator RANDOLPH. Mr. Villforth, we appreciate your counseling with us. We have additional questions that we will give to you. If you would respond to those questions, your replies will be made a part of the printed record.

Would that be agreeable?

Mr. VILLFORTH. Yes, it is agreeable.

[The following was received for the record:]

ANSWERS TO QUESTIONS ON S. 500

Question 1(a) As you are aware, I introduced S. 500 on February 26, 1979. Early in March the Committee, by letter, requested a bill report from the Department of Health, Education, and Welfare. Over 13 months have elapsed and we have yet to receive the report. Can you explain the difficulty in developing the bill report?

The bill report was mailed to the Committee on April 2, 1980. A copy is enclosed.

Question 1(b) Inasmuch as your Bureau, the Bureau of Radiological Health, completed its report some time ago. We would appreciate your submitting that report for the Record, as well as the Food and Drug Administration's (FDA's) report to Health and Human Services. Is there any difficulty in complying with this request?

We will not be able to comply with your request for BRH or FDA reports on S. 500. Those reports are preliminary comments on the legislation, developed in preparation of an HEW position, which is contained in the final bill report. Once that position is finalized it is the Department, FDA, and BRH position on the bill.

Question 2) This past June 20th the "Libassi Report," the report of the Interagency Task Force on the Health Effects of Ionizing Radiation, recommended improving the availability, training, and credentialing of personnel who administer radiation-related procedures. This recommendation was premised on the finding that

diagnostic exposure to radiation in the healing acts should be targeted for early and concerted action. In a statement released that day, the Secretary of HEW, at the time, Secretary Califano, said that FDA will expand and expedite its current program for setting specific guidelines for the use of common x-ray procedures, and specific guidelines for the education, certification, and testing of x-ray, nuclear medicine, and radiation therapy technicians. Would you please review for the Committee what programs FDA and BRH have implemented to effect that recommendation and directive?

A. X-Ray Examination Guidelines

The attachment to our testimony outlined the current efforts of FDA to develop and disseminate x-ray referral criteria--guidance on ordering x-ray procedures based on patient history, signs, and symptoms. This activity began in October 1978, prior to the Secretary's directive, with the Department sponsored National Conference on Referral Criteria for X-Ray Examinations. Pursuant to a recommendation of the Conference, FDA has, thus far, formed three professional panels to examine referral criteria for chest X rays, x-ray pelvimetry, and voiding cystourethrography in children. The Agency has also awarded five research grants to individual clinical investigators to study the clinical value of other x-ray procedures. We anticipate that this work will culminate in a series of policy statements and issue through various FDA and professional communication channels.

B. Technologist Training/Credentialing Guidelines

One month after the Secretary's directive, FDA published in the Federal Register a Notice of Intent to develop voluntary national standards for the qualifications of medical radiation technologists. The Agency has received in excess of 600 comments, which are in the final stages of analysis. This action will lead to the issuance of credentialing guidelines that can be employed principally by State licensure agencies in credentialing x-ray personnel. Agency staff have also participated on a task force of the Conference of Radiation Control Program Directors, which is designing licensure program criteria that will have an integral part in the Federal guidelines.

FDA has collaborated with the American Society of Radiologic Technologists (ASRT) in the development of a model curriculum for x-ray technologist educational programs and with the American Registry of Radiologic Technologists (ARRT) toward the generation of radiation protection questions for inclusion in its national registry examination. It has also contracted with ASRT to devise a continuing education program, which will be made available to credentialed and non-credentialed x-ray equipment operators.

Question 3) In your testimony you outlined the Department's efforts to reach credentialed and non-credentialed radiologic personnel. Although I endorse these efforts, I question how the program will reach the estimated 50,000 to 90,000 non-credentialed radiologic personnel. Please explain.

Reaching non-credentialed x-ray equipment operators with our education materials has been a long-standing problem. To date, most of our educational materials have been used in schools which train individuals destined to become credentialed and in hospitals which largely employ credentialed x-ray technologists. To help resolve the problem, we recently developed an inexpensive modular learning system. It consists of self-learning packages on different topics. This system will be promoted by the American Society of Radiologic Technologists through State radiation control agencies, physician and allied health specialty groups, and established x-ray technology training programs.

In addition, quality assurance programs such as the Dental Exposure Normalization Technique (DENT) and the Breast Exposure: Nationwide Trends (BENT), described in our testimony, improve the performance of all affected technologists by demonstrating how patient exposures can be reduced and image quality improved.

Question 4) In your testimony, you advocated programs to strengthen entry-level competence of radiologic technologists. How is this feasible when in 40 States no formal training or demonstration of competence is required to become an x-ray technologist?

It should be emphasized that even though 40 States do not require that x-ray equipment operators be credentialed, the great bulk of the population exposure in the United States is delivered by credentialed individuals. This does not mean that we are prepared to write off non-credentialed technologists (See answer (B.) to question 2). However, since our data show even credentialed technologists are

not performing as well as they could, we will strive to improve their competence. This means strengthening existing educational and credentialing systems.

Question 5) Which Federal agency do you feel is best equipped to develop and implement standards for licensure or certification and accreditation for providing radiologic services?

The Secretary discussed this issue in the Department's report to the Committee on S. 500. While this Department has traditionally been delegated responsibility to implement programs related to healing arts radiation, the Radiation Policy Council will be reviewing the responsibilities of the various agencies in reducing radiation exposure. This Department will participate in Council discussions relating to this subject.

Question 6) At the time I introduced S. 500, under applicable law, general guidelines for radiation exposure were set by the Environmental Protection Agency (EPA) and individual regulatory standards. On February 21, the President, by Executive Order, established the Radiation Policy Council. What impact does the existence of the Council have on the Former "Lead Agency" role of the EPA in general guidelines?

The EPA's "Lead Agency" role in establishing Federal radiation protection "guidance" will be re-examined by the Policy Council, pursuant to a memorandum from the President to the Chair of

the Radiation Policy Council. It is, therefore, premature for us to make any judgments as to the present system of institutional controls.

Question 7(a) FDA and BRH, under existing law, are "responsible for preventing sickness, injury and death by assuring that procedures are safe, effective, and properly manufactured and used." In the areas of licensure and accreditation for radiologic technologists and training institutions, what are the existing constraints under applicable law to implementing a program as set forth in S. 500?

As we have stated in our bill report, S. 500 duplicates authority the Department already has under current law for licensure and accreditation of radiologic technologists and training institutions, respectively.

Question 7(b) Is legislative action necessary before the public can be assured that only trained and qualified individuals are administering radiation when they are exposed?

The bulk of FDA's authority in the radiation area is derived from the Public Health Service Act (section 356), as amended by the Radiation Control for Health and Safety Act of 1968 (P.L. 90-602). This Act empowers the Secretary, and by delegation, the Commissioner of FDA to:

- "plan, conduct, coordinate, and support research, development, training, and operational activities to minimize the emissions of and the exposure to, unnecessary electronic product radiation."
- "make such recommendations relating to such (radiation) hazards and control . . ."

It is under this authority that FDA has cooperated with the States and professional organizations over the years to improve the performance of radiologic personnel. The Radiation Control Act also permits FDA to work with these groups on a voluntary basis toward the development of national credentialing standards.

In addition, as outlined in our testimony of April 3, 1980, we have made significant progress in reducing medical x-ray exposure through the BENT, DENT, and other programs administered by FDA. We anticipate this progress to continue without additional legislation.

Finally, we note that the Radiation Policy Council is mandated to resolve problems of jurisdiction among Federal agencies and recommend legislation. In light of these two mandates, it would be premature for the Department to recommend legislative action, at this time.

Senator RANDOLPH. We plan on keeping the hearing record open until April 11.

We are glad to have counseling from anyone who has a bona fide interest in this subject, to keep in touch with us. We want all of you to know that we need your counseling and information. That does not just confine itself to those testifying today.

Thank you, Mr. Villforth and your associates, for coming.

Next, we have a panel consisting of Mr. Daniel P. Donohue, Mr. Jack Stanton, and Mr. George Alexander.

Mr. Donohue, will you go first?

Please give your name, the society which you head, and what other material you would like printed for the record.

STATEMENTS OF DANIEL P. DONOHUE, R.T., PRESIDENT, AMERICAN SOCIETY OF RADIOLOGIC TECHNOLOGISTS, DANIEL FREEMAN HOSPITAL MEDICAL CENTER, INGLEWOOD, CALIF.; JACK STANTON, MEMBER, EXECUTIVE COMMITTEE, CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, AND CHIEF, BUREAU OF ENVIRONMENTAL HEALTH, STATE OF NEW HAMPSHIRE, CONCORD, N.H.; AND GEORGE ALEXANDER, PRESIDENT, TECHNOLOGISTS SECTION, SOCIETY OF NUCLEAR MEDICINE, NEW YORK, N.Y., A PANEL

Mr. DONOHUE. Mr. Chairman, members of the subcommittee, my name is Daniel P. Donohue, R.T. I am the director of the School of Radiologic Technology at Daniel Freeman Hospital Medical Center, Inglewood, Calif. I have been a practicing radiologic technologist for more than 20 years and am certified by the American Registry of Radiologic Technologists.

Mr. Keller, the executive director of the American Society of Radiologic Technologists, was unable to participate in this hearing this morning.

As president of the American Society of Radiologic Technologists, founded more than 50 years ago for the express purpose of enhancing through education, the proper and safe delivery of medical radiological services. As such, we welcome the opportunity to appear before you today during these hearings on S. 500 and we commend the subcommittee for its attention to this very timely subject.

In the past year, we have heard considerable concern related to the risk from radiation exposure, especially related to the Three Mile Island incident. And yet, less than 1 percent of the consumer's exposure to ionizing radiation is attributable to the normal operation of nuclear powerplants.

However, 90 percent of public exposure to man-made ionizing radiation results from medical procedures, primarily diagnostic X-ray examinations.

The production of x-radiation as utilized in the practice of medicine is an invaluable tool in the diagnosis and treatment of disease. But the utilization of x-radiation in medicine is not without risks and an inherent potential of biological damage to healthy tissue. As you know, any exposure to ionizing radiation, however small the dose, increases this risk of producing biological damage.

Therefore, the improper utilization of x-radiation in medicine resulting from excessive exposure during a diagnostic examination or the unnecessary exposure resulting from repeated examinations pose a genuine threat to the health of the patient without providing the anticipated benefit to the patient.

I am here this morning to inform the members of this subcommittee that improper utilization and the production of excessive and unnecessary radiation exposure is a widespread practice throughout these United States. Overutilization and improper utilization of x-radiation in the practice of medicine is a genuine and ever-increasing health hazard to the public and must be dealt with now.

There are an estimated 130,000 to 170,000 operators of medical X-ray equipment throughout the United States. Of these, only approximately 90,000 have received formal training or have demonstrated their competency through voluntary certification or State licensing examination. The remaining 40,000 to 70,000 are operating X-ray equipment and administering potentially harmful ionizing radiation to human beings without having to demonstrate technical knowledge, scientific understanding, clinical competency, or professional responsibility for the practice of proper radiological procedures.

In most States of the Union, a physician utilizing X-ray equipment in this practice is under no obligation to ascertain or require any credential or specific training of the person he employs to operate this equipment. Anyone, literally off the street, can be hired this morning and be operating this potentially dangerous equipment the very same day. This person can apply x-radiation on human beings without having any knowledge or awareness of the potential biological hazard to themselves and the patient.

Members of the American Society of Radiologic Technologists strive to perform radiological examinations with minimal risk to the patient and to ourselves and to eliminate excessive and unnecessary radiation in the performance of our profession.

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

As we indicated on June 22, 1979, in response to the Food and Drug Administration's Notice of Intent, to develop recommendations on voluntary national standards for qualifications of medical radiation technologists, Federal Register, March 13, 1979, we believe that qualifications for radiologic technologists would result in a significant reduction of radiation exposure to the patient.

I would point out that this effort being pursued by the FDA appears to be in agreement with section 132 of S. 500, thus lending credence for enactment of this legislation, the Consumer Patient Radiation Safety Act of 1979.

Since 1967, with introduction of the Radiation Health and Safety Act, now Public Law 90-602, the American Society of Radiologic Technologists has supported the enactment of Federal minimum standards of education and training for operators of medical radiation equipment.

We continue to support Federal legislation giving impetus to State licensure based on national standards, preferably the standards advocated by the American Registry of Radiologic Technologists, a national voluntary certification agency.

The ARRT is currently cooperating with licensure boards in several States by offering their credentialing examination to candidates identified by the States.

The ASRT does not believe there is an alternative to uniform national standards. We remain firm in our opinion that without uniform national standards for qualifications of medical radiation technologists, the public will remain unprotected and at the mercy of untrained personnel.

Because of the unique nature and inherent danger of radiation, the ASRT believes that every patient undergoing a radiological examination has the right to have that examination performed properly and with minimal risk by a qualified operator. This right would be assured and protected by S. 500, when enacted.

This bill, S. 500, while embodying the rights of all consumer/patients, encourages State adoption of national standards for the qualifications of educational programs and for personnel that provide radiological health care services. Further, it promotes utilization of a voluntary system in implementing those standards.

Only 10 States in the Nation have seen fit to regulate or require licensure of individuals who operate this biologically hazardous equipment. Within these 10 regulated States, the standards differ widely in both scope and practice. It is our belief that to require each State to initiate a credentialing program without providing uniform standards would not provide the necessary consumer protection they have a right to expect.

Accredited programs for the education of radiologic technologists already exists on a voluntary basis in every State. The U.S. Office of Education currently recognizes the Committee on Allied Health Education and Accreditation as the accrediting agency for these more than 800 programs.

For those 40,000 to 70,000 individuals not certified by the voluntary national certifying organization, a criteria referenced, performance oriented examinations can be utilized as a measurement tool and a prerequisite for licensure. These considerations are offered as substantiating evidence that facilitation, implementation, and cost to State government can be minimized by utilizing national voluntary standards.

While S. 500 encompasses all technological operators of ionizing radiation equipment, it distinguishes between the types of operators and provides for licensure in a particular specialty, such as diagnostic X-ray, radiation therapy, or nuclear medicine. It also affords flexibility in providing for upper career mobility, a concern of health manpower agencies.

In 1968, Senator E. L. Bartlett observed that:

The seriousness of this health hazard, particularly the damage radiation can do to human genes, damage which may not show for generations, have led most, if not all, thoughtful men to agree that excessive or unnecessary doses of radiation should be eliminated.

Senator Bartlett then noted:

There are two ways to eliminate unnecessary radiation—first, to insure by the establishment of performance standards that x-ray equipment does not emit unnecessary radiation; and, second, to insure the licensing of individuals and the accrediting of schools so that technologists operating medical equipment are qualified.

The President of the United States has determined that the time has come for action. On January 26, 1979, he signed Executive Order No. 10831, which approved a number of recommendations for the guidance of Federal agencies. Recommendation No. 8 stated:

Operation of medical or dental x-ray equipment should be by individuals who have demonstrated proficiency to produce diagnostic quality radiographs with the minimum exposure required; such proficiency should be assessed to national performance-oriented evaluation procedures or by didactic training and practical experience identical to, or greater than, training programs and examination requirements of recognized credentialing organizations.

This recommendation had previously been agreed to and endorsed by the Administrator of the Environmental Protection Agency, and the Secretary of Health, Education, and Welfare.

The ASRT held its 52d annual meeting in Houston, Tex., from July 6 through 12, 1979. After considering S. 500, the Consumer-Patient Radiation Health Safety Act of 1979, sponsored by Senator Jennings Randolph of West Virginia, the Society adopted a resolution urging the enactment of this legislation by the Congress. A copy of this resolution is attached for the record.

Senator RANDOLPH. Was this a few people who took this action, or was there an opportunity for the participation of citizens?

Mr. DONOHUE. It was the sentiment of the membership present at the meeting, which numbered over 3,000.

Senator RANDOLPH. And would you say that this was a true expression of your membership?

Mr. DONOHUE. I would so declare; yes, sir.

Senator RANDOLPH. Thank you very much.

Mr. DONOHUE. It is appropriate to note that previous Senate bills have passed the Senate by a vote of 88 to 0, and that similar legislation along the principles of S. 500—H.R. 5349, H.R. 6063, and H.R. 6075—have been introduced into the House.

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

We believe that this legislative area demands prompt and effective action. We urge the full Committee on Interstate and Foreign Commerce to continue its efforts to seek a sound legislative solution and, in particular, to direct its careful attention and consideration to S. 500, H.R. 5349, H.R. 6023, and H.R. 6057, which we believe is essential to protect the rights of the American public to properly performed radiological examinations and from the potential hazards of excessive and unnecessary radiation.

Thank you, Mr. Chairman.

Senator RANDOLPH. Thank you very much.

I have a time problem of concern to me. We may decide to have questions and responses for the record rather than having them here. You all realize that your prepared statement, prepared although not given in full, will be made a part of the record in full.

I am not trying to stop you from delivering important testimony but perhaps you might somewhat, in essence, give what you believe to be the major points, knowing that your statement in its totality will be included.

[The prepared statement of Mr. Donohue follows:]



... the national professional organization for Radiologic Technologists

THE AMERICAN SOCIETY OF RADIOLOGIC TECHNOLOGISTS

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STATEMENT OF
DANIEL P. DONOHUE, R.T. (ARRT), PRESIDENT
AMERICAN SOCIETY OF RADIOLOGIC TECHNOLOGISTS
BEFORE THE SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH
OF THE
SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES
ON S. 500, THE CONSUMER-PATIENT RADIATION HEALTH AND SAFETY ACT OF 1979
APRIL 3, 1980

Mr. Chairman, Members of the Subcommittee, my name is Daniel P. Donohue, R.T. I am the Director of the School of Radiologic Technology at Daniel Freeman Hospital Medical Center, Inglewood, California. I have been a practicing radiologic technologist for more than twenty years and am certified by the American Registry of Radiologic Technologists.

As President of the American Society of Radiologic Technologists, I represent the professional association of radiologic technologists founded more than fifty years ago for the expressed purpose of enhancing through education, the proper and safe delivery of medical radiological services. As such, we welcome the opportunity to appear before you today during these hearings on S.500 and we commend the subcommittee for its attention to this very timely subject.

In the past year we have heard considerable concern related to the risks from radiation exposure especially related to the three mile island incident. And yet, less than one percent (1%) of the consumer's exposure to ionizing radiation is attributable to the normal operation of nuclear power plants. However, ninety percent (90%) of public exposure to man-made ionizing radiation results from medical

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Members of the American Society of Radiologic Technologists as credentialed technologists, strive to perform radiological examinations with minimal risk to the patient and to ourselves and to eliminate excessive and unnecessary radiation in the performance of our profession. X-ray machines and the radiation they deliver are controlled by the operator. The same Chest X-ray examination when performed by an uneducated, untrained operator has the potential to deliver ten (10), twenty (20), or even one hundred (100) times the radiation dose to the patient as the same procedure performed by a properly trained technologist.

As we indicated on June 22, 1979 in response to the Food and Drug Administration Notice of Intent, to develop recommendations on voluntary national standards for qualifications of medical radiation technologists, (Federal Register, March 13, 1979), we believe that qualifications for radiologic technologists would result in a significant reduction of radiation exposure to the patient. I would point out that this effort being pursued by the FDA appears to be in agreement with Section 132 of S. 500, thus lending credence for enactment of this legislation, the consumer patient radiation safety act of 1979.

Since 1967, with introduction of the Radiation Health and Safety Act (now public law 90-602), the American Society of Radiologic Technologists has supported the enactment of federal minimum standards of education and training for operators of medical radiation equipment. We continue to support federal legislation giving impetus to state licensure based on national standards, preferably the standards advocated by the American Registry of Radiologic Technologists, a national voluntary certification agency. The ARRT is currently cooperating with licensure boards in several states by offering their credentialing examination to candidates identified by the states. The ASRT does not believe there is an alternative to uniform national standards. We remain firm in our opinion, that without uniform national standards for qualifications of medical radiation technologists, the public will remain unprotected and at the mercy of untrained personnel. Because of the unique nature and inherent danger of radiation, the ASRT believes that every patient undergoing a radiological examination has the right to have that examination performed properly and with minimal risk by a qualified operator. This right would be assured and protected by S. 500 when enacted.

This Bill, S. 500, while embodying the rights of all consumer/patients, encourages state adoption of national standards for the qualifications of educational programs and for personnel that provide radiological health care services. Further, it promotes utilization of a voluntary system in implementing those standards.

Only ten states in the nation have seen fit to regulate or require licensure of individuals who operate this biologically hazardous

equipment. Within these ten regulated states the standards differ widely in both scope and practice. It is our belief that to require each state to initiate a credentialing program without providing uniform standards would not provide the necessary consumer protection they have a right to expect.

Accredited programs for the education of radiologic technologists already exist on a voluntary basis in every state. The United States Office of Education currently recognizes the Committee on Allied Health Education and Accreditation as the accrediting agency for these more than 800 programs. For those 40,000 to 70,000 individuals not certified by the voluntary national certifying organization,

a criteria referenced, performance oriented examination can be utilized as a measurement tool and a prerequisite for licensure. These considerations are offered as substantiating evidence that facilitation, implementation, and costs to state government can be minimized by utilizing existing national voluntary standards.

While S. 500 encompasses all technological operators of ionizing radiation equipment, it distinguishes between the types of operators and provides for licensure in a particular specialty, such as diagnostic x-ray, radiation therapy, or nuclear medicine. It also affords flexibility in providing for upper career mobility, a concern of health manpower agencies.

In 1968, Senator E.L. Bartlett observed that, "the seriousness of this health hazard, particularly the damage radiation can do to human genes, damage which may not show for generations, have led most, if not all,

thoughtful men to agree that excessive or unnecessary doses of radiation should be eliminated." Senator Bartless then noted, "There are two ways to eliminate unnecessary radiation - first, to insure by the establishment of performance standards that x-ray equipment does not emit unnecessary radiation, and second, to insure the licensing of individuals and the accrediting of schools so that technologists operating medical equipment are qualified."

The President of the United States has determined that the time has come for action. On January 26, 1979, he signed Executive Order Number 10831, which approved a number of recommendations for the guidance of federal agencies. Recommendation Number eight stated: "Operation of medical or dental x-ray equipment should be by individuals who have demonstrated proficiency to produce diagnostic quality radiographs with the minimum of exposure required; such proficiency should be assessed to national performance - oriented evaluation procedures or by didactic training and practical experience identical to, equivalent to, or greater than training programs and examination requirements of recognized credentialing organizations." This recommendation had previously been agreed to and endorsed by the administrator of the Environmental Protection Agency and the Secretary of Health, Education, and Welfare.

The ASRT held its 51st Annual Meeting in Houston, Texas from July 6-12, 1979. After considering S. 500, the Consumer-Patient Radiation Health Safety Act of 1979, sponsored by Senator Jennings Randolph, West Virginia, the Society adopted a resolution urging the enactment of this legislation by the Congress. A copy of this resolution is attached for the record.

It is appropriate to note that previous Senate Bills have passed the Senate by a vote of 88 to 0, and that similar legislation along the principles of S. 500 (H.R. 5349, H.R. 6063, and H.R. 6057) have been introduced into the House.

We commend this subcommittee, Mr. Chairman, for its interest and timely concern with respect to the potential health hazards of medical and dental diagnostic x-rays resulting from the lack of proper safeguards and qualifications of persons who operate ionizing radiation equipment. We believe that this legislative area demands prompt and effective action. We urge the full committee on Interstate and Foreign Commerce to continue its effort to seek a sound legislative solution and, in particular, to direct its careful attention and consideration to S. 500, H.R. 5349, H.R. 6023, and H.R. 6057, which we believe is essential to protect the rights of the American public to properly performed radiological examinations and from the potential hazards of excessive and unnecessary radiation. Thank you, Mr. Chairman.

Senator RANDOLPH. Mr. Alexander, please, if you will identify yourself.

Mr. ALEXANDER. My name is George W. Alexander, Jr. I am president of the technologist section of the Society of Nuclear Medicine.

I am employed as the associate director of training programs, and chief technologist of the Eugene Saenger Radioisotope Laboratory of the University of Cincinnati Medical Center, Cincinnati, Ohio.

Mr. Chairman, I would like to reinforce your position on criteria establishment. It is an excellent idea.

I appear before the committee today representing the position of the Society of Nuclear Medicine and its 10,000 members. We are happy to be here with our colleague from radiologic technology, Mr. Donohue.

Mr. Chairman, we thank you for this opportunity for the Society of Nuclear Medicine to present its comments and views on S. 500, the Consumer-Patient Health and Safety Act of 1979. The society commends the committee for its concern and diligence in studying the questions on how to protect patients from unnecessary exposure to medical radiation.

In order to conserve the committee's time, we have a formal statement, with supporting documents, which we would like to submit for the record, with your permission.

I would like to touch on the highlights of the statement; that is, the points which are most pertinent to the committee. This statement is adopted by the membership of the Society of Nuclear Medicine.

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

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

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

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

Nuclear medicine today encompasses two broad areas of procedures: in vivo and in vitro procedures.

In vivo procedures involve the administration of a small amount of a radioactive drug to the patient either by mouth or into a vein. The drug has an affinity for a certain type of cell or tissue which we call the organ of interest. Very sophisticated instruments record on film a permanent image of the radiopharmaceutical within the organ of interest. Most major organs and tissue systems in the body and/or their functions can be examined in this manner. These procedures are noninvasive, safe and essentially painless to the patient, the only sensation being the needle "stick" when the drug is administered.

In vitro procedures encompass radioimmunoassay. Blood is taken from the patient and tagged with radioactive materials in order to detect minute quantities of hormones and/or other substances in the blood, which are not detectable by chemical means. Special note should be made of the fact that patients for whom these examinations are being conducted receive no radioactive material. Today, radioimmunoassay procedures constitute up to 80 percent of all nuclear medicine procedures.

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

Over the past 10 years, the Society of Nuclear Medicine has sponsored the development of voluntary national standards through the essentials of education and accreditation of the joint review committee on educational programs for nuclear medicine technology, (JRCNMT), and the formation of national certification exclusively for nuclear medicine technology through the Nuclear Medicine Technology Certification Board (NMTCB).

JRCNMT functions in collaboration with the AMA's committee on allied health education and accreditation (CAHEA), which accredits all allied health educational programs. There are approximately 140 CAHEA-approved nuclear medicine technology training programs in the United States.

NMTCB is a voluntary national certification board, developed through task analysis, which methodically examined all duties performed by nuclear medicine technologists. We now feel that, through development of voluntary national standards, we have a strong professional identity, job descriptions for all career levels, task analysis and the professional designation, Certified Nuclear Medicine.

Presently, approximately 75 percent of all nuclear medicine technologists are professionally certified; that is, 13,400 out of 18,000. The Joint Commission on Accreditation of Hospitals—JCAH—requires accredited hospitals to provide nuclear medicine services for their patient populations, and upon inspection, requires copies of each nuclear medicine technologist's certification diploma.

JCAH further serves as yet another check on the safety and use of radiopharmaceuticals in the diagnosis and treatment of human diseases. It is essential for the committee to recognize that performance standards for nuclear medicine technologists already exist, as a result of the society, the JRCNMT, CAHEA, JCAH, NMTCB, as well as others.

The Department of HEW mandated and funded the National Commission for Health Certifying Agencies (NCHCA)—to establish among certifying bodies national standards that attest to the competency of individual participants in health-care delivery, and to grant recognition to certifying bodies that apply and meet the established standards. Both SNM and NMTCB have been accepted into NCHCA as members.

Existing Federal Government regulatory agencies such as NRC and FDA, maintain strict control of the safety and efficacy of use of each radiopharmaceutical which may be used in in vitro procedures or administered to patients as in in vitro procedures. The

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

The SNM is opposed to S. 500 as presently written. It does not recognize the nature and scope of the medical specialty of nuclear medicine as a separate professional entity.

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

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

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

(a) Certification and/or proficiency examinations should be the central point of all licensure approaches;

(b) Essentials of education, training and accreditation of programs are necessary aspects for assuring professional competency and should be incorporated into a licensure approach—JRCNMT "essentials", et cetera;

(c) In any licensure approach, the practicing nuclear medicine technologist must be allowed to perform procedure for which he or she has been trained. The scope of nuclear medicine technology and its diversity from other professional disciplines is not recognized by S. 500;

(d) There should be uniformity and consistency of licensure, regulations and reciprocity between all States;

(e) On-the-job training should be evaluated and included as an acceptable criterion for licensure eligibility;

(f) S. 500 States that administrative control is given to EPA; because EPA has no experience with nuclear medicine applications, the society feels strongly that this responsibility should remain with the experienced agencies, for example, NRC and BRH;

(g) If the Committee continues to believe that Federal minimum standards for licensure are necessary, the society believes that the thrust of such a program must be through State licensure based upon State acceptance and adoption of national certification of each individual discipline.

We appeal to the committee to examine the information regarding our discipline. There is no necessity to impose additional legislation on a profession that is already the most carefully regulated of the entire health care scene.

We look forward to working with the committee and its staff. The SNM greatly appreciates this opportunity to present its views, and hopes the chairman and his colleagues will feel free to look upon the society as interested in assisting with the concerns presently addressed.

[The prepared statement of Mr. Alexander follows:]



THE SOCIETY OF NUCLEAR MEDICINE

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STATEMENT OF THE SOCIETY OF NUCLEAR MEDICINE ON

S. 500, "The Consumer-Patient Radiation Health and Safety Act of 1979"

Presented to
The Subcommittee on Health and Scientific Research
Committee on Labor and Human Resources
United States Senate

April 3, 1980

by

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and

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

The Society of Nuclear Medicine is pleased to have this opportunity to present its views on S.500, the "Consumer-Patient Radiation Health and Safety Act of 1979", regarding the adoption of federal standards of licensure for radiologic technologists. The Society commends the Subcommittee for its concern and diligence in examining the question of how to properly protect patients from unnecessary exposure to medical radiation. We appreciate the Subcommittee's insights into the interrelationship between accreditation, certification, continuing education national standards development and licensing. All of these factors must be carefully considered since they have an important impact on the competency of both radiologic and nuclear medicine technologists and the quality of health care they provide.

SOCIETY OF NUCLEAR MEDICINE

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

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

WHAT IS NUCLEAR MEDICINE TODAY

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

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

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

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

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

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

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

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

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

WHAT IS THE ROLE OF THE NUCLEAR MEDICINE TECHNOLOGIST

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

ACCREDITATION OF NUCLEAR MEDICINE TECHNOLOGY

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

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

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

Another accrediting agency is the Joint Commission on Accreditation of Hospitals (JCAH). JCAH requires that an accredited hospital must provide nuclear medicine services for its patient population. JCAH conducts one-to three-year inspections of each accredited institution, and thus serves as a check on the safety and use of radiopharmaceuticals in the diagnosis and treatment of human diseases. JCAH requires that all nuclear medicine technologists are qualified for the duties performed, and that both formal training and on-the-job experience of each nuclear medicine technologist shall be documented. All nuclear medicine

personnel should participate in in-service education programs according to JCAH, as well as outside workshops and professional society meetings. JCAH requires that the extent of participation in these activities of continued education shall be documented. For the last two JCAH inspections in my department, for example, copies of the certification diplomas and written evidence of continued education of each nuclear medicine technologist were required to be demonstrated. For the understanding of the Subcommittee, enclosed with this statement are the current JCAH standards for nuclear medicine.

CERTIFICATION OF NUCLEAR MEDICINE TECHNOLOGISTS

Certification is often used interchangeably with the term registration. This is a process by which a non-governmental agency or association (usually a professional organization) grants recognition to an individual meeting certain special qualifications of competency. Certification is typically voluntary and conferred upon satisfactory completion of an approved training or educational program, or following accomplishment of a given amount of work experience - in addition to acceptable performance on a qualifying examination. One who is certified is then placed on a registry.

In 1976, the Society of Nuclear Medicine evaluated existing certification processes for nuclear medicine technologists (which at that time were "spin-offs" of medical technology and radiologic technology) and made the decision that the certifying processes then in existence did not adequately meet the needs of the profession of nuclear medicine technology. In 1977, the Society initiated the formation of national certification exclusively for nuclear medicine technology: the Nuclear Medicine Technology Certification Board (NMTCB). A task analysis development project was undertaken by the NMTCB that methodically examined all duties performed by nuclear medicine technologists. A copy of this task analysis is enclosed for the review of the Subcommittee.

NMTCB is not only related to practice but reflects the full scope of practice, e.g., imaging and radioimmunoassay. Nuclear medicine technologists now have a strong professional identity, job descriptions for all career levels, the task analysis and the designation "Certified Nuclear Medicine Technologist" (CNMT). Presently approximately 75% of all nuclear medicine technologists are professionally certified, i.e., 13,400 out of 18,000 currently employed nuclear medicine technologists. It is essential for the Subcommittee to recognize that performance standards for nuclear medicine technologists already exist, as a result of the efforts of the Society, JRCNMT, CAHEA, JCAH, NMTCB - and others, as well.

NON-GOVERNMENTAL ORGANIZATIONS CONCERNED WITH THE DEVELOPMENT OF NATIONAL STANDARDS FOR ALLIED HEALTH FIELDS

The Society has also made great strides in working with non-governmental organizations concerned with the development of national standards. Its representatives serve on all major organizations concerned with allied health and national standards, such as the National Commission for Health Certifying Agencies (NCHCA) and the American Society of Allied Health Professions (ASAHP). Both the Society of Nuclear Medicine (our professional organization) and NMTCB (our certifying body) have passed the formal application process and have been accepted into NCHCA as full members. NCHCA was mandated and funded by the Department of Health, Education, and Welfare for the purpose of establishing national standards for certifying bodies that attest to the competency of individuals who participate in the health care delivery system; to grant recognition to certifying bodies that voluntarily apply and meet the established standards; and to monitor the adherence of these standards by the certifying bodies which it has recognized. With the permission of the Chairman, we wish to submit for the hearing record additional information demonstrating the significance of accreditation and certification in determining competency, in cooperation with CAHEA, ASAHP and NCHCA.

FEDERAL REGULATORY AGENCIES

WHICH AFFECT NUCLEAR MEDICINE TECHNOLOGY

In addition to the above listed agencies and/or commissions, the Food and Drug Administration (FDA) now maintains strict control of the safety and efficacy of all radiopharmaceuticals interstate commerce which may be administered to a patient. Since radiation absorbed dose to the patient is derived from the administered dose of a radiopharmaceutical, patient safety from radiation exposure is already being strictly controlled. The Nuclear Regulatory Commission (NRC), FDA and JCAH all require that all patient doses of radiopharmaceuticals must be verified and recorded prior to administration to a patient, thus avoiding excessive radiation exposure. Retakes in nuclear medicine occur only by taking additional images of an organ without additional administration of the radiopharmaceutical.

NRC grants licenses to institutions and/or individuals to procure, possess and use radioactive materials, and maintains strict control over the radiation safety aspects of the use and handling of these radioactive materials. NRC regulations govern the qualification and education of the individuals who are allowed to use such radioactive materials. The NRC inspects each nuclear medicine facility on a regular basis to ascertain whether there is compliance with these regulations. Non-compliance with existing regulations may mean forfeiture of the license to use radioactive materials.

SUMMARY

Credentialing activities maintain the quality of practice of nuclear medicine technology. Without credentialing based upon the science of nuclear medicine, there are no standards for technologists to meet. Credentialed technologists demonstrate an acceptable level of performance as defined by the Nuclear Medicine Technology Certification Board. Whatever the mechanism, however the ultimate goal of credentialing in nuclear medicine technology is to avoid unnecessary radiation exposure and to improve the quality of health care.

The Society of Nuclear Medicine is opposed to S.500 as presently written. Many of the provisions of the proposed legislation are duplications of existing standards and/or regulations. It is our firm opinion that there is no demonstrated need for duplication of currently existing regulations promulgated by the Nuclear Regulatory Commission and the Food and Drug Administration, as well as standards embodied by organizations such as the National Commission for Health Certifying Agencies and the Commission on Allied Health Education and Accreditation.

Further, there exists no scientific evidence that licensure itself has demonstrated significant changes in radiation protection practices or the recruitment and availability of radiologic technologists. This finding, the product of numerous professional studies, is clearly stated, for example, by a study conducted by the American Society of Radiologic Technologists/American College of Radiology Conjoint Committee on Technology Job Descriptions and Manpower Studies. There exist no published findings to demonstrate otherwise.

S.500 also does not adequately recognize the nature and scope of the medical specialty of nuclear medicine, or that of nuclear medicine technology. Nuclear medicine technology has been confused in the legislative proposal with the equally significant practice of radiologic technology. It should be understood by the Subcommittee, however, that the distinction between these two technologic fields is clear to the entire health professional community. We feel certain that the Subcommittee has no intent to imply that one of these disciplines should co-opt the responsibilities of the other.

The bill might even be viewed by some as an infringement upon states' rights to license occupational groups. The activities of all of the federal and private sector agencies collectively serve to maintain strict control over all aspects of the practice of nuclear medicine,

and thereby provide safeguards against undue radiation exposure to patients who benefit from nuclear medicine procedures. Nuclear medicine techniques are well established with absolute controls over radiation dosage to the patient and to technologists, as well.

If the Subcommittee deems it necessary to pursue the adoption of S.500, however, the Society recommends the following additional points for inclusion:

1. Certification and/or proficiency examinations should be the central point of all licensure approaches. S.500 should recognize and call for the adoption of the voluntary certification examinations which are available currently for nuclear medicine and radiologic technology, respectively. The Society has provided demonstrable in-depth activity and ongoing involvement in the development of voluntary certification examinations for nuclear medicine technologists, culminating in the formation of the Nuclear Medicine Technology Certification Board in June 1977, the first certification process exclusively for nuclear medicine technologists.

2. Essentials of education, training and accreditation of programs are necessary aspects for assuring professional competency and should be incorporated into a licensure approach. The JRCNMT has developed essentials and accredits training programs. S.500 proposes to give to the Secretary of DHEW the authority to promulgate "voluntary" minimum standards as well as authorizing professional organizations to certify such accreditation of educational programs. The proposed legislation should assure recognition of the JRCNMT as the accrediting agency for educational programs in nuclear medicine technology.

3. In any licensure approach, the practicing nuclear medicine technologist must be allowed to perform the nuclear medicine technology procedures for which he has been trained. S.500 does not adequately recognize the scope of practice of nuclear medicine technology or its diversity from other professional disciplines.

4. There should be uniformity and consistency of licensure, regulations and reciprocity among all states. Without the adoption of uniform national standards, reciprocity and career mobility would be severely curtailed. This would drastically hinder the practice of nuclear medicine technology and the delivery of services. There is already a shortage of nuclear medicine technologists.

5. On-the-job training should be evaluated and included as an acceptable criterion for licensure eligibility. A critical manpower shortage of nuclear medicine technologists already exists. Persons who meet national standards in all other respects should not be overlooked as qualified to continue to practice. To do otherwise would create an even more critical health manpower situation.

6. S.500 states that administrative control is given to the Environmental Protection Agency, which has absolutely no experience with nuclear medicine applications. The Society has gone on record as being opposed to one agency, such as EPA, writing regulations and standards applicable to the practice of nuclear medicine which other experienced agencies would be required to follow. The Society stated "... that diversity of responsibility in this area is not only desirable but necessary - on the basis that it is impossible to consider radiation in the generic sense". Moreover, at the present time nuclear medicine practice privileges are already governed by the NRC and participating agreement states. The types, doses and radiation exposure due to radiopharmaceuticals are already controlled so that guidelines promulgated by the EPA would be redundant, superfluous and probably poorly conceived.

7. If the Subcommittee continues to believe that Federal minimum standards for licensure are necessary, the Society believes that the thrust of such a program must be through state licensure, based upon state acceptance and adoption of national certification. States implementing licensure should be encouraged to adopt national certification granted by only those certifying organizations adhering to the certification standards established by the National Commission for Health Certifying Agencies. This alternative incorporates use of national standards but still allows for state control and adaptation to fulfill local needs. National standards thusly adopted by the several states would maintain uniformity and consistency, and permit reciprocity and mobility between the states.

We appreciate the concerns of this Subcommittee, but feel strongly that these concerns are already addressed by both the profession and the federal sector, e.g. FDA, NRC, etc. The consumer public is already well protected with respect to nuclear medicine technology. The Society of Nuclear Medicine has supported the concept of a national (non-federal) certification system that would set national standards for both accreditation and certification through a collaborative effort of the federal government, professional associations and other interested parties. Establishment of the National Commission for Health Certifying Agencies has made the approach to the development of national standards a reality. The Society of Nuclear Medicine and the NMTCB are therefore actively engaged in the promulgation of national standards.

We appeal to the Subcommittee to examine the information regarding our discipline. There is no necessity to impose additional legislation on a profession that is already the most carefully regulated of the entire health care delivery system. The Society of Nuclear Medicine greatly appreciates this opportunity to present its views, and hopes the Chairman and his colleagues will feel free to look upon the Society as interested in assisting further with the concerns addressed in today's hearing.

Position Description: Nuclear Medicine Technologist

Technologist Section, Society of Nuclear Medicine

Nuclear Medicine Technologists, under the direction of physicians licensed to possess radioactive materials, utilize radionuclides and radiopharmaceuticals to perform or assist in the performance of diagnostic examinations—including radionuclidic imaging of organs and organ systems of patients, dynamic studies, assays of body fluids and tissues, and radioassays. These responsibilities require appropriate knowledge of the field of Nuclear Medicine Technology, and those aspects of chemistry, physics, mathematics, and the biomedical sciences that relate to Nuclear Medicine Technology and its growth. Technologists perform studies to evaluate and standardize new or improved methods and equipment for use in Nuclear Medicine Laboratories and Clinics. They also assist the physician in therapeutic procedures using radionuclides. Nuclear Medicine Technologists transmit findings of studies, tests, and examinations to Nuclear Medicine Physicians, who are responsible for the care of the patient. They also participate in medical research. All duties and responsibilities are assigned by Nuclear Medicine Physicians.

(Editor's note: The scope of practice of Nuclear Medicine Technology varies widely across the country. This is most probably due to the varied backgrounds of Technologists and Nuclear Medicine Physicians—and the fact that essentials for educational programs in Nuclear Medicine Technology provide for different types of structured education routes into the profession. Because of this variation, and hence some confusion, members of the Technologist Section requested the Section to develop position (or job) descriptions to define the scope of practice in a more uniform manner. These descriptions are intended to be guidelines for members and others to use and modify as they see fit for their purposes. The descriptions were written to reflect the broadest scope of practice—with knowledge of the great range of duties and the understanding that modification would be necessary in many instances.)

Level I (Staff Technologist):

(A career-entry technologist who performs either in vivo or in vitro routine tasks, or both, under close supervision)

Level II (Senior Technologist):

(A staff technologist who performs most diagnostic work in the department with limited supervision)

Level III (Chief Technologist/Technical Administrator):

(Additional levels on the Nuclear Medicine Technology

career ladder may include Educational Coordinator, Computer Technologist, etc.)

Level I (Staff Technologist)

Principal Duties and Responsibilities:

A. Dose Calculation and Administration—

1. Obtains radionuclides by eluting generator systems maintaining sterile technique.
2. Measures eluant for total activity and checks for contamination.
3. Prepares appropriate dosages of radiopharmaceuticals in preparation for diagnostic procedures.
4. Performs quality control procedures to ensure pharmaceutical quality of agents before administering to patients. This step may include such techniques as paper chromatography, pH determination, and tests for radionuclidic purity. The technologist is responsible for maintaining sterility and integrity of prepared radiopharmaceutical compounds.
5. Calculates amount and volume of activity to be administered following prescribed procedures, according to information on age, weight, and examination.
6. Administers the dose of radiopharmaceuticals to patients undergoing nuclear medicine procedures—either intravenously (where legally permitted), orally, or by inhalation.

B. Imaging Procedures—

1. Receives patients and explains procedure to them in order to obtain cooperation and allay anxieties during performance of procedure. It is the responsibility of the technologist to continually assess the immediate needs and conditions of assigned patients.
2. Visually inspects the patient in order to record any observations that may contribute additional information in the evaluation of test results, e.g., pregnancy, incontinency, surgery, interfering medications, etc.
3. Reviews and abstracts data from patient's chart.
4. Places the patient on the examination table and

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explains, as necessary, positioning and instrumentation operating characteristics, time to complete testing, etc.

5. Sets up imaging devices for studies in accordance with prescribed procedures.
6. Performs standard nuclear medicine dynamic and static imaging procedures on patients, which includes assisting patients in assuming required anatomical body positions and positioning and adjusting the equipment to encompass the area to be studied. The technologist adjusts controls on equipment in accordance with prescribed procedures to produce information of required diagnostic quality.
7. May consult with staff professionals to obtain information concerning the patient's physical condition, preliminary diagnosis, and care in order to take these factors into account while performing diagnostic procedures.
8. Observes patients for a change in status and follows prescribed procedures if a change is observed, which may include taking patient's vital signs or initiating cardiopulmonary resuscitation.
9. Evaluates needs and performs special positioning or examination techniques, certain technicalities, or additional views when necessary, or as requested by the Nuclear Medicine Physician or supervisor, or both.
10. Checks the quality of scans in general and is responsible for the quality control of work performed.
11. Communicates physician's written interpretation of tests, when indicated, to designated hospital personnel.
12. Schedules patients for Nuclear Medicine examinations.
13. Assists in maintaining current inventory of routine laboratory supplies and orders supplies in coordination with supervisor.
14. Maintains work areas in clean and orderly condition and ensures that examination rooms are properly supplied, equipped, and operational before each examination.

C. Instrumentation—

1. Operates imaging equipment (scintillation cameras, rectilinear scanners, portable cameras) and related accessories (videotape, multiframing devices, xenon apparatus, computers, etc.) for routine studies.
2. Performs quality control procedures on all instruments, including voltage and linearity checks and tests of uniformity and resolution, to ensure that all equipment is in proper working order.
3. Records status and results of instrument checks in appropriate log books.

4. Performs minor routine preventive maintenance on instrumentation and suggests equipment repair to supervisor.

5. Acquires computer-generated data for patient studies.

6. Checks operation and calibrates survey and monitoring devices against known standards.

D. Nonimaging procedures—

1. Operates all laboratory auxiliary equipment (pipets, centrifuges, water baths, pH meters, balances, etc.) during the performance of routine laboratory procedures.
2. Prepares solutions and materials when applicable and performs serial dilutions as required.
3. Performs venipuncture at proper times, separates blood components, and stores specimens appropriately.
4. Furnishes nurses and outpatients with accurate instructions concerning urine, stool, and blood collections.
5. Prepares samples for counting in either a liquid or well scintillation detection system, or both.
6. Counts specimens in scintillation counting system, performs appropriate calculations, and records results in laboratory record books.
7. Maintains quality control program for all laboratory assays and maintains records of all quality control procedures.
8. Judges acceptability of results and decides on necessity of repetition.

E. Radiation Protection—

1. Receives and checks all radionuclide shipments for contamination according to radiation safety regulations.
2. Performs various tasks associated with receiving, processing, distributing, and storing radioactive materials.
3. Disposes of radioactivity and contaminated materials in accordance with departmental, hospital, and federal regulations, maintaining records of all disposition.
4. Using appropriate instrumentation or other devices, monitors personnel, work areas, and patient rooms where applicable to ensure that levels of radiation do not exceed those levels defined in institutional and NRC regulations. Reports all excessive radiation exposure to the proper authority.

Educational Requirements:

The basic education necessary to qualify for the Level I position in Nuclear Medicine Technology is one of the following:

1. Graduation from an approved school of Nuclear Medicine Technology or equivalent qualifications.

2. Certification in Nuclear Medicine Technology or eligibility for certification.

Supervisory Control over the Position:

The Level I Technologist is under the immediate supervision of the Level II Technologist, who, in turn, is directly responsible to the Level III Technologist. All routine duties are performed under supervision with all problems and complications reported to the Level III Technologist and the Nuclear Medicine Physician in that order.

LEVEL II (Senior Technologist)

The Level II Nuclear Medicine Technologist performs a more extensive range of nuclear medicine procedures and tasks that require an advanced level of job knowledge and skill, normally acquired through continuing education.

Principal Duties and Responsibilities:

In addition to the principal duties and responsibilities of the Level I Technologist, the Level II Technologist:

1. Plans, schedules, assigns, and coordinates the day-to-day work of technical assistants, technologists, and students.
2. Assists in the development of new computer applications in Nuclear Medicine.
3. Assists in development of new tests by performing comparison studies and clinical trials, and implements these new procedures in the absence of a Level III Technologist.
4. Assists in developing quality control procedures and instructs other technical personnel on technical aspects of their routine use.
5. Assists in clinical teaching, evaluation of students' performance, and may oversee the work of both staff and student Technologists.
6. Assists in the conduct of specialized tests and studies either in vitro or in vivo, or both.
7. Maintains regular contact with physicians and other health care personnel regarding the nature, scheduling, or results of procedures performed within the Nuclear Medicine Department.

Education Requirements

In addition to the basic educational requirements for a Level I Technologist, one or preferably two years experience in nuclear medicine technology at Level I is required for Level II Technologists, in which competence has been demonstrated in:

1. Performing all procedures with adequate quality to assist physicians in the care of patients.
2. Working with professional and other technical personnel in a unified team effort.
3. Identifying and assessing patient's needs.

Supervisory Controls over the Position:

Same as for Level I Technologist, however the Level II Technologist performs work assigned with limited super-

vision. The Level II Technologist is immediately responsible to the Level III Technologist, who is directly responsible to the Medical Director of Nuclear Medicine.

LEVEL III (Chief Technologist/Technical Administrator)

The Level III Technologist performs responsible administrative, supervisory, and advanced technical work in a Nuclear Medicine Department. In addition to all the duties and responsibilities of other Nuclear Medicine technical staff, the Level III Technologist must have the ability to recognize, anticipate, and solve problems in a prompt and efficient manner. The Level III Technologist must have the ability to supervise and guide employees and to meet and deal effectively with administrative and professional personnel of other services and divisions.

Principal Duties and Responsibilities

1. Develops short- and long-term goals for the Nuclear Medicine Department and upon approval by superiors, implements plans to accomplish these goals.
2. Develops usage of laboratory space for both existing and new equipment, and participates with hospital administration in planning or expanding a Nuclear Medicine Facility.
3. Develops and administers an operational budget for the Nuclear Medicine Department.
4. Prepares and maintains records relative to licensing requirements of the Nuclear Regulatory Commission and the Food and Drug Administration.
5. Counsels employees regarding performance, conduct, attendance, and related matters. The Level III Technologist is responsible for overall hiring, training, evaluation, discipline, and discharge of the Nuclear Medicine technical and clerical staff.
6. Communicates with various vendors of radiopharmaceuticals and equipment as to the needs of the laboratory.
7. Organizes and conducts technologist staff conferences.
8. Implements safety procedures to protect personnel and patients from radiation exposure in the event of a radioactive spill.
9. Evaluates equipment maintenance and orders repairs when needed. Evaluates new equipment available on the market and prepares budget statements, cost analysis, and justification figures.
10. Regularly reviews records of personnel radiation exposure, dose calibration, and results of assays of radionuclides purity, sterility, and pyrogen-free status and, in case of discrepancy, takes appropriate action.
11. Assesses need for and orders radiopharmaceuticals for operation of the Nuclear Medicine Department.

12. Participates in formal in-service training programs in the department and conducts in-service education programs for hospital personnel orientation to Nuclear Medicine.
13. Determines and documents duties and responsibilities of each position under his or her direction, maintaining current and accurate position descriptions.
14. Coordinates the Nuclear Medicine Technology Training Program in the absence of an Educational Coordinator. The Level III Technologist instructs interns and students, reviews student applications and selects trainees, prepares and updates program curriculum, and oversees performance of students on training assignments to ensure satisfactory completion of the program, where applicable.
15. Directs preparation and maintenance of all pertinent department records.

Educational Requirements:

To qualify for the position of Level III Nuclear Medicine Technologist, certification in Nuclear Medicine Technology is mandatory. In addition, one of the following is necessary:

1. Four years of successful nuclear medicine technology practice, in any combination of Level I or Level II experience.
2. Two years of college desired, plus adequate experience as determined by the Medical Director of the Nuclear Medicine Department.

Supervisory Control over the Position:

The Level III Technologist is directly responsible to the Medical Director of Nuclear Medicine for all clinical activities and duties performed. Assigned duties and responsibilities are performed independently within the delegated authority. Guidance and clarification are provided when necessary and as unprecedented situations arise.

Nuclear Medicine Services

Nuclear medicine services and consultation shall be conveniently available to meet the needs of the patients as determined by the medical staff. Principle

The mechanism for providing diagnostic and therapeutic nuclear medicine procedures shall be clearly defined. Standard I

The hospital shall have a mechanism for providing nuclear medicine procedures that is adequate for the scope and complexity of the hospital programs offered. When there is an organized nuclear medicine department/service, it shall be directed by a physician qualified in nuclear medicine, and staffed appropriately. When only limited procedures are performed in the hospital, as in the case of in vitro testing in the clinical laboratory, an organized nuclear medicine service shall not be deemed to exist. When nuclear medicine procedures are performed outside the hospital for hospitalized patients, the outside sources must be approved by the medical staff and must meet the requirements of these standards.

INTERPRETATION

The director of the organized nuclear medicine department/service shall be a member of the medical staff. The credentials files of the director and of all other physicians practicing diagnostic and/or therapeutic nuclear medicine in the hospital shall reflect their training, experience, and current competence in the specialty. The director shall assure that proper radiation safety principles and practices are observed and that all technical personnel are qualified for the duties performed. The formal training and on-the-job experience of each nuclear medicine technologist shall be documented. Appropriate credentials shall be required for any pharmacist involved in the preparation of radiopharmaceuticals. When limited nuclear medicine procedures are performed within the hospital, supervision shall be provided

by a physician who is qualified in nuclear medicine and who shall assure personnel safety that is compatible with the degree of hazard and in keeping with the safety requirements outlined in this section of the *Manual*.

5 The services of a health or radiation physicist should be available, at least on a consultant basis, for educational purposes and for safety evaluations of all equipment, and storage and handling practices.

All nuclear medicine personnel should participate in in-service education programs as well as outside workshops and professional society meetings. The extent of participation shall be documented and shall be realistically
10 related to the size of the staff and the scope and complexity of the nuclear medicine services performed. The director shall contribute to the in-service education of nuclear medicine personnel.

The director shall document the review and evaluation of the services provided to strive to assure the optimal degree of quality and safety, as well
15 as to assure their appropriateness. Refer also to the Quality Assurance section of this *Manual*.

All nuclear medicine procedures performed in the hospital shall be in accordance with appropriate institutional or individual licensure requirements.

Standard II Nuclear medicine services, when provided within the hospital, shall have adequate space and facilities to meet, with safety, the diagnostic and therapeutic needs of the patients.

INTERPRETATION Space and facilities for the nuclear medicine department/service should include that necessary for the reception, examination, and diagnostic study of patients, as well as for related clerical work and for conferences. Ade-
25 quate accommodations shall be provided for the clinical care of therapeutic patients. Facilities shall be provided for the safe preparation, storage, and disposal of radioactive materials so that radiation levels in all areas are as low as practicable and do not exceed accepted standards. The nuclear medicine service area shall be protected from sources of interfering radiation.

30 The type, quantity, and quality of equipment for the nuclear medicine procedures performed shall be adequate to conduct reliable diagnostic studies as determined by the director and the medical staff. Standards having energy radiations equivalent to those of the radionuclides used in patient studies should be utilized for routine calibration, and should be readily
35 available.

Standard III There shall be quality control policies and procedures governing nuclear medicine activities that assure diagnostic and therapeutic reliability and safety of patients and personnel.

INTERPRETATION All radioactive materials, reagents, and standards shall be prepared, stored,
40 and checked at a defined interval to be determined by the director, to assure accuracy, patient safety, and precision of results. All reagents must be labeled to indicate identity, date of preparation, and assay. Instrument calibration procedures sufficient to affirm proper performance shall be conducted each day the instrument is used, and the results recorded. All safety
45 survey instruments in the hospital should be calibrated at least annually. The recommendations of the National Council on Radiation Protection and Measurements should be known and applied.

When required by federal, state, or local regulations, by licensure requirements, or by the medical staff, a radioisotope committee shall be established. At least one member of this committee must be a physician experienced in the safe handling of radioisotopes, in the measurement of radioactivity, and in determining radioisotope dosage for various patient studies or treatments. Representatives of various fields of specialization should be included on the committee, as determined by the nature of the program being conducted. In large hospitals, this committee may be absorbed into a radiation safety committee. When either of these committees exists, it shall work in cooperation with the hospital safety committee. The committee should meet as often as required, but not less than every six months, and shall maintain written minutes of each meeting. The committee concerned with nuclear medicine activities should have at least the following responsibilities:

- To review all proposals for diagnostic and therapeutic uses of unsealed radionuclides; 15
- To recommend to the medical staff those practitioners having suitable training and experience to perform nuclear medicine procedures;
- To develop regulations for the use, transport, storage, and disposal of radioactive materials used in nuclear medicine procedures; 20
- To recommend remedial action when there is failure to observe protection recommendations, rules, and regulations; and
- To establish rules to guide nursing and other individuals who are in contact with patients receiving therapeutic amounts of unsealed radionuclides; rules relating to the discharge of such patients; and rules to protect personnel involved when such patients undergo surgical procedures or autopsy. 25

Quality control procedures shall be developed to guide personnel in the standardized performance of diagnostic studies and therapeutic procedures, and to assure that the identity, strength, and integrity of all radiopharmaceutical agents are maintained. 30

Policies and procedures relating to safety within the nuclear medicine services areas shall be developed and enforced. These shall include as a minimum:

- a requirement for wearing the appropriate exposure-monitoring devices at all times when in the area; 35
- guidelines to be followed in the event of radioactive contamination of personnel, equipment, or environment;
- a requirement that there be written authority for all nonphysicians who administer radioisotopes parenterally when legally permissible; 40
- a requirement for security of all "hot" and "decay" areas in order to protect all individuals in the hospital;
- rules prohibiting oral pipetting of radionuclides and eating or drinking in the work areas;
- establishment of an effective radiation protection survey program to be performed at least every six months; and 45
- protective shielding for syringes, injection vials, and stock sources of radioactivity.

For other than radiation safety requirements, see also the Functional Safety and Sanitation section. Refer also to the Infection Control and the Pathology and Medical Laboratory Services sections of this *Manual*. 50

Standard IV Records required by federal, state, and local authorities, as well as records consistent with competent practice of nuclear medicine, shall be maintained.

- INTERPRETATION 5 Nuclear medicine diagnostic and therapeutic procedures shall be performed only upon the written request of the responsible physician or a member of the house staff. Such procedures may also be provided for authorized physicians who are not members of the medical staff for their patients who are not being evaluated or treated in the hospital. Reports of nuclear medicine interpretations, consultations, and therapy shall be included in the patient's record; duplicate records should be kept on file in the nuclear medicine department/service. The patient's medical record shall also reflect the identity, date, and amount of radiopharmaceutical used, as well as any specific preparation of the patient. For further requirements relating to medical records, see the Medical Record Services section of this *Manual*.
- 15 Records to be maintained on radionuclides and radiopharmaceuticals should include at least the following information:
- The dates, amounts, and methods of receipt and disposal;
 - The supplier and lot number; and
 - The use, date, amount administered, and the identity of any recipient.
- 20 Instrument log books to be maintained shall include at least the following:
- Calibration records of equipment and monitors showing dates, name of technologist, and sources of reference standards;
 - Maintenance and repair records, showing dates and sources of service; and
 - 25 • The findings of federal, state, or local evaluations or those of a consultant radiation physicist, and the action taken to correct any deficiencies found.

Records shall be maintained to show the radiation exposure of all nuclear medicine personnel, as well as the results of routine radiation safety surveys.

Essentials of an Accredited Educational Program for the Nuclear Medicine Technologist

Initially adopted 1969; revised 1976

Adopted by the
AMERICAN COLLEGE OF RADIOLOGY
AMERICAN MEDICAL ASSOCIATION
AMERICAN SOCIETY FOR MEDICAL TECHNOLOGY
AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS
AMERICAN SOCIETY OF RADIOLOGIC TECHNOLOGISTS
SOCIETY OF NUCLEAR MEDICINE

Program Review Committee
JOINT REVIEW COMMITTEE ON EDUCATIONAL PROGRAMS
IN NUCLEAR MEDICINE TECHNOLOGY

OBJECTIVE

The organizations indicated above have obvious interest and concern in the development of educational programs designed to prepare the nuclear medicine technologist. To organize their concerns and provide an orderly mechanism for both program evaluation and preparation of recommendations on accreditation status, these organizations have established a Joint Review Committee on Educational Programs in Nuclear Medicine Technology. As the agent of the five sponsoring organizations and of the Committee on Allied Health Education and Accreditation (CAHEA) in matters relating to educational programs in nuclear medicine technology, the Joint Review Committee is dedicated to the maintenance of high standards of education. Its membership is comprised of representatives from each of the sponsoring organizations.

The education and health professions cooperate in establishing and maintaining standards of appropriate quality for educational programs in nuclear medicine technology and in providing recognition for educational programs that meet or exceed the minimum standards outlined in these *Essentials*. These standards are to be used as a guide by the Joint Review Committee and program directors.

DESCRIPTION OF THE OCCUPATION

The practice of nuclear medicine includes the utilization of radioactive materials for therapeutic and diagnostic "in vivo" and "in vitro" procedures and any combination thereof. The skills of the nuclear medicine technologist shall complement those of the nuclear medicine physician and other professionals in the field.

The nuclear medicine technologist must be able to perform effectively in three major areas of responsibility:

A. Patient Care

1. Must understand and relate to the patients' concerns and fears about their illnesses and pending diagnostic procedures or therapy.

I. SPONSORSHIP

Educational programs may be established in

- A. Junior and senior colleges, universities, and technical vocational institutes
- B. Hospitals and clinics

PREAMBLE

2. Must recognize emergency patient conditions and initiate life-saving first aid prior to the arrival of a physician.

B. Technical Skills

1. Prepares and manages quality control of radiopharmaceuticals to patients by intravenous, intramuscular, subcutaneous, and oral methods.
2. Understands and utilizes radiation detection devices and other laboratory equipment that measure the quantity and distribution of radionuclides deposited in the patient or a patient specimen.
3. Performs "in vivo" and "in vitro" procedures, understanding these tasks sufficiently well to supplement selected examinations and procedures for the benefit of the patient and to improve the diagnostic quality of the data produced.
4. Utilizes knowledge of radiation physics and safety regulations to practice radiation safety, thereby limiting the exposure to the patient, the public, and fellow radiation workers to acceptable, minimal levels of radiation.
5. Is aware of quality control techniques and applies them appropriately to all procedures and products in the laboratory.
6. Participates in research activities that demand a thorough knowledge of the many facets of nuclear medicine.

C. Administrative Functions

1. May supervise other nuclear medicine technologists, laboratory assistants, and other personnel.
2. Participates in the procurement of supplies and instrumentation required to operate the facility.
3. Records all operations of the laboratory including the receipt and disposition of radioactive materials, instrument and procedural quality control data, patient procedures, and medical records.

REQUIREMENTS FOR ACCREDITATION

C. Medical schools

The institution must be accredited or otherwise acceptable to the Committee on Allied Health Education and Accreditation (CAHEA).

Colleges, universities, and technical vocational institutes without clinical facilities must have appropriate clinical affiliations.

II. INSTRUCTIONAL FACILITIES

- A. **General**—Adequate classrooms, laboratories, and clinical facilities must be provided.
- B. **Laboratory**—Appropriate modern equipment and supplies for directed experience must be available in sufficient quantities for full participation by the individual student.
- C. **Library**—A library must be readily accessible and contain an adequate supply of current reference volumes, periodicals, and other material related to the curriculum.

III. CLINICAL FACILITIES

- A. The clinical phase of the educational program must be conducted in a broad clinical setting under competent medical direction.
- B. In the clinical teaching environment, an effective ratio of students to clinical instructors must be maintained.
- C. The type and quantity of nuclear medicine procedures must be adequate for the clinical training of the student.
- D. The clinical facility must have adequate quantity and varieties of nuclear medicine instrumentation to allow for student instruction.
- E. Where classroom and clinical instruction are not provided in the same institution, accreditation will be granted to the sponsoring institution, as identified by established criteria. However, responsibility for quality of the total teaching program must be shared by both institutions involved (i.e., college and hospital).

IV. FINANCES

- A. Financial resources for continued operation of the educational program must be assured through regular budgets.
- B. The institution shall not charge excessive student fees.
- C. The sponsoring institution or its clinical affiliates must not substitute students for paid personnel to conduct the work of the clinical faculty.

V. ADMINISTRATORS AND FACULTY

A. Educational Directors

The educational direction shall be assumed by a physician, nuclear medicine technologist, or other allied health personnel (i.e., physicist, professional educator).

Every program must have a qualified medical director and nuclear medicine technologist director responsible for the clinical training, and program coordination and for the organization, administration, periodic review, continued development, and general effectiveness of the program.

B. Medical Director

The medical director must be a physician qualified in the use of radionuclides and a diplomate of the American Board of Nuclear Medicine, of the American Board of Radiology (in the area of nuclear radiology), or of the American Board of Pathology (in the area of radioisotopic pathology) or be otherwise acceptable to the Committee on Allied Health Education and Accreditation.

C. Technologist Director

The technologist director shall devote full time to the laboratory where the educational program is conducted. The technologist must be certified in nuclear medicine technology by the American Society of Clinical Pathologists Board of Registry or the American Registry of Radiologic Technologists. This technologist must have at least three years of experience at a combination of staff and senior nuclear medicine technologist levels and shall have educa-

tion and experience embracing methods of instruction, educational psychology, and human relations.

D. Faculty Appointments

If the clinical facility is not an integral part of the institution initiating the program (i.e., university, technical vocational institution), the physician, technologist director, and instructors shall be members of the faculty or staff of the sponsoring institution.

E. Change of Director

If any of the directors of the educational program are newly appointed, immediate notification must be sent to the AMA Department of Allied Health Evaluation. The curriculum vitae of the new directors, which should include details of training, education, and experience in the field, must be submitted. If the new director's credentials are satisfactory, accreditation of the program will be continued.

F. Teaching Staff

The instructional staff must be qualified through academic preparation and experience to teach the subjects assigned. Faculty shall have adequate and appropriate training in the areas of curriculum design and teaching techniques. The staff shall include at least one instructor who is certified in nuclear medicine technology and actively engaged in the clinical practice of nuclear medicine technology. A planned program for the continued education for the faculty shall be provided.

G. Advisory Committee

For programs involving more than a single institution, an advisory committee must be appointed to assist the directors in continuous program development and evaluation, in faculty coordination, and in ensuring effective clinical relationships. Programs having minimal or no extra-institutional activities shall provide for periodic review and updating of program standards and curriculum content by the director and institutional staff.

VI. STUDENTS

- A. **Selection**—In colleges, universities, and technical vocational institutes, selection of students shall be made in accordance with the generally accepted practice of the institution. Directors of the clinical aspects of the program shall be involved in the selection. In hospital-sponsored programs, selection of students must be made by an admissions committee of individuals responsible for the program. Admissions data shall be on file at all times in colleges, universities, or hospitals sponsoring the program.

- B. **Admission Requirements**—Persons admitted into nuclear medicine technology programs shall have completed high school or its equivalent and have completed post-secondary courses in the following areas:

1. Anatomy and physiology
2. Basic physics
3. Basic mathematics
4. Medical terminology
5. Oral & written communications
6. General chemistry
7. Psychology and sociology
8. Medical ethics and jurisprudence

Under unusual circumstances some of the prerequisites may be completed during the year of nuclear medicine training.

Qualified medical technologists [MT(ASCP) or eligible], radiographers [RT (R) (ARRT) or eligible], and registered nurses [RN], are presumed to have the necessary credentials to meet the entrance requirements.

Educational institutions such as junior colleges, universities, and technical vocational institutes may provide

these prerequisite courses as part of an integrated program in nuclear medicine technology (i.e., 2 to 4 years). In these programs, educational institutions are encouraged to provide such basic elements of a general education as are necessary to qualify the students for an associate or bachelors degree.

- C. **Health**—Applicants shall be required to submit evidence of good health. Student health service shall be available for evaluation and maintenance of the student's health. When students are learning in a clinical setting or a hospital, the hospital or clinic shall provide students with the protection of the same physical examinations and immunizations as are provided to hospital employees working in the same institution.

VII. STUDENT RECORDS

Satisfactory records of student performance in the educational program shall be maintained. Monthly and annual reports of the department must be prepared and available for review. Records shall include the following:

- A. Transcripts of high school and college credits and other pre-admission credentials.
- B. Certification by a physician as to the candidate's good health upon admission.
- C. Record of class and laboratory participation and accomplishment of each student in accordance with requirements of the institution.
- D. Attendance and grades.
- E. Record of clinical performance under supervision.

VIII. PROFESSIONAL CURRICULUM

A. Length

1. General—The structure of the curriculum shall be based on not less than one calendar year of full-time study. This is to provide didactic content of appropriate scope and depth as well as clinical experience of sufficient variety to develop needed knowledge and skills.
2. Innovative Programs—Performance objectives for all phases of curriculum and for graduation shall be clearly defined in terms of measurable behavior. Therefore, the curriculum may also be structured to allow students to progress at an individual pace. This will provide an opportunity for students to meet performance standards specified for graduation in less than normal curriculum length as well as provide an opportunity for students who require more time to extend the length of their instructional program. *Students completing the program in less than one year must be advised of current requirements of national certifying bodies.*

B. Structure—Instruction should follow a planned outline which includes:

1. Assignment of appropriate instructional material.
2. Classroom presentations, discussions, and demonstrations.
3. Supervised clinical experience.
4. Examinations, oral and written, for didactic and clinical aspects of the program.

C. Content

1. Patient care
2. Nuclear physics
3. Instrumentation and statistics
4. Health physics
5. Biochemistry
6. Immunology
7. Radionuclide chemistry
8. Radiopharmacy
9. Administration
10. Radiation biology

11. Clinical nuclear medicine—"in vivo" and "in vitro" studies

12. Radionuclide therapy

13. Introduction to computer application/operation or data manipulation

- D. **Records**—Complete curriculum shall be kept on file including rotation of assignments, lists of instructional aids used to augment the learning experience of the student, copies of the course outlines, and class schedules. Directed experience and teaching plans shall be kept on file and available for review. Copies of the practical and written examinations should be maintained and continually re-evaluated.

IX. EDUCATIONAL OBJECTIVES

After participation in the program, each student must be expected to have attained a certain level of knowledge and understanding that is consistent with specific performance objectives. Following is a minimal list of objectives.

- A. **Physical Science.** The technologist must demonstrate a fundamental knowledge and understanding of the following:

1. Elementary aspects of the structure of matter with special emphasis on the composition, stability, and energy levels of atomic nuclei.
2. Modes of radioactive decay with special emphasis on Beta decay, electron capture, metastable states, and internal conversion.
3. Particle and photon radiation accompanying radioactive decay with special emphasis on photon radiation.
4. Interactions of radiation with matter, with special emphasis on photoelectric and Compton interactions.
5. Radiation detectors with special emphasis on scintillation and semi-conductor detectors for photons.
6. Collimated radiation detectors with special emphasis on the characteristics of flat-field, focused, and parallel-hole diverging, and of pin-hole collimators in response to point, line, and plane sources.
7. Electronic instruments such as amplifiers, pulse-height analyzers, scalars, count-rate meters, and computers.
8. Statistics of counting random events.
9. Mathematical operations, including logarithms and exponential functions.

- B. **Radiation biology and protection.** The technologist must demonstrate a fundamental knowledge and understanding of:

1. Biologic effects of radiation exposure.
2. Administrative and technical means of reducing unnecessary radiation exposure to patients, personnel, and the environment.
3. Techniques of measuring levels of radioactive contamination and technique of decontamination.
4. Government regulations regarding exposure and material handling.

- C. **Radionuclides.** The nuclear medicine technologist must be able to demonstrate knowledge and understanding of radiopharmaceuticals in the following specific areas:

1. Production of radionuclides by reactors and particle accelerators, the use of radionuclide generators, the concept of specific activity and the special chemical characteristics of the carrier-free state.
2. Formulation of radiopharmaceuticals, including general techniques of preparing agents used in the nuclear medicine laboratory; and quality control procedures, including tests for radiochemical purity, quantitative assay, sterility and pyrogens.

3. Operation of electronic equipment appropriate for radioassay and quality control.
 4. Understanding of biochemical and physiological properties or radiopharmaceuticals including the mechanism of localization.
- D. "In vivo" procedures (imaging and "in vivo" laboratory work). The technologist must demonstrate knowledge and understanding of:
1. Stationary and moving radionuclide imaging devices.
 2. Stationary imaging including imaging of brain, cerebral spinal fluid spaces, thyroid, lung, heart, liver, spleen, kidney, bones, and other organ systems.
 3. The use of single and multiple detectors for time-dependent studies such as cerebral blood flow, thyroid uptake, cardiac output, differential renal function.
 4. Body composition tests such as blood volume, and red blood cell volume.
 5. Erythrokinetic studies including red cell production and destruction and quantification of blood loss.
 6. Gastrointestinal absorption studies of substances such as iron and vitamin B12.
 7. Gastrointestinal loss studies such as proteins, blood.
- E. "In vitro" procedures. The technologist must demonstrate knowledge and understanding of:
1. The hazards of working with toxic chemicals, infectious biologic materials, and radionuclides, with special awareness of proper handling and disposal of such materials.
 2. Common laboratory instruments and equipment including pipets, centrifuges, pH meters, analytical balances, calculators, and scintillation counters.
 3. The principles of saturation analysis and competitive protein binding assays in order to follow a protocol, with an appreciation of the indications for and limitations of the technique, including procedures such as principles of physiology and biochemistry pertaining to specimen collection and analyses.
 4. A good laboratory quality assurance program, including establishment of such a program and appreciation of the necessity of maintaining adequate laboratory records.
- F. Therapeutic uses of radionuclides including knowledge and understanding of:
1. More common therapeutic applications of radionuclides, dose ranges for each indication, and proper techniques for calculating quantities of administered radiopharmaceuticals.
 2. Special problems of patient care, radiation safety, and follow-up.

3. Special problems of handling excreta from such patients.

X. ADMINISTRATION

- A. **Catalog**—An official publication including a description of the curriculum shall be issued at least biennially. It shall include information regarding the organization of the program, a brief description of required courses, names and academic rank of faculty, entrance requirements, tuition and fees, and information concerning hospitals and facilities used for directed experience. The catalog must also include information about the current accreditation status of the program.
- B. **Accreditation**—Evaluation, including survey team visits, of a program of study can be initiated only by the express invitation of the chief administrator of the sponsoring institution or his officially designated representative.
- C. **Withdrawal**—The institution may withdraw its request for initial accreditation at any time (even after evaluation) prior to final action. The Committee on Allied Health Education and Accreditation and collaborating organizations may withdraw accreditation whenever the educational program is not maintained in accordance with the standards outlined above, or when there are no students in the program for two consecutive years. Accreditation may be revoked only after notice in time to review and respond has been given to the chief administrative officer of the sponsoring institution and program director indicating that such action is contemplated and providing reasons therefor.
- D. **Reevaluation and Review**—The program director and chief administrative officer are given the opportunity to become acquainted with the factual part of the report prepared by the visiting team and to comment on its accuracy before final action is taken. At the request of the institution, a resurvey may be made. Accreditation decisions may be appealed by letter to Committee on Allied Health Education and Accreditation.
- E. **Reports**—An Annual Report must be made to the Committee on Allied Health Education and Accreditation and collaborating organizations through the Joint Review Committee on Educational Programs in Nuclear Medicine Technology. A report form is provided and should be completed, signed by the director of the educational program, and returned promptly.
- F. **Resurvey**—The AMA and collaborating organizations will periodically resurvey educational programs for consultation and evaluation.

Task Analysis

NMTCB Task Analysis of Nuclear Medicine Technology

The Nuclear Medicine Technology Certification Board

Job relatedness is the basis upon which the Nuclear Medicine Technology Certification Board developed its entry-level competence examination. In order to ensure job relatedness, this task analysis was derived by the Board with input from practicing technologists across the country. It is intended as a broad outline of the tasks that are performed in the clinical setting by a competent technologist. The examination content is based upon the tasks enumerated and the implied skill and knowledge necessary to perform those tasks. This task analysis will constantly evolve as the field of nuclear medicine continues to change. As new technologies are incorporated into routine practice, the task analysis will be modified to reflect those changes. The NMTCB always welcomes comment and input regarding the task analysis. Comments should be forwarded to the NMTCB office in Stone Mountain, GA.

I. NUCLEAR INSTRUMENTATION—QUALITY CONTROL

A. Perform routine imaging system evaluations:

1. Scintillation cameras—

- a. Perform field uniformity check—
 - 1) select radionuclide source of appropriate quantity and energy;
 - 2) check pulse height analyzer photopeak adjustment;
 - 3) obtain uniformity images using identical standardized imaging parameters, i.e., counts, information density (I.D.), intensity, etc.
- b. Analyze field uniformity images—
 - 1) compare with previous uniformity image and identify any nonuniformities;
 - 2) differentiate source of nonuniformities using proper procedures, i.e., check collimator, pulse height analyzer (PHA) peaking, detector, cathode ray tube (CRT), lenses;
 - 3) obtain service if indicated.
- c. Perform detector linearity check—

- 1) place source for uniformity check and a parallel line phantom in proper position;
- 2) obtain two images orientated 90° to each other using standardized imaging parameters;
- 3) identify any line distortion on the image;
- 4) determine the source of nonlinearity, i.e., camera system, components, detector-source geometry, and arrange for service if nonlinearity is present.
- d. Perform spatial resolution checks—
 - 1) use uniformity check source;
 - 2) utilize a high resolution phantom compatible with the specified resolution of the camera;
 - 3) obtain resolution images oriented 90° to each other using standardized imaging parameters;
 - 4) compare with prior resolution images;
 - 5) obtain service if resolution degradation is observed.
- e. Conduct sensitivity checks—
 - 1) position source with an appropriate half-life;
 - 2) assure that identical geometry and measurement parameters are used each time.
- f. Check image recording equipment—
 - 1) perform lens focus check;
 - 2) check and adjust CRT dot focus and shape;
 - 3) assess integrity of CRT phosphor.
- g. Maintain the required records for quality control checks.

2. Rectilinear scanners—

- a. Assess performance of NaI(Tl) scintillation spectrometer—
 - 1) calibrate with Cs-137;
 - 2) determine percent FWHM energy resolution;

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- 3) conduct a sensitivity check;
- 4) perform a 60-cycle test count if available.
- b. Check calibration of photorecorder—
 - 1) compare three film exposures taken at three information densities for equal film density;
 - 2) assess operation of contrast enhancement and background erase using a transmission gray wedge;
 - 3) compare results with previous results to determine any changes in system operation;
- c. Maintain required records of the quality control procedures.

B. Scintillation counters:

1. Calibrate with Cs-137.
2. Determine percent FWHM energy resolution.
3. Conduct sensitivity checks.
4. Check background and determine cause for higher-than-normal background.
5. Take a 60-cycle test count if possible.
6. Conduct a chi-square evaluation.
7. Perform an energy linearity check at installation.
8. Perform volumetric calibration at time of installation.
9. Maintain records of these procedures as required.

C. Gas-filled detectors:

1. *Survey meters (G-M tubes)*—
 - a. calibrate according to NRC specifications;
 - b. perform reference check-source test and compare with previous results;
 - c. maintain records as required.
2. *Dose calibrator (ionization chamber)*—
 - a. ascertain linearity over entire range of radionuclide activity to be measured;
 - b. test for significant geometrical variation in activity measured as a function of sample volume or configuration and determine correction factors;
 - c. test accuracy for commonly used radionuclides that have adequate reference standards available;
 - d. check for constancy using a long-lived radionuclide standard;
 - e. maintain records of the procedures as required.

II. DOSE CALCULATION AND ADMINISTRATION

A. Dispense radiopharmaceuticals:

1. *Quantitate exact dose*—
 - a. verify label on radiopharmaceutical vial in-

cluding concentration, specific activity, total activity, lot number, assay time, and date;

- b. determine actual elapsed time between assay calibration and required dose calculation time;
- c. calculate activity remaining using the appropriate decay factor for the time elapsed;
- d. calculate activity needed for procedure;
- e. determine volume of the radiopharmaceutical required for patient dose.
2. *Prepare dose of radioactivity*—
 - a. dispense liquid preparation—
 - 1) draw up correct volume of the radiopharmaceutical into a syringe using aseptic technique and observing proper radiation safety precautions;
 - 2) verify the dose of radioactivity using a dose calibrator;
 - 3) record patient name, examination, activity, volume, lot number, time, date, and prescription number, if appropriate.
 - b. dispense gaseous preparation—
 - 1) calibrate and dispense radioactive gas from bulk load system or unit dose system;
 - 2) load radioactive gas into administration machine if appropriate;
 - 3) maintain appropriate records.

B. Administer dose of radiopharmaceutical:

1. assemble the proper materials for venipuncture;
2. determine proper method and route of administration;
3. evaluate patient's venous anatomy and determine a suitable site for venipuncture;
4. reassure the patient and try to relieve any apprehension;
5. disinfect the site of puncture;
6. administer dose with proper venipuncture techniques;
7. observe patient for possible reactions;
8. discard radioactive materials in appropriate waste containers.

III. IMAGING PROCEDURES

A. Provide patient care:

1. Receive patient and provide for proper nursing care during imaging procedure.
2. Provide for patient comfort, before, during, and after the procedure.
3. Maintain good communication with patient, explain procedure, answer questions, and listen to patient's comments.
4. Provide functionally safe and sanitary conditions for patient.

5. Recognize emergency conditions—
 - a. determine "vital signs" when necessary, including pulse rate, respiratory rate, temperature, and blood pressure;
 - b. administer cardiopulmonary resuscitation when necessary;
 - c. maintain intravenous fluids, oxygen, and other life-support equipment.

B. Prepare patient:

1. Verify patient identification and written orders for study.
2. Check for contraindications and obtain pertinent history.
3. Obtain formal consent when necessary.
4. Check patient clothing and linen for objects (scars, inflamed areas, etc.) that may attenuate and contaminate.
5. Prepare patient with premedications (Lugol's, perchlorate), instruct patient to void, etc., include any preparation necessary for the imaging procedure required.
6. Wait appropriate length of time after administration of radiopharmaceutical to begin imaging procedure.

C. Perform imaging procedures:

1. *Select imaging parameters—*
 - a. select proper instrument and auxiliary equipment necessary to perform imaging procedure;
 - b. prepare instrument for procedure, i.e., select proper collimator, imaging parameters, setting, etc.;
 - c. select appropriate parameters for data acquisition using a computer;
 - d. recognize artifacts that are due to instrument malfunction.
2. *Position patient and obtain images—*
 - a. select required positions for procedure;
 - b. place patient in correct position using supportive materials and immobilizers to obtain scintigrams for each view;
 - c. determine correct detector-to-patient distance;
 - d. indicate appropriate anatomical landmarks for each view of a procedure.
3. *Perform data processing—*
 - a. perform any necessary data manipulations to achieve desired end product of imaging procedure;
 - b. process film according to manufacturers specifications and film processor optimum operation;

- c. review study to assure correct information is supplied and any special views required have been obtained;
- d. analyze data acquired and report results to physicians for interpretation;
- e. maintain quality control for all aspects of the imaging procedure.

D. Perform administrative procedures:

1. Maintain adequate supplies of radiopharmaceuticals and all other materials including film to ensure that patient studies may be performed whenever necessary.
2. Schedule patient studies, ensuring that appropriate study is scheduled. Interact with hospital staff to effect proper and timely arrangements for patient study.
3. Determine the most appropriate sequence for multiple procedures.
4. Maintain appropriate records of patient doses, quality control procedures, patient reports, and other required records.
5. Maintain procedure manual and update manual on a regular periodic basis.

Note: Apply the aforementioned tasks for the following types of procedures: central nervous system, endocrine, cardiopulmonary, genitourinary, gastrointestinal, and hematologic.

IV. RADIOPHARMACY

A. Maintain radiopharmaceutical laboratory:

1. Initiate purchase orders for supplies of radiopharmaceuticals and other supplies.
2. Perform "wipe tests" of the exterior package on all radioactive shipments received.
3. Log in the receipt of radioactive materials in a record book.
4. Monitor all packaging materials and deface radiation symbols on boxes before discarding.
5. Store radioactive materials and nonradioactive kits in the appropriate area.
6. Determine necessity to reorder radiopharmaceuticals and kits to prevent delays.

B. Obtain generator eluate:

1. Assemble generator and position behind lead barriers.
2. Elute generator using aseptic technique.
3. Assay the eluate using a dose calibrator or whole-vial assay.
4. Record the assay results and time in a log book.
5. Check the eluate for radionuclidic and chemical contamination and record results.

C. Compound radiopharmaceuticals:

1. Review daily work schedule and prepare appropriate radiopharmaceutical compounds using [^{99m}Tc] pertechnetate to include sulfur colloid, microspheres or macroaggregated albumin, phosphates, DTPA, etc.
2. Determine the amount of radioactivity to be added to a radiopharmaceutical kit and record the volume of generator eluate used. Be aware of any activity limits in preparation of kits.
3. Prepare radiopharmaceutical assay form for each lot of material.
4. Check total activity in reaction vials in dose calibrator.
5. Calculate the concentration of radioactivity of the compound and label vial as to the date and time of preparation, lot number, the concentration and the volume.
6. Check all preparations for proper pH, color, clarity, and particle size if appropriate and record on radiopharmaceutical assay form.
7. Determine the radiochemical purity of the compound by chromatography or electrophoresis.

D. Dispose of radioactive waste:

1. Monitor all radioactive dose vials and determine if acceptable to discard.
2. Monitor alumina columns from generators to determine if acceptable to discard.
3. Maintain long-term storage area to allow for decay of radioactivity.
4. Maintain log on radiopharmaceutical disposal.

V. RADIATION PROTECTION

A. Maintain local state or federal license and assure compliance with regulations:

1. Notify appropriate authority when change in safety program occurs.
2. Amend license when necessary.
3. Review regulations periodically.
4. Maintain required records.
5. Post appropriate signs in designated areas.
6. Design program to follow regulations regarding the receipt and disposition of all radionuclides.
7. Design and carry out program to follow regulations regarding therapeutic doses and follow up.
8. Recommend purchase of any protection equipment to meet regulations.
9. Package radioactive material according to regulations and keep accurate records of transfer.

B. Follow appropriate protection procedures:

1. *Employ personnel monitoring devices—*
 - a. review monthly personnel exposure records in regard to maximum permissible dose limits;

- b. take appropriate measures to reduce exposure when necessary;
 - c. keep exposure as low as is reasonably achievable using appropriate protection parameters continuously;
 - d. notify the NRC of excessive exposure when appropriate.
2. Select and use proper shielding to reduce radiation exposure, i.e., employ inverse square law and half-value layers.
 3. Use proper methods for the storage of radioactive materials.
 4. Identify and use proper procedures for those radionuclides which pose special hazards.

C. Surveys:

1. Calibrate survey instruments.
2. Set frequency and locations for surveys and follow schedule.
3. Use proper survey meters for each type and level of activity.
4. Follow regulations regarding personnel surveys and interpret results.
5. Perform wipe tests where applicable.
6. Perform leak tests on sealed sources when appropriate.
7. Record data in some standard format.

D. Perform decontamination procedures:

1. Block access to area and confine the spill.
2. Remove contamination or reduce the activity to acceptable levels.
3. Monitor the area and personnel and repeat decontamination procedure until levels of activity are acceptable.
4. Store and dispose of contaminated material following regulations.
5. Maintain adequate records concerning the clean up.

E. Dispose of radioactive waste:

1. Maintain appropriate records.
2. Dispose of waste properly according to license specifications.

F. Participate in inservice program to instruct other personnel about radiation hazards and principles of radiation safety:

1. *Teach concepts including—*
 - a. the biological effects of ionizing radiation;
 - b. limits of dose, exposure and radiation effect;
 - c. types of ionizing radiation.
2. Provide instruction on appropriate radiation safety measures.
3. Provide instruction on proper emergency procedures to be followed until radiation personnel arrive at the site of accident or spill.

VI. NONIMAGING PROCEDURES

A. In vivo:

1. Operate laboratory equipment—

- Check accuracy and operation of pipetting devices.
- Use microhematocrit centrifuge and determine hematocrit.
- Compute relative centrifugal force, operate centrifuges, and maintain routine tachometer checks.
- Maintain refrigerator for storage of reagents and standards.
- Maintain quality control records on all laboratory equipment.

2. Prepare doses and standards—

- Quantitate exact dose—
 - determine decay constant and calculate remaining activity;
 - determine volume necessary to deliver required activity;
 - draw dose into syringe using appropriate materials;
 - confirm calculated activity by using a dose calibrator.
- Prepare standard—
 - choose appropriate volumetric glassware for dilution of the standard;
 - add a portion of solvent to glassware and a solution to prevent sticking;
 - add a dose similar to that given the patient and dilute up to calibration mark;
 - dilute capsule in appropriate solvent if necessary for a standard.

3. Collect proper specimen for procedure—

- Blood collection—
 - select proper equipment for blood collection (needles, syringes, anticoagulants, etc.);
 - perform venipuncture at appropriate time intervals;
 - add hemolyzing compounds when necessary;
 - centrifuge blood and separate blood components;
 - store aliquot of serum, plasma, or whole blood according to protocol.
- Urine collection—
 - choose appropriate container for urine collection;
 - add a small amount of preservative to container;
 - instruct patient and nursing staff about the method and length of urine collection;

4) aliquot urine sample and measure total urine volume;

5) measure specific gravity of urine if required;

6) collect additional urine if volume collected is insufficient.

c. Stool collection—

- choose appropriate container for stool collection;
- instruct both patient and nursing staff as to correct method of stool collection;
- homogenize stool and aliquot sample for counting; or
- place sample of stool in carton for counting, maintaining same geometry.

4. Operate counting equipment—

- Set pulse height analyzer on scintillation detector and center the photopeak within the analyzer settings chosen for the procedure.
- Count in vitro samples, standards, and room background for a statistically significant number of counts, making corrections for geometrical differences if necessary.
- Outline organs to be counted externally and count for a statistically significant number of counts.
- Choose correct detector-patient distance.

5. Perform calculations—

- Subtract room background or patient background from all samples.
- Apply appropriate formulas, including conversion and dilution factors.
- Calculate results according to the procedure employed.
- Plot graph if necessary and determine $T^{1/2}$ or extrapolate to zero time.
- Calculate organ ratios.
- Report both patient calculated values and the normal range of the specific procedure used.

Apply these tasks to the following procedures where applicable: blood volumes (Cr-51 and RISA), red cell survivals, ferrokinetic studies, gastrointestinal protein loss, gastrointestinal blood loss, thyroid uptakes, and Schilling test.

B. In vitro:

1. Operate laboratory equipment—

- Check accuracy and operation of all pipetting devices used.
- Maintain constant temperatures in water baths.
- Compute relative centrifugal force, operate centrifuge and maintain routine tachometer checks.

- d. Calibrate and operate pH meters.
 - e. Calibrate and use laboratory scales and balances.
 - f. Operate vortex mixers and shakers maintaining constant conditions.
2. *Collect blood sample—*
- a. Select proper equipment for blood collection (needles, syringes, etc.)
 - b. Choose proper anticoagulant for specific procedure.
 - c. Perform venipuncture at appropriate time intervals.
 - d. Collect blood sample on ice as required.
 - e. Centrifuge blood and separate blood components.
 - f. Store aliquot of patient sample as dictated by the protocol.
3. *Perform assay—*
- a. Allow assay components and patient specimens to equilibrate to room temperature as required.
 - b. Prepare assay reagents.
 - c. Add RIA components according to the protocol.
 - d. Incubate standards and samples in the appropriate environment for the required time.
 - e. Separate the bound from the free radioactivity using the necessary laboratory equipment.
 - f. Load samples in counter and set instrument counting.
 - g. Count all samples for the appropriate time to give a statistically significant number of counts.
 - h. Reduce data to net counts by subtracting room background and nonspecific binding counts.
- i. Calculate the desired fraction (bound/total, bound/free, free/total, etc.) for generation of the standard curve.
 - j. Plot above fractions obtained for the standards on the appropriate graph paper.
 - k. Determine data for all patient and controls from the derived standard curve.
 - l. Transfer assay results to laboratory data record and to patient's request form.
4. *Quality control—*
- a. Develop and maintain quality control procedures for all assays, using appropriate control sera.
 - b. Record daily results of all controls on quality control charts.
 - c. Perform periodically the appropriate control sera checks.
 - d. Maintain records of antibody binding for each assay to note any reagent deterioration.
 - e. Recognize a significant shift in assay control and take appropriate action.
 - f. Compare another laboratory's results with your own.
5. *Assay evaluation—*
- a. Perform all tasks necessary to assess the accuracy, precision, sensitivity, and specificity of the assay.
 - b. Develop a normal range for each assay.
 - c. Test for the biological validity of the assay.
6. *Kit evaluation—*
- a. Determine intra-assay and interassay variability.
 - b. Determine assay accuracy by performing recovery studies.
 - c. Choose kit with the best overall performance.

Senator RANDOLPH. Thank you very much.

In the committee I chair on the Environment and Public Works, we had a new assignment some 3 years ago with jurisdiction of nuclear regulation. We realize the problems. Many of our members are cautious about nuclear power. We tried very diligently in the report that accompanied the Three Mile Island accident which report is to be made public within the very near future—to present a broad appraisal of this critical issue.

There is a tremendous interest in this subject, the nuclear fall-out, and related issues. The people's attention is riveted on this subject and yet several times today we have heard testimony about the extent of other exposure to manmade radiation.

Mr. Donohue, would you repeat what you said about the incidence of exposure—the 90 percent?

Mr. DONOHUE. It has been estimated——

Senator RANDOLPH. I just want it reaffirmed.

Mr. DONOHUE. Over 90 percent of the exposure to the public would be from medical and dental X-radiation, not from nuclear, specifically.

Senator RANDOLPH. What does that say, both of you, if you wish to make a comment? What are you saying? Are you saying that we have to do something in this field?

Mr. DONOHUE. If I might allude to something there, Senator—I am quite nervous here. You will have to pardon me.

I was involved out in the State of California, one of the States that has State licensure and has had for almost 10 years—at the time of the enactment of the law and the regulations pursuant to the law, I was party to providing some courses in education to some 900 individuals who had not been trained to operate X-ray equipment before, nurses, girls Friday in doctors' offices. Some of the implications they told us were rather frightening. This is to indicate the States that do not have such licensure are still performing these practices. They were holding patients during exposure. They were not provided with radiation safety survey devices to see the amount of exposure they were receiving. Since they did not know how to operate the machine or control the machine, they were told to turn it on; don't change the setting. They had no knowledge of the controls, and if the radiograph came out bad, they were told, just take a longer exposure; don't columnate the beam, because if you columnate the beam, you might cut off something that we are very interested in seeing.

We heard from ladies and gentlemen who attended medical assistant programs where they were trained for X-ray procedures for 4 to 6, to 10 hours of their total training. They had files of X-rays they had taken on each other as guinea pigs in order to learn it. I was amazed by this type of information, but I was not really surprised; and I would say that without some safeguards—the people do not know the dangers, actually, that they are performing; and since that is the case, unfortunately—a poor examination is not the only question—but what about the patient who, because of that examination, may have a condition or disease that goes undiagnosed, and they may not see a doctor for another several years? These are the concerns that we have with untrained, unskilled, uncredentialed operators out there operating this equip-

ment. They do not know the dangers and the hazards associated with this, not only for the patient, but for themselves as well. They were quite concerned when they took courses relevant to radiation protection and saw that by adjusting their technique on the control panel, they could significantly reduce the exposure to that patient.

I might respond to something Mr. Villforth said earlier with regard to the fact that new materials are being developed to reduce dosage, et cetera.

If the people are not trained and skilled and knowledgeable of these particular materials, how are they going to utilize them? He indicates that we are only talking about a small segment, some 10 percent or so of the population that are being exposed to the noncredentialed operators.

Is it the Bureau of Radiological Health's suggestion that we write off 10 percent of the population? That scares me. Everyone should and has the opportunity to have a properly performed radiological procedure that will give maximum benefits with minimum risk; and I do not think you can do that without some minimal standards which is what S. 500 speaks of.

Senator RANDOLPH. There is no licensure requirement in the District of Columbia?

Mr. DONOHUE. No, there is not, sir.

Senator RANDOLPH. Do you want to make a comment?

Mr. ALEXANDER. In the field of nuclear medicine, we have very strict control of our procedures. Our instruments do not give off radiation.

A suggestion might be that the X-ray machines be stringently regulated. I am not a radiologic technologist and, therefore, I cannot speak for them. This is a possibility, however.

Another thing is that there are several impressive attributes in the field of nuclear medicine for reducing radiation.

One of these is the fact that we have much newer concepts. The exposure orders of magnitude are much lower than they have been in the past and in some cases we obtain better results, compared with other modalities.

Another thing I would like to address is that the Society of Nuclear Medicine, and the technologist section, have worked very diligently with Mr. Villforth and his group from BRH in trying to set up standards which our technologists must meet. An example might be the quality assurance program.

At the University of Cincinnati Medical Center, we started the quality assurance program about 7 or 8 years ago. These programs produce better quality procedures and thus consumer patients are protected.

Senator RANDOLPH. Mr. Stanton, we appreciate you holding up for a moment.

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

Currently, nine States and Puerto Rico have active credentialing programs for X-ray operators. Seven other States have enabling legislation to implement credentialing.

In general, the Conference supports the intent of S. 500; in particular, there are several comments, most of which are specifically from our Task Force on Credentialing of Allied Health Operators.

Our organization has been expressing concern about the need to reduce unnecessary and unproductive radiation exposure of the consumer public for many years. As early as 1974, the Conference went on record as favoring some form of credentialing of allied health radiation operators as a desirable mechanism to assure that operators of X-ray equipment have met a standard of education and training to qualify themselves to properly administer X-rays to humans.

The specific comments from the Task Force are as follows:

One, the definition of "radiation," section 104(4), seems to be much broader than indicated in sections 102 and 103. Such a broad definition could be interpreted to include radiation outside the area of healing arts practices.

We recommend that "radiation" be defined as ionizing radiation lawfully prescribed and applied to consumer-patients in the course of medical and dental diagnosis or treatment.

Two, consideration should be given to adding physicians' assistants and persons in extern programs to the definition of "medical practitioner" in section 104(3). The number of persons in both of these activities is rapidly expanding.

Three, because part II, section 121 is a restatement of the Presidential directive entitled "Radiation Protection Guidance to Federal Agencies for Diagnostic X-Ray," issued January 26, 1978, and published in the Federal Register on February 1, 1978, it appears to be redundant in the proposed legislation.

Four, section 131(b) is unclear and contradictory in that the last sentence seems to require the Secretary to utilize organizations recognized by the Commissioner of Education for such purposes provided that the Secretary shall find such organization is not continuing to adhere to such standards.

We suggest that removal of the word "not" would clarify this section. We would also prefer to have the Secretary permitted to authorize nonprofit evaluation organizations to certify accreditation as well as appropriate professional organizations. In some areas, a group of educational institutions may wish to form an independent consortium for this purpose but could not be legally defined as a professional organization.

Five, section 136(a) provided that the Secretary may make grants to State radiation protection agencies. Because some States may choose to place this program in an existing State agency which certifies persons in other professions, it seems that this should be changed to " * * * make grants to appropriate State agencies administering the programs authorized under this Act. * * *".

Six, the conference strongly objects to the apparent intent of section 142 which would essentially tie all other Federal financial assistance programs to the implementation of this one piece of legislation.

Before I close, I would like to point out that the aforementioned comments were prepared before Executive Order 12194, creating the Radiation Policy Council. It is conceivable that such action may alter the thinking of our task force.

The Conference appreciates the opportunity to comment on the issue and offers our continued cooperation in the future development of coordinated Federal-State actions.

Senator RANDOLPH. Thank you very much. I think the suggestions you make are helpful to us. I know that the process of final passage and enactment of a law does call for accommodation—changes in language. The thrust of the legislation: are you for it or against it?

Mr. STANTON. Is that me as an individual State program director, or me representing the Conference?

Senator RANDOLPH. The Conference.

Mr. STANTON. Representing the Conference, the answer is an unequivocal yes; we are in support of S. 500.

Senator RANDOLPH. I thank you very, very much.

I wonder if we might ask your cooperation, Mr. Donohue, Mr. Alexander, and Mr. Stanton. If you would stay with us, step aside so that I might hear hopefully two more witnesses from the next panel. I have gone over the questions with Mr. Altmeyer, of our staff. We would like to continue with questions to you as well as the others.

So if we could please now hear from Dr. Brown and Ms. Butler.

I wish the record to reflect that other members of the committee had hoped to be here, particularly Senator Javits. He had a conflict in which he had to chair, at the last minute, an important hearing.

I can assure you that others would have wished they could have been here, if possible.

Dr. Brown, would you then please proceed?

STATEMENTS OF DR. WILLIAM E. BROWN, CHAIRMAN, COUNCIL ON DENTAL EDUCATION, AMERICAN DENTAL ASSOCIATION, ACCOMPANIED BY MS. JERI YUNKER, PRESIDENT, AMERICAN DENTAL HYGIENISTS ASSOCIATION; DR. MARIO V. SANTANGALO, ASSISTANT SECRETARY, COUNCIL ON DENTAL EDUCATION AND COMMISSION ON ACCREDITATION, AMERICAN DENTAL ASSOCIATION; MS. JANELLE BUTLER, PRESIDENT, AMERICAN DENTAL ASSISTANTS ASSOCIATION; AND MICHAEL LEMOV, COUNSEL, AMERICAN DENTAL ASSISTANTS ASSOCIATION, A PANEL

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

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

I would like to introduce for the record Ms. Jeri Yunker, who is currently president of the American Dental Hygienists' Association, and Dr. Mario Santangalo, who is assistant secretary of the Council on Dental Education and the Commission on Dental Accreditation.

With your permission, I would simply like to summarize the formal statement, which was transmitted to the committee earlier this week. I ask that our formal statement be included in the record in its entirety.

Diagnostic X-rays are crucial to the delivery of modern dental care. Yet, in recognizing the value of radiographic examinations, we are concerned with both the dental and general health needs of the patient, and committed to reducing unnecessary ionizing radiation insofar as we can.

The most recent American Dental Association policy statement on the utilization of X-rays appeared in the March 1978 issue of the American Dental Association's Journal.

It stated, and I quote:

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

I would like to comment a little bit about curriculum and the inclusion of radiology.

Radiology is an integral part of the dental, dental hygiene, and dental assisting curriculum.

Speaking now to the dental education curriculum, total time averages between 4,500 and 5,000 clock hours.

The 1976 study of dental curriculum in the United States reported that instruction in radiology spans some 2½ to 3 years of a 4-year curriculum. There are 88 mean hours of direct instruction, 100 mean hours of oral diagnosis, which includes additional hours of radiology, and an undetermined number of hours in various other disciplines and in clinical experiences that dental students have.

This 1976 study also demonstrated that over the past 10-year period, from 1966 to 1976, dental curriculums demonstrated a marked increase in emphasis on radiation and radiation protection.

I would like to comment just a little bit now about how the various personnel in a dental office manage radiographs.

It is clear in dentistry that almost everything is done in the private office setting and that, in fact, the dentist, legally and professionally, is responsible for everything that happens. Whether it be a dental assistant or a dental hygienist, he or she is working under the supervision of that professional while he is also in the office.

I think you should know that all dental X-rays are diagnostic. They are not therapeutic. I think you might know further that each dental X-ray requires a fraction of a second exposure and includes but a very small area of exposure.

I would like to next talk about the American Association of Dental Schools and what it is doing to help decrease exposure to ionizing radiation even further.

At its meeting just 2 weeks ago in Los Angeles, it developed the following policy statement:

Dental education institutions have as a primary responsibility the preparation of qualified, competent dentists and dental auxiliaries capable of effectively, without undue risk, using ionizing radiation.

Two, students should be trained to critically assess the need for diagnostic radiographic information, evaluate the risk-benefit ratio for each diagnostic procedure,

and establish an appropriate differential diagnosis based on clinical, laboratory and radiographic information.

Three, dental education institutions have the responsibility of minimizing to the greatest degree possible the potential risk to students, faculty, staff, and the general public from any radiographic procedure.

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

In addition to policy which has been in existence for a number of years, the section on oral radiology, dealing with dental, advanced education and auxiliary curriculum, developed a similar statement to help them better prepare students. In 1976, the dental hygienists and the dental assistants likewise developed appropriate standards and guidelines which are in the process right now of being updated as they pertain to instruction in radiology.

The Commission on Dental Accreditation visits each program under its jurisdiction once every 7 years. This includes accredited dental schools, dental hygiene programs, laboratory technology and graduate programs.

I think you might like to know that during its site visits, the team evaluates course content—depth and scope; the time devoted to teaching the subject of radiology in all subdisciplines; the sequencing of the subjects in the curriculum; the faculty numbers and qualifications; technical support personnel numbers and qualifications; equipment—generators and darkroom; guidelines and policies on controlling use of ionizing radiation; guidelines and policies on monitoring use of ionizing radiation; review of the institution's practices relating to use or nonuse of radiographs in the patient-screening process; use of radiographs during treatment, such as in endodontic therapy and during oral surgical procedures; teaching technique with use of mannequins rather than live subjects; policy or policies in retaking radiographs; and, quality assurance program in radiology.

These are some of the things that the Commission does on site and, in addition, the team will review actual radiographs produced in the institution and the records of patients for quality and completeness. We also look very carefully at the qualifications, the credentials, of the faculty.

At the meeting last December, the Commission on Dental Accreditation developed a statement which was subsequently sent to all of its educational programs. I would like to quote it because I think it indicates our support.

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

The Council on Dental Education and the Commission on Dental Accreditation are giving special emphasis to the area of ionizing radiation on all site visits to dental educational institutions.

It should be pointed out that the American Association of Dental Schools is in the process of developing policy statements and curricula guidelines on the teaching, use, monitoring and control of ionizing radiation. Using these and other references, the Commission on Dental Accreditation will draft statements on the critical issue of ionizing radiation to be included in accreditation guideline documents.

Schools of dentistry can expect that more emphasis, monitoring and critical review of a school's ionizing radiation practices will be pursued with vigor in future

site visits. Any deficiencies noted will be brought to the attention of the parent institution in the accreditation report.

I think you would be interested in two or three recommendations that turn up regularly on onsite visit reports.

First, a professional must examine each patient before radiographs are ordered;

Second, a separate table in the patient's chart must list the X-ray exposures for each patient and these must be accumulated and maintained over time;

Third, a single department or individual must control all radiation produced in the institution.

Within the last week, a survey instrument has been developed and shortly will be transmitted to all institutions to collect detailed information on curriculum, qualifications of faculty, facilities and equipment and also relating to control and monitoring.

I think you should also know that new standards—we have always had standards for 30 years, but new standards for teaching radiology to dental students and dental assisting students and dental hygienists have been developed and will be effective January 1, 1981. These are clearly spelled out in the formal statement.

Then, finally, as I come to a close, I would like to point out that as of June 1979, talking about formal programs, there were 298 accredited dental assisting programs in the United States; and as of June of 1979, there were 6,644 graduates during that year. There are uncounted nonaccredited dental assisting programs throughout the United States and we simply do not have all of the data on that.

A comment on licenses.

The American Dental Association is strong in its support for State and regional licensing; and I think, Mr. Chairman, you have received the formal position of the ADA on the licensing issue.

I think you should also know that in this country now, there are four regional licensing examination systems, and these four incorporate, I believe, approximately 34 States. Additionally, the profession has not been convinced that there is a need for additional licensing. The rationale is thoroughly described in the formal statement.

Finally, I would like to say that, although we support strongly the concept of eliminating unnecessary ionizing radiation, and frankly, let me commend you, sir, for your efforts in this regard, it is our position that in terms of dental radiology, the American Dental Hygienists Association, the American Association of Dental Schools, the Commission on Dental Accreditation, and the American Dental Association are moving vigorously to achieve these same objectives and have demonstrated their effectiveness.

Hence, in our judgment, S. 500 is simply not necessary.

[The prepared statement of Dr. Brown follows:]

STATEMENT OF
THE AMERICAN DENTAL ASSOCIATION
ON
S.500 - CONSUMER-PATIENT RADIATION HEALTH AND SAFETY ACT
BEFORE THE
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH
COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE
April 3, 1980

Mr. Chairman and Members of the Subcommittee, my name is Dr. William E. Brown from Oklahoma City, Oklahoma. I am Dean of the College of Dentistry at the University of Oklahoma. Currently, I also serve as Chairman of the Council on Dental Education and the Commission on Dental Accreditation of the American Dental Association. The Council is the policy recommending body to the Association's House of Delegates in matters relating to education. On the other hand, the Commission is an autonomous agency of the profession which is nationally recognized as the accrediting body for dental, dental auxiliary, dental specialty and general practice dental residency programs. The Commission is recognized by both the United States Office of Education and the Council on Postsecondary Accreditation. Although I am appearing before this Subcommittee today in behalf of the American Dental Association, I wish to point out that I am authorized to speak in behalf of the American Association of Dental Schools. I am a member of that organization's Council of Deans.

I am accompanied by Dr. Mario V. Santangelo, the Assistant Secretary of the Council on Dental Education and the Commission on Dental Accreditation.

In behalf of our organizations, let me assure you at the outset that the dental profession, along with the dental educational community, share the public's concern about the use of any unnecessary ionizing radiation by dentists or dental auxiliary personnel. As an integral part of the profession of dentistry, let me state emphatically that the dental educational community likewise recognizes that it has not only the responsibility but also the obligation for preparing all graduates, whether they be dentists, dental hygienists or dental assistants, competently in all aspects of radiology. Faculty at educational institutions are not only committed to educating and training students in the judicious use of ionizing radiation, but are also equally committed to ensuring against its abuse.

As a preface, I believe that it is most important to emphasize to the Subcommittee that the use of x-radiation for diagnostic and treatment planning purposes in dentistry is unquestionably essential for modern practice. There is no doubt whatever that radiographs are an indispensable laboratory aid. In recognizing the value of radiographic

examinations, the American Dental Association has consistently stated, however, that the use of x-radiation for diagnostic purposes should be made only after careful consideration of both the dental and the general health needs of the patient. The deciding factor is the total welfare of the patient. The nature and extent of diagnosis for required patient care constitute the only rational basis for determining the need or the frequency of dental radiographic examination. The most recent statement of Association policy with respect to x-ray utilization appeared in Recommendations in radiographic practices. The stated policy is:

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

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

We believe that formal and continuing education are key factors in assuring that an individual is and remains competent in the use of x-radiation. We believe further that through such education individuals can be made to recognize the need to reduce or to eliminate unnecessary radiation because of its possible harmful effects to both patient and operator. It is in the area of education and training that I will now focus my attention.

With reference to education and training, I should emphasize that radiology is an integral part of the curriculums of each of the 60 dental schools in the United States. Further, instruction and clinical experiences in dental radiology are required for the accreditation of dental hygiene and dental assisting programs. In dental education, radiology instruction generally spans between two and one-half and three years of the traditional four-year educational sequence. Although comparable data are not available for dental hygiene and dental assisting education, a comprehensive study of dental curriculums of all United States dental schools in 1975 and published in the report -- Dental Education in the United States - 1976 -- showed that 59 of the 60 dental schools (one school had not admitted its first class at the time of the study) provided from 19 to 278 clock hours of instruction in radiography. The mean number of hours of instruction was 88.0; and the median number of instructional hours was 70.0 hours. In addition, supplementary instruction in radiology, specifically radiographic interpretation, frequently is provided in a number of other disciplines, such as oral diagnosis and treatment planning. Schools provide a range of 12 to 489 hours of instruction in oral diagnosis; with a mean of 118.9 hours and a median of 96.0 hours. The use and interpretation of radiographs are also an

essential part of every subdiscipline of dentistry and additional instruction in radiology is incorporated in the study of each subdiscipline even though this component is not specifically identified as instructional hours in radiology. More importantly, almost one-half of the schools reported an increased emphasis in all areas of radiographic instruction, and almost one-third of the schools reported having increased the number of clock hours devoted specifically to radiographic instruction.

It is important to emphasize that in the section of the curriculum study report dealing with changes in curricular emphasis during the past 10 years, almost one-half of the 59 fully operational dental schools reported an increased emphasis in all sub-areas of instruction in dental radiology. Radiation safety and protection and interpretation of radiographs were specifically identified as the two areas which received the greatest increase in attention. It is apparent from the data that dental education recognizes the need to review and to update instructional content in dental radiology and that it is placing added and renewed emphasis on the hazards of ionizing radiation, radiation hygiene, radiation safety and protection. In short, dental education takes very seriously the obligation of being assured that students are taught to use ionizing radiation intelligently and not to abuse it.

Mr. Chairman, with that brief background, I should like at this time to give a brief review of a number of activities relating to radiation which have or are taking place within the American Association of Dental Schools, the American Dental Association and the Commission on Dental Accreditation. In these matters, the AADS works very closely and cooperatively with the Commission on Dental Accreditation.

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

Perhaps I should clarify the fact that development of curricular guidelines by the AADS in any discipline does not suggest that the Commission on Dental Accreditation mandates educational institutions to implement such guidelines. Guidelines developed by AADS are intended to be advisory and helpful to faculty and institutions. Such guidelines are not intended to be restrictive or prescriptive require-

ments. Mandating implementation of instructional guidelines could be construed as being tantamount to infringing upon the academic freedom and rights of institutions and faculty. On the other hand, it should be noted that if the Commission on Dental Accreditation notes specific deficiencies in the teaching of radiology during accreditation site visits, it does urge faculty to consider utilizing such guidelines with a view to improving the teaching program.

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

To illustrate the continued commitment of AADS in addressing the issue of education and training, that Association's House of Delegates, at its 1980 meeting, adopted the following statements for inclusion in the AADS Policy Statements section on objectives. The approved Statements are:

1. Dental education institutions have as a primary responsibility the preparation of qualified, competent dentists and dental auxiliaries capable of effectively without undue risk using ionizing radiation.
2. Students should be trained to critically assess the need for diagnostic radiographic information, evaluate the risk/benefit ratio for each diagnostic procedure, and establish an appropriate differential diagnosis based on clinical, laboratory, and radiographic information.
3. Dental education institutions have the responsibility of minimizing to the greatest degree possible the potential risk to students, faculty, staff, and the general public from any radiographic procedure.
4. Radiographic quality assurance programs should be implemented to assure the optimum quality of each diagnostic radiograph incorporating procedures that will restrict to an absolute minimum the amount of radiation received by the patient.

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

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

At this point, I should like now to address some remarks on a number of activities with which the Commission on Dental Accreditation is actively involved. Specifically, I wish to emphasize to the members of this Subcommittee that major effort is devoted during accreditation site visits to reviewing the education and training that dental and dental auxiliary students receive in radiology. Let me assure you that the Commission, during the accreditation review process, makes every effort to ensure that the education and training provided prepares dental and dental auxiliary graduates to be competent in all aspects of radiology.

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

1. Course content - depth and scope
2. Time devoted to teaching the subject of radiology in all subdisciplines
3. Sequencing of the subject in the curriculum
4. Faculty - numbers and qualifications
 - (a) Authority and responsibilities of radiology faculty
5. Technical support personnel, numbers and qualifications
6. Equipment - generators and darkroom
 - (a) Location of equipment
7. Guidelines and policies on controlling use of ionizing radiation
8. Guidelines and policies on monitoring use of ionizing radiation
9. Review of institution's practices relative to:
 - (a) Use or non-use of radiographs in the patient screening process

- (b) Use of radiographs during treatment, such as in endodontic therapy and during oral surgical procedures
- (c) Teaching technique with use of manikins rather than live subjects
- (d) Policy or policies in retaking radiographs

10. Quality assurance program in radiology

More specifically, the Commission requires, as a part of its accreditation review, that faculty who are responsible for providing instruction in specific subject areas complete a section of the self-study manual dealing with radiology and provide detailed objectives and outlines of their courses. That section of the self-study manual is attached for the record. Specifically, with radiology, attention during the accreditation site visit is devoted to the depth and scope of content in each of the following sub-areas of radiology: radiation physics, interaction of x-radiation with matter, factors affecting radiographic image production, biological effects of ionizing radiation, radiation safety and protection, radiographic techniques and interpretation of radiographs. In addition to the review of the didactic or lecture component of the course, the site visit team also devotes considerable time and effort to reviewing the clinical component of the radiation education program. The Commission also reviews the mechanism employed by the institution to monitor use of radiation to ensure the protection of the operator, the patient and the public at large. During such visits, randomly selected patients' records are also reviewed to assess, among other things, if quality control of radiographs is being maintained, whether there is clear documentation of all radiographic exposures on the patient's record and whether the sequential log of exposure to ionizing radiation is recorded. Further, the Commission reviews the credentials of faculty teaching radiography to ensure that those having this responsibility have the appropriate training.

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

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

with the ionizing radiation policies and practices established within the respective health sciences centers.

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

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

During that meeting, the Commission also concluded that an in-depth study of dental radiology teaching should be conducted. The study will include all programs accredited by the Commission. A survey instrument has been developed to collect detailed information on radiology curriculum, qualifications of faculty who provide instruction in radiology, facilities and equipment, and clinical practices relating to controlling and monitoring use of ionizing radiation.

To further illustrate the desire of the Commission to focus appropriate attention to teaching of radiology to auxiliaries, recently revised accreditation Standards for dental hygiene and dental assisting, which become effective January 1, 1981, state that: the curriculum must include scientific principles of radiography and practice in performing oral radiographic procedures. The Standards also state:

Students must demonstrate competence in making diagnostically acceptable radiographs on manikins and must demonstrate knowledge of radiation safety measures prior to making radiographs on patients. Through scheduled instructional sessions, students must have the opportunity to develop competence in making radiographs on a variety of patients. Experience should include primary, mixed and permanent dentitions as well as edentulous or partially edentulous patients. The minimum number of acceptable radiographs of each type which each student must complete during the radiography course must be

specified. Students must demonstrate minimum competence in making diagnostically acceptable radiographs on patients in the program facility prior to making radiographs during extramural clinical assignments. Faculty instruction and evaluation must be provided throughout the student's radiographic technique experience.

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

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

In view of the efforts and increased activities of the Commission on Dental Accreditation and the American Association of Dental Schools to work collaboratively in ensuring that students are provided with quality and appropriate instruction in radiology, it should demonstrate rather conclusively that the dental profession is not only interested in but has taken positive steps to ensure that the nation's public health and safety are safeguarded. Further, it should be clear that it is the intent of both organizations that graduates appreciate the need to minimize exposure to potentially hazardous and unnecessary radiation. Both organizations believe that they are dealing most effectively with the issues identified in S.500. Both organizations believe that it is unnecessary for the federal government to develop and promulgate minimal standards and guidelines for the accreditation of educational institutions which conduct education programs in radiologic services. Our organizations believe that it is the profession's public responsibility to assure adequate protection of public health from unnecessary radiation exposure and to assure efficacious patient radiologic services. In view of the Commission's actions, there appears, in our judgment, to be little merit in having the federal government impose dictates on educational institutions when these issues are being addressed effectively and most efficiently by the Commission on Dental Accreditation and the AADS.

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

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

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

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

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

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

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

While the profession has reservations about other specific aspects of that document, it did concur that licensure did not appear to be the most appropriate form of regulation for dental assistants. It has been the profession's belief that the Commission's accreditation program and the current certification process, providing it requires completion of an accredited program, gives the public effective protection.

It should be pointed out that as recently as March 1979 in an address delivered at the Occupational Licensure Conference of the American Enterprise Institute in Washington, D.C., the Chairman of the Federal

Trade Commission summarized the concern of that agency about the danger to the public of licensing occupations indiscriminately.

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

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

I should like to conclude by stating that the ADA, ADHA, and AADS do not believe that this proposed bill is needed. S.500 would authorize governmental assumption of an activity which is already being carried out through well-established private efforts and which results in well trained and qualified radiologic personnel. The present accreditation and licensing system works well and follows in the traditional mode of developing quality education in this country. There is no justification for a governmental usurpation or duplication of these activities such as that proposed in S.500.

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

EXCERPTS FROM ACCREDITATION REPORTS
CONCERNING RADIOGRAPHY

The visiting committee devoted considerable attention in reviewing clinical practices relating to monitoring and controlling use of ionizing radiation. As pointed out previously, the Division of Radiology does not have an educationally qualified dental radiologist. Although the faculty members is effectively monitoring and controlling the quality of radiographs taken in the Division, this faculty member does not have responsibility or authority for controlling use of ionizing radiation and ensuring use of good radiological practices in other clinical disciplines.

Although the visiting committee recognizes that, at the present time, this faculty member does not have responsibility and authority over monitoring quality of radiographs, controlling use of ionizing radiation or monitoring x-ray equipment in a number of clinical departments in which satellite x-ray facilities are located, the visiting committee is of the firm belief that such responsibilities and authority should rest exclusively with this Division and its faculty and staff. The visiting committee noted that school-wide guidelines have not been established on monitoring quality or controlling use of ionizing radiation and that a number of other major problems exist relative to use of ionizing radiation by other disciplines. Immediate steps must be taken to correct a number of the major concerns of the visiting committee.

It is recommended that a qualified individual be identified and charged with the responsibility of implementing and monitoring a system on the use of all ionizing radiation in the school. It is also recommended that the dental Dean give full and complete responsibility and authority for establishing school-wide guidelines and policies on radiographic practices and for monitoring the use of ionizing radiation and x-ray equipment, monitoring quality control for radiographs and control of use of ionizing radiation to the Director of the Division of Radiology and that, in turn, this faculty member delegate responsibilities to trained radiological technicians. To completely implement a comprehensive program for monitoring and controlling radiographic quality and use, it is essential that the institution secure the services of a trained dental radiologist.

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Although the number of radiographs taken on patients appeared generally consistent with current standards, the quality of radiographs observed in many patient records was highly variable and even substandard. Patient records do not show all radiographic exposures

made being recorded in a single area on the record. Many records contained loose, unmounted radiographs in the radiographic jacket. Lead aprons are chained to the chairs and are available at each radiographic station. The visiting committee was pleased to note that they are used. It appears that the dental Dean has initiated a program to assess and improve the quality of radiographs. This should be coupled with a comprehensive program to monitor and control radiation exposure. No specific policy or guidelines exist currently. Trained radiology faculty should provide in-service training to all clinical faculty on radiation hazards and hygiene and guidelines and draft policies and procedures should be developed to monitor and to control radiation exposure of patients.

It is recommended that the Department of Oral Diagnosis, with input from trained dental radiology faculty, should assume the responsibility to implement guidelines for monitoring the radiation exposure of all dental patients and in controlling use of radiation. School-wide control on use of radiation and quality control of radiographs should be under the exclusive purview of trained dental radiology faculty, without exception.

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The visiting committee commends the dental school for its efforts to limit the use of ionizing radiation. The Director of Dental Radiology, together with appropriate faculty from each clinical department, is in the process of formulating criteria for radiation exposure and anticipates the development of a log in the patient record to record individual patient exposure. The visiting committee noted that radiographs exposed in other clinical areas are presently not recorded. In addition, it was noted that patients being screened receive radiographs prior to examination by a professional. The visiting committee strongly urges that the development of the log to record exposures be expedited, and that patients be examined in the screening process prior to being exposed to radiographs routinely.

It is recommended that patients to be screened receive an examination prior to receiving x-ray exposure and that all x-rays taken in any department be recorded in a designated place in the patient's chart to ensure that there is a composite record of each patient's exposure to radiation.

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The oral diagnosis and oral medicine department has six, full-time faculty with the chairperson assuming all responsibility in radiology. The chairperson does not act as a radiation control officer, but feels this is the responsibility of those teachers in the respective areas

where the equipment is housed. The visiting committee strongly disagrees with this thesis. This department includes emergency service, oral diagnosis and treatment planning, oral medicine (management of the medically compromised dental patient) and radiology. There is opinion among other departments that oral diagnosis and oral medicine should assume responsibility (with students) for screening patients.

It is strongly recommended that a qualified and trained dental radiologist be given responsibility and authority for monitoring and controlling use of ionizing radiation, as well as recording of cumulative radiation in the dental chart.

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The visiting committee devoted considerable attention in reviewing clinical practices related to the monitoring and control of the use of ionizing radiation. It should be pointed out that the Division of Radiology, under the direction of a recently appointed, educationally qualified and well-trained dental radiologist is efficiently monitoring and controlling the quality of radiographs, as well as the use of ionizing radiation, thereby ensuring the good use of radiological practices. The visiting committee was also most pleased to learn that this faculty member has the unquestioned support of the Chairman of Diagnostic Services within whose purview the Division of Radiology is placed administratively.

However, in the visiting committee's judgment, immediate steps must be taken to correct a number of problems related to the use of radiographic practices. These concerns include the following:

- a) Students expose each other for the purpose of learning radiographic technique. Manikins should be used for this purpose.
- b) Radiographs are used in the screening process prior to rather than following a clinical examination. Professional judgment on the need for radiographs subsequent to a clinical examination should dictate the need for specific and selected radiographic examinations.
- c) There is a need to establish criteria for determining whether radiographic retakes are necessary.
- d) There is a need to provide in-service training to clinical faculty on current knowledge of the biological effects of ionizing radiation, good radiographic practices and radiation hygiene, radiographic technique and the capacities and limitations of specific radiographic methods.
- e) There is a need to use the fastest speed image receptors, high kilovoltages, low exposure time and optimal processing technique compatible with specific diagnosis requirement.

REPORTS OF COUNCILS AND BUREAUS

Recommendations in radiographic practices—March 1978

Council on Dental Materials and Devices

The American Dental Association, through its Council on Dental Materials and Devices, has published a series of articles on radiation hygiene and practice. Beginning in the April 1967 issue of *The Journal*, articles have appeared on protection of the patient during radiographic procedures, protection of office personnel and dentist, modernization of X-ray equipment, use of fast-speed film, and proper darkroom procedures. An updated summary of Council recommendations is included here. In general, the Council's recommendations are a republication of its January 1975 recommendations and agree with those of other bodies in the area of radiation hygiene and practice.

Most of the recommendations are self-explanatory; however, the Council believes that some comment should be made on recommendation no. 1, on the frequency of radiographic examinations in dental practice. The American Dental Association has consistently stated that the use of X radiation for diagnostic purposes should be made only after careful consideration of both the dental and the general health needs of the patient. The deciding factor is the total welfare of the patient. The nature and extent of diagnosis for required patient care constitute the only rational

bases for determining the need or the frequency of dental radiographic examination. The Council does not agree with a routine requirement of post-operative radiographs to show proof of service rendered. In other words, diagnostic radiography should be limited to those instances in which the dentist anticipates that the information he is likely to obtain will contribute materially to proper diagnosis, treatment, or prevention of disease, or all of these. The number of exposures to be made in the examination and the history of the patient's radiation exposure, especially to the head and neck, should be considered in making such an evaluation. The Council's recommendations follow:

1. Use professional judgment to determine the frequency and extent of each radiographic examination. Determine the minimum number of film exposures that will produce the desired diagnostic information.
2. The basis for film selection should be the maximum emulsion sensitivity (film speed) consistent with the image resolution (sharpness) required for the diagnostic task. Only film of an American National Standards Institute Speed Group "D" rating or faster should be used.
3. The tissue area (and volume) exposed to the primary X-ray beam (for each film) should not exceed the

minimum coverage consistent with meeting diagnostic requirements and clinical feasibility. When a cylindrically collimated X-ray beam is used, the beam striking the face should not be more than 2.75 inches (7 cm) when the source to skin distance is greater than 7 inches (18 cm). The beam should not exceed 2.38 inches (6 cm) if the source to skin distance is less than 7 inches (18 cm). Further restriction of the beam to reduce patient radiation exposure is preferred and can be obtained by smaller collimation such as rectangular collimation circumscribed by the aforementioned circular limits.

4. The X-ray machine should contain a minimum total filtration consistent with federal and state requirements. In general, total filtration should be equivalent to 1.5 mm aluminum up to 70 kilovolt (peak) and 2.5 mm for equipment operating above 70 kV(p). (More detailed information can be obtained from the Bureau of Radiological Health and state public health departments.) The filtration should be located in the useful beam as near the X-ray source (focal spot of the tube) as is practicable. Higher beam energy (kV[p]) allows decreased exposure; however, image contrast is reduced as energy increases, especially above 90 kV(p). Therefore, the maximum beam energy compatible with adequate image contrast should be used.

5. Shielded open-end cylinders or rectangular-collimating devices should be used in conjunction with the long-cone technique. The combination of these devices and techniques will reduce the amount of scatter radiation reaching the patient's skin. All scattered radiation should be eliminated or contained, except for that occasioned by the passage of X rays through the tissues to reach the film.

6. Expose the X-ray film properly. Film exposures should be established for optimal density, using complete development. Films should be processed under the film manufacturer's recommended conditions with proper processing equipment. Image development should be extended to produce the maximum film density for the different X-ray exposures used without

inducing significant chemical fog. Overexposure corrected by underdevelopment subjects the patient and office personnel to unnecessary radiation and may result in loss of diagnostic information in the resulting radiographic image.

7. Lead aprons should be used on all patients to prevent unnecessary radiation of the gonads and thyroid glands.

8. Never hold a film in place for a patient. Use film holders, bite tabs, or other methods to position the film during exposure.

9. Unless protective shielding is provided for the operator, the installation should be so arranged that the operator can stand at least six feet from the patient and outside the path of the useful beam when exposures are being made. Work loads of more than 30 mamp minutes per week may require the use of an adequately shielded screen. Information on shielding design, including determination of barrier requirements, can be obtained from "Dental X-ray protection NCRP report no. 35," National Council on Radiation Protection and Measurements, Washington, DC, 1970.

10. State radiological health personnel or other qualified experts (see NCRP report no. 35) should periodically conduct radiation protection surveys (including personnel monitoring quality control) of your office so that adequate measures can be taken to protect the health and safety of all patients and occupationally exposed personnel at all times.

11. Continue education in radiology as well as in other areas of dental practice.

In essence, the decision to use diagnostic radiography rests on professional judgment of its necessity for the benefit of the total health of the patient. This decision having been made, it then becomes the duty of the dental professional to produce a maximum yield of information per unit of X-ray exposure.

POSITION STATEMENT ON FEDERAL INTERVENTION IN LICENSURE*

The American Dental Association has repeatedly recorded its support for the principle of dental licensure at the individual state level and its opposition for placing this important function under federal control. The purpose of this statement is to identify the reasons underlying the Association's position.

A basic premise of the Association's position is that American dentistry has reached a level of quality and availability not matched elsewhere in the world. The system of state licensure has been an important factor in dentistry's development. Therefore, the Association would oppose replacement of the state licensure system. In the opinion of the Association, federal control of dental licensure would not only fail to solve existing problems involving delivery of dental care to the public, but also could be expected to create new problems.

Maldistribution: One of the most widely recognized and most complex problems facing dentistry involves the distribution of dentists throughout the country. Typically, inner city and rural areas have difficulty attracting dentists. Some proponents of abandoning the state licensure system believe that federal licensure would help alleviate the distribution problem. Presumably, federal licensure would eliminate red tape for dentists moving from one state to another. Then, underserved areas might be able to attract dentists from other states.

Although the Association recognizes the maldistribution problem, it does not believe federal licensure to be a potential solution. A review of dentist to population ratios by county and state indicates greater variance within states than among states. Currently, nothing impedes a dentist licensed in a state from moving to an underserved area in the same state.

Since this has not occurred, it is doubtful that dentists from other states would flock to these underserved areas.

Mobility of Dentists: Even though not important as a solution to maldistribution of dentists, the Association is committed to seeking a mechanism that would allow competent practitioners to relocate in a different state with a minimum of inconvenience. This goal is not incompatible with the system of state licensure. Licensing a dentist licensed in another state on the basis of his credentials meeting specific professional criteria is one mechanism currently being vigorously pursued. In considering various alternatives, however, the Association has maintained the position that each state should retain sufficient safeguards to ensure that any dentist granted a license in the state is competent to serve the people of the state. Any lesser condition would fail to provide adequate public protection.

Experimentation: The current state-based licensure system is composed of 53 jurisdictions, each attempting to develop the most effective system possible for regulating the practice of dentistry. When new systems or regulations are proposed, initial evaluation must, of necessity, be based upon supposition. Because hard evidence about new proposals is seldom available, new proposals usually evoke mixed reactions. Although few new ideas gain majority approval quickly on a national level, many are approved by one or more states. Experience of these states forms a basis for other states to make a higher quality decision about the proposal within a relatively short time. In a sense, a few states provide a controlled experiment for the majority. Examples of this process can be found in acceptance of national board scores, development of the concept of licensure by credentials, growth of regional clinical testing services, and assignment of duties to dental auxiliary personnel.

Influence on the Dental Curriculum: Dental schools have a responsibility to graduate individuals capable of practicing dentistry. Since meeting licensure requirements is a prerequisite to practice, dental schools also prepare students to pass licensure examinations. Consequently, the agency that establishes licensure standards can have an influence over dental curriculums. Under the state licensure system this influence is shared among 53 jurisdictions, and thus moderated. With a single federal agency setting standards, the influence of licensure examinations might become excessive and virtually dictate the content and emphasis for all dental curriculums. This centralization would tend to make a static situation which would inhibit evolution and change. Also, the cooperation that has developed among educators, examiners, and the practicing profession at the state level has been effective in dealing with the relationship between licensure requirements and the dental curriculum. The same degree of cooperation could not be expected at the federal level.

Enforcement: Licensure involves more than issuing licenses to candidates who qualify. Regulatory agencies also must ensure that licensed dentists maintain competence and practice in accordance with the law. It is in this policing function that federal licensure seems most inadequate. To be most effective, regulatory responsibility should be placed at the lowest level of government capable of performing the function—in this instance, the state, through its board of dentistry.

Summary: For the reasons cited, the American Dental Association strongly opposes federal licensure and federal intervention in the state licensure system.

*Adopted by the 1975 House of Delegates of the American Dental Association

PART 3. ORAL BIOLOGY

NOTE: PART 3 IS TO BE COMPLETED BY THE CHAIRPERSON IN COOPERATION WITH THE FACULTY OF THE DEPARTMENT, DIVISION OR SECTION OF ORAL BIOLOGY, IF SUCH A DEPARTMENT, DIVISION OR SECTION EXISTS.

1. What was the basic philosophy for the development of the oral biology department? What is its function or purpose?
2. Describe the overall contribution of oral biology to the dental school or dental college in general, i.e., teaching programs at all levels, research, service, etc. By what means are the various oral biology contributions to the dental school or dental college evaluated?
3. How many members comprise the oral biology faculty? What disciplines are included? What criteria were used in the selection of faculty? Is there a need to increase or decrease faculty in the department and how is the department planning to adjust to these changing needs?
4. What is the source of salary funding for full-time members of the oral biology faculty? If a significant part of the support of such faculty is from "soft money" sources and funding is discontinued, what provisions would be made to continue these faculty?
5. Do the faculty of this department or division engage in research? What is the percentage of time each devotes to research? Do the faculty engage in cooperative research efforts with the clinical and/or basic science departments?

PART 4. CLINICAL SCIENCES

NOTE: QUESTIONS 1-10 ARE TO BE RESPONDED TO INDEPENDENTLY BY THE FOLLOWING CLINICAL DISCIPLINES: ENDODONTICS, OPERATIVE DENTISTRY, ORAL SURGERY, ORTHODONTICS, PEDODONTICS, PERIODONTICS, FIXED PROSTHODONTICS, REMOVABLE PROSTHODONTICS, ORAL DIAGNOSIS/ORAL MEDICINE AND DENTAL RADIOLOGY.

SINCE EACH CLINICAL SCIENCE DEPARTMENT WILL BE RESPONDING INDEPENDENTLY TO THIS PART OF THE SELF-STUDY MANUAL, THE RESPONSES OF EACH DEPARTMENT ARE TO BE INCLUDED AS SEPARATE ENTITIES IN THE COMPLETED MANUAL. RESPONSES FROM EACH DISCIPLINE SHOULD BE CLEARLY IDENTIFIED BY DEPARTMENTAL DESIGNATION. IT IS IMPORTANT TO POINT OUT THAT THE VIEWS AND PERCEPTIONS EXPRESSED AND CONCLUSIONS MADE BY EACH DEPARTMENT MUST NOT BE CHANGED IN CONTEXT BY THE DENTAL ADMINISTRATION OR BY THE AD HOC COMMITTEE ASSIGNED RESPONSIBILITY FOR COORDINATING THE SELF-STUDY MANUAL. THEIR LIBERTIES MUST BE LIMITED TO EDITING AND THEY MUST NOT CHANGE THE CONTEXT OR SUBSTANCE OF THE DEPARTMENTAL RESPONSES.

1. Review the educational objectives for the specific discipline and evaluate if each objective is being achieved in the department's teaching program. How is this determined? What external measures does the department now employ or is the department contemplating employing to ensure that the objectives are being achieved? If the department is not achieving each of its objectives to the specific discipline's satisfaction, to what do the faculty attribute the deficiency(ies)? What steps have been taken to correct the deficiency(ies)? What additional resources (faculty, facilities, funds, support personnel, etc.), if any, are needed to achieve the objectives more effectively?
2. What is the total time (clock hours) committed to the teaching of this discipline? Of this time, identify for the typical student the amount of time (in clock hours), including summers, spent during the formal predoctoral program.

	Year 1	Year 2	Year 3	Year 4
Lecture and Seminars				
Laboratory				
Clinic				
Electives/selectives				
Other				

Assess whether these time allocations are inadequate, adequate or excessive to achieving your objectives. If a change were made, how would this affect the distribution of time? If time allotments are changed, how would existing resources be reallocated?

3. What changes, if any, are considered necessary in the sequencing of the departments' courses or offerings over the entire dental curriculum?
4. During an average preclinical laboratory session (if there is a laboratory component) and clinical session, how many students are in attendance? How many faculty are assigned during each laboratory session?

In the Table below, fill in for a typical week the average number of students treating patients clinically in this discipline (all classes). Do the same for the number of faculty available for the corresponding time period. Evaluate the adequacy of the number of faculty to provide for adequate instruction and teaching at any clinical session.

Identify Discipline _____									
FACULTY & STUDENTS IN CLINICAL DISCIPLINES									
Mon.		Tues.		Wedn.		Thurs.		Fri.	
Fac.	Stu.	Fac.	Stu.	Fac.	Stu.	Fac.	Stu.	Fac.	Stu.
A.M.									
P.M.									

- How is the student clinical competence within this clinical discipline determined? Are the faculty satisfied that the above method(s) of student evaluation is/are identifying the students' strengths and weaknesses? If not, what changes would the faculty like to initiate in the evaluation process? What constraints prevent the achievement of the above? How is clinical judgment of a student determined in this discipline?
- List the number of pertinent clinic procedures accomplished by the typical last year's graduate. For each procedure, indicate the average number done by the 10 per cent of the class who accomplished the most. For each procedure, indicate the average number done by the 10 per cent of the class who accomplished the least. Is the underachieving student receiving special consideration within this teaching program? If so, how? Does the departmental faculty consider the clinical accomplishments in procedures and experience adequate to ensure competence and achievement of the discipline's general educational goals or objectives? Identify strengths and weaknesses and outline measures being taken to correct any deficiencies.
- How are the qualifications of a faculty appointment within the department determined? What are the criteria used in faculty appointment? By whom and how are faculty competence and course programs evaluated? How frequently? Evaluate for effectiveness and identify strengths and weaknesses and measures to be taken to correct the deficiencies. Describe the faculty "in-service" training program within the department.
- Evaluate the adequacy of the number of and quality of the faculty in the department in terms of educational background and preparation and relative to responding adequately to the program requirements.
- Describe the methods by which the department's program(s) is/are integrated and coordinated with other clinical disciplines. With the basic science disciplines. With the behavioral sciences. Evaluate these methods for effectiveness. If ineffective, outline steps to be taken to correct such deficiencies.
- Describe the research effort(s) of the faculty in the department. What are the constraints on expanding the research efforts?

PART 5. BEHAVIORAL SCIENCES

NOTE: QUESTIONS 1-4 ARE TO BE RESPONDED TO BY FACULTY HAVING RESPONSIBILITY FOR INSTRUCTION IN THE BEHAVIORAL SCIENCES.

1. Describe the behavioral sciences courses or concepts taught and identify the strengths and weaknesses in these areas. What plans do you have for correcting deficiencies?
2. Do you feel that the amount, scope and sequencing of behavioral science instruction is adequate? If not, what changes would you suggest?
3. Describe the efforts that were made to integrate the behavioral sciences with the clinical disciplines. Are the efforts effective? If not, do you have plans for improvement?
4. Is any effort made to evaluate students application of the behavioral sciences in patient treatment? If so, describe and evaluate the effectiveness.

Senator RANDOLPH. I assure you that even though you are in opposition to the bill, we appreciate the objectivity with which you view these matters, and I will personally carefully check the testimony and the supporting evidence that you have.

I do want to tell you, however, that I am not always discouraged by something that goes on for 10 years. I introduced a constitutional amendment for 18- 19- and 20-year-olds to vote in this country in 1942. Finally, my constitutional amendment passed in 1971. So, as you can see, we kept at this for a long time.

I am not saying that this is an analogous situation. But I have faced efforts with a long legislative history in the past.

I want to say something to you that has perhaps no direct bearing.

I remember when we started with pneumoconiosis. I knew about this problem. We moved ahead with that legislation, putting it ahead of occupational safety and health by 1 year, 1969, waiting for 1970 to go into the other issue, the nationwide picture. That was the plight of the coal miner. In the first legislation—when it was passed and became law, as proof of pneumoconiosis, we relied strictly on X-rays. Later, in 1976, we came back realizing from the experiences that this proof was not exclusive. We had to consider other evidence of respiratory and pulmonary disease.

I am only saying that, along the way, we learn. This is not just a piece of legislation, I want you to understand, which is dropped in the hopper. Before we did it, years ago, we studied the issues and we believe in what we are doing. I do not want to make too strong a statement except to say it is not a passing matter.

I can assure you there will be no failure to take into consideration all the viewpoints that are given.

Mr. Altmeyer will question you and the others.

Thank you very much.

If you can proceed now, Ms. Butler.

Ms. BUTLER. I have been an actively employed dental assistant for 21 years.

I will summarize my statement and I appreciate the fact that the entire statement be included in the record.

I am accompanied today by Michael Lemov, of Leighton, Conklin, Lemov & Jacobs, counsel for the ADAA.

I am pleased to testify on behalf of the ADAA regarding the Consumer-Patient Radiation Health and Safety Act under consideration by this Committee.

The ADAA is a voluntary professional organization of approximately 20,000 dental assistants nationwide. We believe our members serve an important role in the dental health care delivery system, often including the responsibility for taking and developing dental radiographs prescribed by the dentist.

We are pleased to support enactment of legislation for Federal encouragement of State credentialing efforts in the area of exposure to radiation in diagnostic medical and dental procedures. We therefore support S. 500 or comparable legislation, such as H.R. 6057, initiated in the House of Representatives.

This year, approximately 275 million X-rays will be performed by medical and dental X-ray operators. This represents 90 percent of all manmade radiation to which the general public is exposed.

Some of these procedures will be duplicative because the operator who originally took the radiograph was improperly trained and had to repeat the procedure. In addition to future repercussions for patients' ill-health costs, unnecessary procedures inflate the estimated \$5 billion annual cost of diagnostic X-rays.

The Federal Government cannot justify further delay in taking minimum reasonable steps to reduce the amount of unnecessary radiation to which patients and health professionals are exposed. One obvious need in reducing unnecessary exposure to radiation is the assurance of adequate training and qualifications for the professionals most often responsible for operating medical and dental diagnostic equipment that emits radiation.

This conclusion reflects the findings of the Interagency Task Force on Health Effects of Ionizing Radiation. In its "Report of the Work Group on Exposure Radiation," issued in June 1979, the task force found that: "The improvement of user technique is an important exposure reduction effort."

The task force's recommendations on this finding included the following:

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

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

We believe both H.R. 6057 and S. 500 offer a balanced approach toward alleviating unnecessary exposure due to inadequately trained and qualified operators of medical and dental X-ray equipment.

It should be noted that ADAA's attention is directed solely toward the individuals who operate the X-ray equipment and not toward the physicians and dentists who prescribe the X-ray.

ADAA does not encourage their inclusion within the scope of the proposed legislation because we perceive no need for the Federal Government to encourage State accreditation and certification activities for those health professionals.

Instead, ADAA urges that the committee focus upon the individuals who, far more often than physicians and dentists, actually are responsible for operating X-ray equipment—the radiologic technologists, the dental assistants and other such medical and dental professionals.

I might add that I know of a dental assistant in New Orleans who, through no fault of her own, not knowing the hazards of radiation, lost her hair. She is still actively employed. This has been authenticated by her physician. It was because of radiation in her everyday life in the dental office as a dental assistant.

Although voluntary credentialing for such personnel exist through private, nonprofit, independent organizations, the voluntary aspect of those programs means that not all persons who expose patients to X-rays become covered by the program.

For example, ADAA estimates that there are approximately 150,000 dental assistants who may perform radiologic procedures. At this time, ADAA's certifying board tests only 25,000 assistants.

Clearly, in the absence of a mandatory requirement, only a small portion of the operators will pursue voluntary certification.

As one of the groups most affected by these legislative proposals, ADAA wholeheartedly supports this timely focus upon the operators of radiologic equipment. Current State laws, in most instances, include absolutely no standards for dental assistants and other X-ray operators who take radiologic exposures.

Furthermore, in the few States which have registry or licensure requirements for dental auxiliaries who expose radiographs, there are rarely adequate standards for knowledge or proficiency in exposure techniques. Without initial and continuing measurements of radiologic competency, even these credentials are inadequate to assure safety for the public.

We applaud the Congress for passage of the Radiation Control for Health and Safety Act of 1968. As stated in the act's declaration of purpose, Congress found that "the public health and safety must be protected from the dangers of electronic product radiation."

That law was directed toward the establishment of standards and regulatory procedures concerning radiation emissions from electronic products.

It is clear to us, however, that no matter how many laws are passed to regulate X-ray equipment, patient health and safety cannot be insured until the persons who operate those machines are adequately trained and have demonstrated their competence as well. It has been alluded to several times today—just last week there was the 1-year anniversary of Three Mile Island, and it has been confirmed that that was due to an operator error.

However, because H.R. 6057 intrudes the least upon the States' jurisdiction, I will focus my comments upon the provisions of that bill, which we find somewhat preferable to the other pending bills.

There are two important aspects of H.R. 6057 which I would like to address. These are: (1) The allocation of Federal and State responsibilities, and (2) the financing of organizations and/or programs established to perform accreditation and credentialing functions pursuant to the bill's requirements.

We believe the Federal-State allocation of responsibilities in H.R. 6057 is very sensible. The Secretary of HEW is directed to establish minimum standards in two areas: (1) For the accreditation of educational programs conducted by institutions for persons who administer radiologic procedures; and (2) for the certification of persons who administer radiologic procedures.

As the above summary demonstrates, the Federal Government is not authorized to impose the standards that the Secretary devises upon the States. The Federal Government will not engage in credentialing. Rather, the Secretary would promulgate guidelines and standards which will provide assistance to concerned States and institutions in this field.

This is not to say, however, that the Federal Government would not use some influence to encourage States to address this vital area of health and safety promptly.

Congress has a legitimate interest in seeing that at least minimal requirements are eventually being followed nationwide. Three years after the date of enactment, Federal funds targeted for serv-

ices or equipment used in radiologic procedures will be cut off in those States which have not adopted the Federal or comparable standards. This approach is much less stringent than earlier bills which would have simply imposed Federal standards upon States after a certain period of time. It permits States to establish their own programs, tailored to their own needs yet assisted to a degree by Federal funds.

This brings me to my second topic: The expense involved in providing these health and safety benefits.

There are two aspects to this; namely, how the programs are to be financed and how much of the cost the Federal Government will pick up.

Under the terms of these bills, the Secretary may delegate and provide up to 50 percent funding to approved nonprofit autonomous organizations which accredit education programs or certify persons who administer radiologic procedures. The grants would cover the costs for developing and operating accreditation or individual certification programs.

One such organization is the certifying board of ADAA, which provides extensive evaluation of radiation hygiene and radiographic exposure techniques in its examination of applicants for dental assisting certification.

The certifying board is separate and autonomous from ADAA, and its sole responsibilities are testing, credentialing and recredentialing. The certifying board currently administers seven dental-related testing programs for dental auxiliaries and one continuing education renewal program for certified dental auxiliaries.

As a testing agency responsible for testing dental assistants, the board offers its services to State boards, dental examiners, and other governmental agencies which need to test the competency of dental auxiliaries.

ADAA is aware of the reluctance on the part of Congress to venture into health professional credentialing activities, an area which some of those testifying here today may believe should be left to the States.

Our membership believes, however, that the Federal action envisioned in H.R. 6057 and/or S. 500 is not Federal credentialing. It is only the encouragement of State credentialing according to national guidelines. It is the minimum necessary to insure the public health and safety. Most States have failed to act promptly to prevent improper and/or inadequate radiologic techniques. Therefore, it is imperative that this subcommittee recommend the kind of public health measures that we have described today.

We appreciate this opportunity to present our views and look forward to working with you and your staff toward the attainment of these vital health and safety goals.

Mr. ALTMAYER. Thank you, Ms. Butler.

Initially, Senator Randolph asked if Mr. Donohue, Mr. Stanton, and Mr. Alexander would remain and that we could ask questions of the panel here now, and then go back to those three.

The Senator asked me to compliment all the witnesses for their insightful and thorough testimony on the subject matter of S. 500 and on radiation exposure, and to particularly commend the American Dental Association and the Council of Dental Accredita-

tion and the Commission on Dental Education for your efforts in promoting quality training for dental students and dental auxiliaries.

Likewise, he asked me to compliment all of the other groups in that area as well.

The ADA, obviously, has been in the forefront for a much longer period of time.

Dr. Brown, these questions have been discussed with Senator Randolph.

What we are attempting to do is identify certain issues for the hearing record. It will be useful for the committee to know the number of States which require proof of competency for dental assistants in radiographic procedures.

Would you have a figure on this?

Likewise, Ms. Butler, if you want to collaborate with Dr. Brown in these answers, please feel free.

Dr. BROWN. Yes.

I have data here that I would be glad to give you which lists them by State. There are 15 States that require some kind of educational experience in order for the dental assistant to secure radiographs. There are seven States that require a written and oral clinical examination. There is some overlapping between the two. This document, I am happy to share with you.

Mr. ALTMAYER. Please give that to the stenographer, and it will be submitted for the record.

[The prepared statement of Ms. Butler and the data referred to above follow:]

REMARKS OF JANELLE BUTLER, PRESIDENT, AMERICAN DENTAL ASSISTANTS
ASSOCIATION

Mr. Chairman and Members of the Committee, I am Janelle Butler, President of the American Dental Assistants Association (ADAA). I am accompanied here today by Michael R. Lemov, of Leighton, Conklin, Lemov & Jacobs, Counsel for ADAA. I am pleased to testify on behalf of ADAA regarding the Consumer-Patient Radiation Health and Safety Act under consideration by this Committee. ADAA is a voluntary professional organization of approximately 20,000 dental assistants nationwide. We believe our members serve an important role in the dental health care delivery system, often including the responsibility for taking and developing dental radiographs prescribed by the dentist. We are pleased to support enactment of legislation for federal encouragement of state credentialing efforts in the area of exposure to radiation in diagnostic medical and dental procedures. We therefore support S.500 or comparable legislation such as H.R.6057, initiated in the House of Representatives.

As professionals, ADAA members are concerned about unnecessary radiation to which their patients and they, themselves, may be exposed. This concern is not idle speculation, but rather reflects an ever-increasing awareness on the part of our profession and the general public of the potential dangers of low-level radiation.

This year approximately 275 million X-rays will be performed by medical and dental X-ray operators. This represents 90 percent of all man-made radiation to which the general public is exposed. Some of these procedures will be duplicative because the operator who originally took the radiograph was improperly trained and had to repeat the procedure. In addition to future repercussions for patients' ill-health costs, unnecessary procedures inflate the estimated \$5 billion annual cost of diagnostic X-rays.

As is often required where detrimental health effects are not immediately discernable or capable of precise measurement, we must continually reevaluate the safeguards

designed to reduce unnecessary exposure to radiation in light of increased knowledge of those hazards. ADAA believes that repeated findings by the medical and scientific community with respect to the cumulative impact of exposures and the combined effects of man-made radiation and other environmental agents cannot be ignored. ^{1/} While some scientists urge only further study of radiation hazards, we think that research is no longer enough. There is sufficient evidence available today to indicate clearly that now is the time for action.

The federal government cannot justify further delay in taking minimal reasonable steps to reduce the amount of unnecessary radiation to which patients and health professionals are exposed. One obvious need in reducing unnecessary exposure to radiation is the assurance of

^{1/} See for example, the Reports of the Interagency Task Force on the Health Effects of Ionizing Radiation, June 1979; and the Report of the National Academy of Science's Committee on the Biological Effects of Ionizing Radiation (BEIR Report).

adequate training and qualifications for the professionals most often responsible for operating medical and dental diagnostic equipment that emits radiation. This conclusion reflects the findings of the Interagency Task Force on the Health Effects of Ionizing Radiation. In its Report of the Work Group on Exposure Reduction, issued in June, 1979, the Task Force found that:

The improvement of user technique is an important exposure reduction effort.

The Task Force's recommendations on this finding included the following:

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

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

We believe both H.R.6057 and S.500 offer a balanced approach towards alleviating unnecessary exposure due to

inadequately trained and qualified operators of medical and dental X-ray equipment. It should be noted that ADAA's attention is directed solely towards the individuals who operate the X-ray equipment and not towards the physicians and dentists who prescribe the X-rays. Physicians and dentists are already trained and qualified. ADAA does not encourage their inclusion within the scope of the proposed legislation because we perceive no need for the federal government to encourage state accreditation and certification activities for those health professionals. Instead, ADAA urges that the Committee focus upon the individuals who, far more often than physicians and dentists, actually are responsible for operating X-ray equipment - the radiologic technologists, the dental assistants and other such medical and dental professionals.

Although voluntary credentialing programs for such personnel exist through private, nonprofit, independent organizations, the voluntary aspect of those programs

means that not all persons who expose patients to X-rays become covered by the programs. For example, ADAA estimates that there are approximately 150,000 dental assistants who may perform radiologic procedures. At this time ADAA's Certifying Board tests only 25,000 assistants. Clearly, in the absence of a mandatory requirement, only a small portion of the operators will pursue voluntary certification.

Last July, ADAA testified before the House Interstate and Foreign Commerce Committee's Oversight and Investigations Subcommittee when it held hearings on unnecessary exposure to radiation from medical and dental X-rays. We urged the House members to support legislation similar to that proposed by Senator Randolph's bill, S.500. We are pleased to note that within a few months three separate bills were introduced: H.R.5934 by Congressman Lent; H.R.6023 by Congressman Lundine; and H.R.6057 by Congressman Luken. These three House bills and S.500 are all designed to provide patient health and safety benefits by ensuring that the persons who administer radiological

procedures have taken accredited courses and have been certified as competent by states under federal guidelines.

As one of the groups most affected by these legislative proposals, ADAA wholeheartedly supports this timely focus upon the operators of radiologic equipment. Current state laws, in most instances, include absolutely no standards for dental assistants and other X-ray operators who take radiographic exposures. Furthermore, in the few states which have registry or licensure requirements for dental auxiliaries who expose radiographs, there are rarely adequate standards for knowledge or proficiency in exposure techniques. Without initial and continuing measurements of radiographic competency, even these credentials are inadequate to assure safety for the public.

We applaud the Congress for passage of the Radiation Control for Health and Safety Act of 1968. As stated in the Act's Declaration of Purpose, Congress found that "the public health and safety must be protected from the dangers of

electronic product radiation." That law was directed toward the establishment of standards and regulatory procedures concerning radiation emissions from electronic products. It is clear to us, however, that no matter how many laws are passed to regulate X-ray equipment, patient health and safety cannot be ensured until the persons who operate those machines are adequately trained and have demonstrated their competence as well.

Because of the current scrutiny of any new federal program involving regulation or expenditures, I would like to bring to your attention certain key features of the proposed legislation which pertain to these concerns. At the outset let me state our conclusion that enactment of any of these bills would not demand commitment by federal or state governments to expensive programs nor burden them or any X-ray operator with an unreasonable degree of regulation. However, because H.R. 6057 intrudes the least upon the states' jurisdiction, I will focus my comments upon the provisions of that bill, which we find somewhat preferable to the other pending bills.

There are two important aspects of H.R.6057 which I would like to address. These are (1) the allocation of federal and state responsibilities and (2) the financing of organizations and/or programs established to perform accreditation and credentialing functions pursuant to the bill's requirements.

We believe the federal-state allocation of responsibilities in H.R.6057 is very sensible. The Secretary of HEW is directed to establish minimum standards in two areas: (1) for the accreditation of educational programs conducted by institutions for persons who administer radiologic procedures; and (2) for the certification of persons who administer radiologic procedures. In addition, the Secretary is authorized to give technical assistance to the states, including the preparation of a model law for consumer-patient radiation safety which states could adopt. Finally, the Secretary may make grants to states, educational institutions and nonprofit organizations that are fostering the implementation of the Act.

As the above summary demonstrates, the federal government is not authorized to impose the standards that the Secretary devises upon the states. The federal government will not engage in credentialing. Rather, the Secretary would promulgate guidelines and standards which will provide assistance to concerned states and institutions in this field.

This is not to say, however, that the federal government would not use some influence to encourage states to address this vital area of health and safety promptly. Congress has a legitimate interest in seeing that at least minimal requirements are eventually being followed nationwide. Three years after the date of enactment, federal funds targeted for services or equipment used in radiologic procedures will be cut off in those states which have not adopted the federal or comparable standards. This approach is much less stringent than earlier bills

which would have simply imposed federal standards upon states after a certain period of time. The current bills permit states to establish their own programs, tailored to their own needs yet assisted to a degree by federal funds.

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

Under the terms of these bills the Secretary may delegate to approved nonprofit autonomous organizations the duty to accredit education programs or to certify persons who administer radiologic procedures. In order to promote the goals of the legislation, the Secretary is authorized to make grants to educational institutions under Title VII of the Public Health Service Act and to make grants to states and nonprofit organizations for

up to 50 percent of their costs for developing and operating accreditation and certification programs.

We would like to point out that some of these activities could be paid for by the fees generated by institutional applicants for accreditation or individual applicants for certification. For example, at last July's hearing before the House Oversight and Investigations Subcommittee, Joseph Ward, Chief of the Radiologic Health Section of California's Department of Health Services, testified that California's certification program cost roughly \$400,000 to operate in 1978. There were 13 persons assigned to the program, which offered certification examinations each month at two locations in the state. About half of the cost was covered by an annual fee paid by the technologists. This seems a modest price to pay for such significant health and safety benefits. Moreover, Mr. Ward testified that California expected to save approximately \$50 million a year in future ill-health

costs associated with the exposure reductions made by the program.

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

Similarly, independent private certifying organizations need not be created from scratch as several are already in existence. One such organization is the Certifying Board of ADAA which provides extensive evaluation of radiation hygiene and radiographic exposure techniques in its examination of applicants for dental

assisting certification. The Certifying Board is separate and autonomous from ADAA, and its sole responsibilities are testing, credentialing and re-credentialing. The Certifying Board currently administers seven dental related testing programs for dental auxiliaries and one continuing education renewal program for certified dental auxiliaries. As a testing agency responsible for testing dental assistants, the Board offers its service to state boards, dental examiners and other governmental agencies which need to test the competency of dental auxiliaries.

ADAA is well aware of the reluctance on the part of Congress to venture into health professional credentialing activities, an area which some of those testifying here today may believe should be left to the states. Our membership believes, however, that the federal action envisioned in H.R.6057 or S.500 is not federal credentialing. It is only the encouragement of state credentialing according to national guidelines. It is the minimum necessary to ensure the public health and safety. Most

states have failed to act promptly to prevent improper and/or inadequate radiologic techniques. Therefore, it is imperative that this Subcommittee recommend the kind of public health measures that we have described today.

We appreciate this opportunity to present our views and look forward to working with you and your staff towards the attainment of these vital health and safety goals.

* * *

ABBREVIATIONS
USED IN THIS REPORT

1. Functions may be permitted for:

All	All and any dental assistant
AQP	Advanced Qualified Person (Ohio)
CDA	Dental assistant certified by the Certifying Board of the American Dental Assistants Association
C & R	Dental assistant who is both certified by the Certifying Board of the American Dental Assistants Association and registered by the state board of dentistry.
Class II	Class II Dental Assistant (Oregon)
DA II	Category II Dental Assistant (North Carolina)
EDDA	Expanded Duty Dental Assistant (Hawaii)
EDH	Expanded Duty Hygienist (Arizona)
EFDH	Expanded Function Dental Hygienist (Wyoming)
RDA	Dental assistant registered by the state board of dentistry by statutory approval.
RDAEF	Registered Dental Assistant in Extended Functions (California)
TDA	Trained Dental Assistant (Connecticut)

II. Required Education:

Acc. Prog.	Graduation from an educational program accredited by the Commission on Accreditation of the American Dental Association
Acc. Prog. (EFT)	Graduation from a accredited educational program which includes training in the particular expanded function
EFTC	Expanded function training course

III. Required Supervision:

Direct	Direct supervision by the licensed dentist, present in the room.
Indirect	Indirect supervision by the licensed dentist, present in the office or treatment facilities.
General	General supervision by the licensed dentist who has responsibility for the function performed by the auxiliary but in not necessarily present in the office.
Undefined	The licensed dentist must supervise the auxiliary performing the function, but the type of supervision is not defined.
Not Specified	The function may be delegated by the licensed dentist, but supervision is not stated as a requirement.

IV. Required State Board Examinations (for Dental Assistants)

W	Written State Board Examination
Cl	Clinical State Board Examination

Table 2
Dental Assistant

MAKING RADIOGRAPHIC EXPOSURES

STATE	NOT PERMITTED	PERMITTED FOR	REQUIRED EDUCATION	REQUIRED STATE BOARD EXAMINATION	REQUIRED SUPERVISION
Alabama	*	ALL	None	None	Indirect
Alaska		All	None	None	Undefined
Arizona		All*	EFTC	W & Cl	Indirect
Arkansas		All	None	None	Not Specified indirect
California		All	EFTC	None	General
Colorado		All	None	None	General
Connecticut		All	None	None	General
Delaware		All	None	None	General
Dist. Columbia	X				
Florida		All	None	None	General
Georgia		All	None	None	Direct
Hawaii		All	None	None	Direct
Idaho		All	None	None	Not Specified
Illinois		All	None	None	Not Specified indirect
Indiana		All	None	None	Indirect
Iowa		All	None	None	Undefined
Kansas		All	None	None	Indirect
Kentucky		All	EFTC	None	Indirect
Louisiana		All	None	None	Direct
Maine		All	None	None	Indirect
Maryland		C & R	EFTC**	W & Cl	No Answer
Massachusetts		All	None	None	Indirect
Michigan		All	None EFTC	None W & Cl	Indirect
Minnesota		R	EFTC	W	Indirect
Mississippi		All	None	None	Direct
Missouri		All	None	None	Indirect
Montana		All	EFTC	None	Indirect
Nebraska		All	EFTC	None	Indirect
Nevada		All	None	None	Direct
New Hampshire		All	EFTC	None	Indirect
New Jersey		C & R	None	***	Not Specified
New Mexico		All	None	None	Indirect
New York		All	None	None	General
North Carolina		All	EFTC	None	Indirect
North Dakota		C	Acc. Prog.	None	Indirect
Ohio		All	None	None	Indirect
Oklahoma		All	EFTC	None	Indirect
Oregon		All	None	W & Cl	General indirect
Pennsylvania		All	None	None	Not Specified
Rhode Island		All	None	None	General
South Carolina		All	None	None	Indirect
South Dakota	X				
Tennessee		RDA	EFTC	W	Indirect
Texas		All	None	None	General
Utah	*	ALL	—	—	—
Vermont		ALL	EFTC	None	Indirect
Virginia		All	None	None	Direct
Washington		All	None	None	General
West Virginia		All	None	None	Undefined
Wisconsin		ALL CDA	None EFTC	None	Direct
Wyoming		All	None	None	Indirect
Puerto Rico		RDA	EFTC	W & Cl	Undefined

* Certified by State Board after taking an approved exam. 7

** Not required for Certified Dental Assistants or graduates of accredited programs.

*** Exam given by Environmental Protection Department.

Mr. ALTMAYER. Ms. Butler, would you concur?

Ms. BUTLER. Our statistics show 10 States plus Puerto Rico.

Mr. ALTMAYER. For radiologic technologists.

Dr. Brown, could you approximate the percentage of dental offices throughout the country in which dental assistants routinely take X-rays?

Dr. BROWN. We have zero data on this. It would have to be an approximation. I think it is probably a fair approximation to say that most radiographs are secured either by a dental hygienist or a dental assistant. More than that, I think, would be unfair.

Mr. ALTMAYER. S. 500 limits—

Mr. LEMOV. We would like to answer that question. I wonder if you could repeat that for Ms. Butler.

Mr. ALTMAYER. The question was an approximation of the percentage of dental offices throughout the country in which dental assistants routinely take X-rays.

Ms. BUTLER. A very substantial number; and this is, I know, a fact. I cannot give you figures. We would be happy to supply those for you.

Mr. ALTMAYER. It would be very helpful if either the Dental Association or the Dental Assistants' Association was able to obtain some estimate. We realize aside from calling all the dental offices, it is impossible; but any approximation would be useful in that regard.

Dr. Brown, S. 500 exempts licensed dental practitioners from its provisions.

Do you feel that this is justified on a national basis with respect to protecting the public health; or would an evaluation of each State's licensure requirements in this area and selected exclusion be more reasoned?

Dr. BROWN. I think the exclusion is quite logical. I have been involved in dental education now for approximately 30 years. I have watched it develop. In fact, over the last year or two, the increasing interest in ionizing radiation makes it appropriate to look at what our students do and the quality of performance. I am staggered by the high level of quality. It is far more than I had anticipated.

Just yesterday, I conferred with our chief radiologist in terms of percentage of retakes and he estimates well under 5 percent of all radiographs need to be retaken. Our central regional examining board includes both dental hygiene, dental auxiliaries, and dental applications, a component that deals with proficiency in radiographs and radiology, both in terms of technology proficiency and in terms of understanding the territory.

I think the system up to that point is frankly working quite well in most regions today.

Additionally, many institutions now incorporate at least once a year some kind of continuing education program for dentists, dental hygienists, and dental assistants. I think the exclusionary component of the bill is appropriate.

Ms. BUTLER. I commend Dr. Brown for all of the accredited programs throughout the United States. They are very good programs, as he explained to you.

But I must remind you that dental assistants, as mentioned previously, are hired very often off the street. Only 10 States plus Puerto Rico require any minimum requirement for taking these radiographs.

Mr. LEMOV. May I make a comment?

I want to point out that the position of the American Dental Assistants Association supports the exclusion of doctors and dentists from this bill because they are licensed already. I did notice a figure in Dr. Brown's testimony which I wonder perhaps if he could comment on.

On page 2, he cites a study of dental education in the United States done in 1976 and indicates that the amount of hours in the dental schools surveyed varied from 19 hours in one school, apparently, to 278 hours of education in another dental school. That is an extremely wide variation between the very excellent programs that the ADA is running.

Mr. ALTMAYER. As I recall, you did address the question before in the Eckhardt subcommittee this past summer; if you could reiterate your statement—

Dr. BROWN. At the time of the survey, there were several schools just getting started and not fully operational. In collecting the information, they were asked to respond only to the materials that were being taught as of April 1, 1976. For those several schools that were perhaps just 1 year into a program, their students only received that much during the first year. So it was largely because of that.

A secondary factor would be the difficulty in getting comparable information. Some institutions would give us estimates of radiology that were being taught in various subdisciplines, where other institutions, according to our best information, gave us the data in terms of hours that pertain only to the formal courses labeled dental radiology. I think those are the two explanations for the wide range.

Mr. ALTMAYER. This next question would be directed just to Dr. Brown.

Although it is generally accepted that dental practitioners are qualified, by formal training and examinations, to perform radiologic procedures, we are still faced with the fact that dentists employ approximately 120,000 dental assistants who often have no formal training or demonstrated competence with respect to radiologic procedures and yet administer those procedures.

Would you explain this seeming dichotomy?

If the question is not clear, what Senator Randolph is trying to elicit your testimony on is, although the American Dental Association and the American Dental Hygienists Association require that their individuals be qualified to administer radiation and X-ray procedures, the fact remains that there are, as Ms. Butler said, many dental assistants without formal training.

Does the American Dental Association condone the dental assistants taking X-rays without the benefit of formal training or proof of competence; and what would your association be doing in this area.

Dr. BROWN. The association is on record, and has been, I would say, for about 10 years, that formal education for dental assistants

is the way to go, whatever the function might be, and, of course, dental radiology is only one of their functions. Roughly 10 years ago, the American Dental Association essentially discovered what at that time was the 104-hour course, a course by dental associations during evenings, anything but formal.

We are on record as being strong supporters of formal education for whatever their function. One of the problems put right up front is that many dental assisting formal programs today have insufficient numbers of applicants to fill their programs. It is a very serious problem. I do not have the reasons for it, but it is something that worries us a great deal.

I think also for your information, that the certifying board of the American Dental Assisting Association actually waived the formal education requirement 1 year or 2 years ago to permit nongraduates of accredited dental assisting schools to be eligible to take the certifying examination. With reluctance, the American Dental Association, went along with that standards revision; that is, agreeing with the rationale that the abilities of nonformally trained assistants can be determined if such candidates pass the certifying examinations. But this change in the policy of the certifying board of ADDA was one that ADA reluctantly approved to test the system.

The certifying board has, I think, just administered the first exam under this new regulation but the results are not yet in. However, I personally believe that of all dental assistants were formally trained, that would certainly be ideal but we have not reached such a goal.

Mr. ALTMAYER. I am sure you would concur.

Ms. BUTLER. Yes.

Mr. ALTMAYER. Mrs. Yunker, we appreciate your accompanying Dr. Brown as president of the American Dental Hygienists Association.

Would you care to expand on Dr. Brown's testimony with respect to training received and licensure requirements for dental hygienists, especially with respect to radiologic procedures?

Ms. YUNKER. We think that the dental hygienist has a substantial educational and credentialing experience to be qualified to take radiographs in any setting. Our policy has been that anyone who is taking X-rays in a dental office ought to be at least as qualified as the dental hygienist. We have always accepted and certainly encouraged the certifying of dental assistants. We feel that the dental assistant certification program, since it is also approved by the American Dental Association, represents credentialing standards for dental assistants which are comparable, in radiologic technology, to those obtained by dental hygienists through licensure.

We do think that the dental hygienist and the certified dental assistant should be excluded from this bill because of the process of credentialing and education for each that is already in place.

Mr. ALTMAYER. This question would be directed to both Dr. Brown and Ms. Yunker.

How much variance is present in State laws with respect to standards for licensure and required formal training in your respective professions?

Dr. BROWN. For dentists and dental hygienists?

Mr. ALTMAYER. For dentists and dental hygienists.

Among the 50 States, is there any study that analyzes the required amount of formal training or the proof of competence; or how much variation does exist?

Dr. BROWN. The Commission on Dental Accreditation, is recognized by State licensing agencies to evaluate and assess the quality and effectiveness of dental and dental auxiliary education in the United States and thereby, to determine the competence and eligibility of licensure candidates. The Commission and the American Association of Dental Schools prescribe educational standards and guidelines. Dental radiology is included among these. The dental profession maintains a very fine line between prescribing guidelines and demanding certain parameters of performance, because that is not the way higher education is conducted in this country. Thus the Commission tries to give direction in the design of educational programs but it also allows as much freedom to educational institutions as is possible.

When Commission survey teams make site visits, evaluators look very specifically at those things that relate to the patient, operator safety, control—such as, students not getting their hands on X-ray film when they should not—and reporting. The Commission really pays attention to such specifics.

But when it comes to curricula hours, we have so many different ways of learning, self-study material which students can take home, work at at their leisure, in addition to formalized class hours. So we believe it is inappropriate to make those kinds of prescriptions. Yet, we are looking for performance clearly at the end.

In response to your question about licensure jurisdiction, there are 50 State and regional boards—among which there is a great deal of cooperation. There is a great deal of similarity in both the dental hygiene and dental applicants, at least among those three regional boards, there is a great deal of continuity, not the uniformity but similarity. These professional boards have only taken place over the last 10 years. It is a new venture and one we look upon with great optimism as helping smooth out some of the low points.

Mrs. YUNKER. The American Dental Hygienists Association is concerned about the variance that could exist in the clinical examinations on the State level. A few years ago, HEW granted money to ADHA to review the clinical testing procedures and to develop a standard clinical evaluation examination which could be used by State dental boards. That study was completed and is now utilized by three regional testing agencies: Central, southern and western; plus State boards in California, Texas, Hawaii, and North Carolina. In part these testing agencies are using this basic standard, clinical evaluation instrument which was developed by ADHA under an HEW contract. So there is now a criterion referenced clinical dental hygiene examination available to and used by several State and regional boards of dental examiners in dental hygiene. This examination instrument includes a radiology component.

Mr. ALTMAYER. It would be helpful if both yourself, Dr. Brown, Ms. Yunker, could submit for the record, before April 11, a short

narrative of what is being done with respect to ameliorating the variation among various jurisdictional licensing standards.

Of the 150,000 dental assistants in the country, approximately how many are certified by the Certification Board? You may have already covered that.

Ms. BUTLER. Approximately 19,000.

Mr. ALTMAYER. And those individuals that are certified, does the certification test include operation of radiologic procedures?

Ms. BUTLER. The test itself does test this; yes.

Mr. ALTMAYER. You have stated that the Certifying Board offers services to State boards which have need for testing competencies of dental auxiliaries.

How many States avail them of this service?

Ms. BUTLER. I know only of California. There are probably more. We would be happy to get this information for you. But I do know of that one.

[See, April 9, 1980, letter to Senator Williams from Michael Lemov, a copy of which is attached.]

Mr. ALTMAYER. That would be very helpful.

[The following information was supplied for the record:]

Supplemental Statement
of the
American Dental Association
on
Standardization in Dental Licensure
For Inclusion in Hearing Record
on S. 500

To be licensed as a dentist in any state, an individual must fulfill three types of requirements: an educational requirement, a written examination requirement and a clinical examination requirement. The degree of standardization among states varies by type of requirement.

Educational Requirement: All states accept graduation from a U. S. dental school accredited by the Commission on Dental Accreditation as fulfilling the educational requirement. The Commission on Dental Accreditation, which is the recognized accrediting agency for dental schools in this country, also accredits Canadian dental schools through a reciprocal agreement with the Council on Dental Education of the Canadian Dental Association. Graduates of accredited Canadian dental schools are eligible for licensure in all states except Alaska and Mississippi. Lack of standardization in educational requirements relates primarily to graduates of dental schools located outside the United States and Canada. Foreign-trained dentists are currently eligible for licensure in 15 jurisdictions. Specific educational requirements for foreign-trained dentists vary substantially among these jurisdictions.

Written Examination Requirement: Currently, all states except Alabama and Delaware accept satisfactory performance on National Board dental examinations as fulfilling or partially fulfilling the written examination requirement. The stipulation that satisfactory performance may only partially fulfill the written examination requirement is necessary because states often supplement National Board coverage with relatively short written examinations on such things as the state's dental law.

Clinical Examination Requirement: The clinical examination requirement was the last type of requirement to approach standardization. Fifteen years ago, each state conducted its own clinical examination. Currently, four regional clinical testing services conduct examinations for 34 jurisdictions. Economies of scale have enabled regional testing services to refine and improve methodology for examining performance in clinical dentistry. Improved examination quality is expected to entice participation by additional jurisdictions. In the long term, standardization among regions may occur.

Conclusion: The American Dental Association believes that standardization among state licensure requirements is evolving appropriately. The current process involves refinement of requirements as well as standardization. Preemptive action to mandate immediate standardization would retard efforts to refine methods.

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April 9, 1980

Honorable Harrison Williams, Chairman
Senate Committee on Labor and Human
Resources
4230 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Williams:

The following material is submitted for the record on behalf of the American Dental Assistants Association in response to questions posed during the Committee on Labor and Human Resources' hearing on April 3, 1980, on the Consumer-Patient Radiation Health and Safety Act, S.500.

At the hearing Committee Counsel Thomas Altmeyer asked the following two questions which we stated we would answer in writing:

- (1) In what percent of the dentists' offices do dental assistants routinely perform x-ray procedures;
- (2) Which states use the services of the Certifying Board of ADAA to test and certify dental assistants.

(1) We regret that our limited resources have prevented us from conducting the type of detailed survey necessary to respond precisely to this question. We suggest that a survey conducted by ADA of its dentist members would provide the most accurate response to this inquiry.

However, on the basis of our 20,000 members' experiences and from what ADAA has learned in its daily communications with practicing dental assistants, we believe that in a substantial number of dental offices employing a dental assistant, he or she will be responsible for taking some or all of the prescribed radiographs.

It must also be noted that many of the procedures performed by the dental assistants are performed without the immediate supervision of the dentist or other trained radiologist.

(2) At present only California contracts with the Certifying Board to test and certify the dental assistants for the state. In the past Minnesota also used the services of the Board to certify its dental assistants.

In addition Ohio, Vermont, and New Jersey require dental assistants to be certified by the Board before they can be registered by the state. North Carolina permits dental assistants who have been certified by the Board to perform a greater variety of functions than non-certified assistants.

Since 1960, the Certifying Board has certified approximately 55,000 dental assistants. However, certification is valid for a maximum of two years. The Board estimates that 19,000 dental assistants hold valid certifications from the Board in any given year.

At this time we would also like to respond to other issues raised during the hearing. These other issues are as follows:

- (1) The potential duplication of current HEW authority and the proposed legislation;
- (2) The percentage of the population dose of radiation administered by non-credentialed personnel; and
- (3) The relatively minor difference between the performance of credentialed and non-credentialed x-ray operators recorded in FDA/BRH studies.

(1) In his oral and written statement John Villforth, Director of the Bureau of Radiologic Health, opposed S.500 on the ground that it "duplicates authority already vested in HEW, under the Public Health Service Act and the Federal Food, Drug and Cosmetic Act."

ADAA believes that this statement is not accurate. While HEW is authorized to prepare and distribute educational materials for radiologic technologists and to assist States with licensure programs, HEW's function is limited to promoting voluntary efforts. On the other hand, S.500 and comparable legislation such as H.R. 6057 make promulgation of minimum standards by the Secretary mandatory and require the States to adopt accreditation and certification programs within three years or else lose federal funding.

Since HEW expects to complete by December, 1980, its voluntary national standards for the qualification of medical radiologic technologists, ADAA suggests that these standards might be used as the basis for the minimum standards required by S.500 and H.R.6057, without additional cost to the federal government.

(2) ADAA questions the basis for the assertion that only 10% of the annual population dose of radiation results from procedures performed by the approximately 50% of x-ray operators who are non-credentialed. The basis for BRH's conclusion is apparently that credentialed personnel are used primarily in hospitals and clinics where a greater number of x-rays, using a larger dose of radiation, are performed.

ADAA requests that the Department's data or survey underlying the above statement be made part of the record so that ADAA and other interested persons can review and comment further on the basis for the agency's conclusions.

(3) While ADAA has not seen any of the "front-end analysis" studies referred to by Mr. Villforth at the April 3, 1980, hearing, ADAA is concerned that the alleged similarity in performance between credentialed and non-credentialed personnel might be used to undermine the need for and public benefit of training and credentialing x-ray operators.

With respect to the study's findings, ADAA offers the following questions which must be considered when evaluating the data:

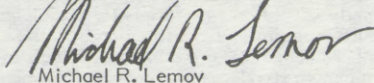
- (a) By whom were the operators credentialed?
- (b) Under what standards were the operators credentialed?
- (c) How long ago were the operators credentialed?
- (d) Have the operators participated in continuing education or recredentialing programs?

As in the case of (2) above, ADAA requests that the study referred to be made part of the hearing record so that its findings may be evaluated and be subject further comments by ADAA and other interested parties.

Again, we thank the Committee for giving us the opportunity to testify before it. We would be pleased to assist the Committee further in this matter.

Sincerely,

LEIGHTON CONKLIN LEMOV AND JACOBS



Michael R. Lemov
Special Counsel, American Dental Assistants
Association

MRL:dmg

Enclosure

SUMMARY
OF THE
FINAL REPORT
ON THE
DENTAL HYGIENE
CLINICAL PERFORMANCE EVALUATION



*American Dental Hygienists' Association
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January, 1980

SUMMARY OF THE FINAL REPORT OF THE EVALUATION SPECIALIST ON THE DENTAL HYGIENE CLINICAL PERFORMANCE EVALUATION

The following summary of Dr. John Eisner's Phase III Final Report on the Dental Hygiene Clinical Performance Evaluation Study is presented herein. This summary provides an overview of the results attained for interested testing agencies and/or regional board agencies. The hope is that the information will acquaint interested parties with basic material concerning the formulation and implementation of the Clinical Evaluation Study. The original report may be inspected upon request should additional information be needed.

INTRODUCTION

The purpose of the Dental Hygiene Clinical Performance Evaluation Study was to create a performance-based, criterion-referenced dental hygiene board examination. A criterion-referenced examination is one in which the desired level of clinical performance is predetermined and all candidates are measured against that standard. This is much preferred to a norm-referenced board examination in which a candidate's performance is measured against the performance of other candidates at a given testing site. The weakest candidates are failed, but no specific performance standards are used to guide examiners decisions. This means that from testing site to testing site, standards of evaluation vary, creating the potential for a non-standardized, unfair examination. Because of this, norm-referenced testing is unacceptable in licensure situations.

The difference between criterion-referenced examinations and norm-referenced examinations is that of an **absolute** standard as compared to a **relative** standard of performance. The final listing of all performance criteria can be found in Appendix B.

Part I — Developing a Clinical Performance Examination

Establishing Minimally Acceptable Performance Levels

Since the decision to construct a criterion-referenced examination had been made at the beginning of the study, the Clinical Evaluation Study's Task Force and Steering Committee were faced with the recurring problem of defining "minimally acceptable performance". In the final analysis, the answer to this problem was based on a consensus of professional judgements among examiners and their advisors within the testing agency. These expert judgements were based solely on the experience of the examiners, practitioners, and educators, and represent the standards which they think should be met by licensed hygienists.

These initial opinions were reexamined after "mock board" or actual testing results had been analyzed. The minimum performance levels in this report were modified during the final year of the study based on analysis of test results. The performance levels which finally have been recommended are listed in Appendix A. They may be modified by a testing agency to be either more or less stringent; however, it is suggested that all changes be made only after: 1) analysis of actual examination results within the state or region, 2) extensive discussion between the testing agency, practitioners, and educators within the state or region, and 3) a review of the effect that such a change will have on the establishment of a nationwide single standard of performance for a particular skill.

Establishing a Pass/Fail Evaluation Procedure

The setting of minimum performance levels clearly suggests that if candidates demonstrate sufficient competence to attain the desired performance level, they will pass the section. If competence is not demonstrated, then failure will result. Since this separation of candidates is the sole purpose of licensure examination, a simple pass/fail designation is sufficient and desirable.

Defining Candidate Errors

Early in the study, it was agreed that examiners would independently evaluate each candidate. This choice was made because it was known that examiners do not always agree with each other; furthermore, when a decision to pass or fail a candidate is made, an independent verification by a second examiner helps to ensure an accurate decision, provide a fairer assessment of each candidate's performance and protect an examining agency from accusations of arbitrary judgement by candidates who failed the exam.

Standardization

Each candidate must be evaluated in an identical manner. The Steering Committee established a sample size of seven teeth for all patients in the Oral Prophylaxis section and similarly standardized sample sizes for all other sections of the examination.

Assigning Section Weights

A review of the final listing of functions which are tested in this examination indicates that the test is divided into three major parts, including eight sections and five subsections. The Task Force made decisions regarding the relative importance of each part or section compared to all other portions of the examination. The results of these decisions are displayed in the last column of Appendix A. The assignment of weights or points to each section is a decision made on the basis of professional judgements just as the decisions regarding minimally acceptable performance standards were. Each agency or board collectively must determine the weight of each section.

If a written examination in a subject such as Jurisprudence is also included in the 100 points allotted for the examination, a further modification of the examination weights must be considered. A reduction of five points from the Radiographic Recognition and Dental Charting sections is recommended if a total of ten points is to be assigned to such written tests.

It is strongly recommended that whenever possible, an analysis of the effect that a revised weighting system will have on the overall failure rate for the examination, should be undertaken prior to the actual use of the new system in a broad situation. A change of weights without prior testing could lead to unexpected and dramatic shifts in the failure rate.

Setting the Performance Level

The last critical decision to be made by a testing agency is the overall performance level or pass/fail decision point for the test. Seventy per cent was chosen by the Task Force as the minimum passing grade for this test and the individual section weights have been adjusted to coincide with this level. For example, there has been some debate about whether a failure on the Subgingival Prophylaxis section should result in a failure of the entire examination. The assignment of 30 points to this section would virtually assure this result; however, if such a philosophy prevailed, a testing agency would be hard pressed to defend the testing of the other dental hygiene functions. Therefore, the weight of the Subgingival Prophylaxis section has been set at 25 points. As a result, a candidate can fail this section and still pass the test.

Part II — Controlling Contaminating Variables

The uncontrolled influence of contaminating variables can create a potentially unfair test. Therefore, the Steering Committee has designed a clinical examination which controls as many of these variables as possible. These variables will be listed and dealt with in the following sections.

Candidate Variables to be Controlled

As the increased difficulty of this examination is recognized, some candidates will become aware of the advantage of charting all sections on Part I prior to the examination. To eliminate this advantage, one jurisdiction successfully implemented a plan to screen all patients for acceptability by the examiners prior to the examination, then pool and randomly redistribute the patients.

Another candidate variable to be controlled involves patient selection. Previous research has clearly shown that candidates with "light" patients almost always pass while candidates with difficult patients are more likely to fail. Examiners must rigorously enforce the minimum calculus deposit requirements to insure fairness to all candidates.

Radiographs are another variable. When exposed prior to the examination, candidates could receive assistance. A board member or dental hygiene examination proctor should be assigned to monitor the exposure of films in order to ensure that no assistance has been given and no retakes have been allowed.

Whether radiographs are exposed prior to or on the day of the clinical examination, they are returned to the candidate for mounting after being processed. This affords opportunity to switch the series which was submitted for the test with a film series of proven high quality. As a solution to this problem, testing agencies should distribute the required number of films to each candidate. These films should be marked, so that after processing, they can be readily identified as test films. For

example, one corner cut off or a letter, number or design could be placed on the film. No switching of films would then be possible as long as a different method of identification was used each year.

Consideration should be given to establishing reasonable maximum working times for each part of the examination. It has been suggested that one hour be allotted for Part I and 1½ hours for Part II. This has not been an apparent problem, but the possibility exists for some candidates to spend far more time than others to complete their assignments.

These candidate variables can be eliminated or brought under control through the design of appropriate test administration procedures. Failure to control these variables will result in a test which has no validity.

Patient Variables to be Controlled

Analysis of the distribution of errors and failures on the Dental Charting Section indicated that candidates whose patients had many chart entries to record made more errors and failed more often than did candidates whose patients had only a few charting requirements. The proposed solution to this was the application of a constant 90% performance level based on the number of items charted.

Analysis of data collected after examination of the 210 candidates in 1977 revealed a similar pattern of imbalance in the Periodontal Measurements section of the test when the number of errors and failures were analyzed for each category of patient difficulty. The measure of patient difficulty used in this case was the amount of subgingival deposits as determined by the examining team during patient check-in. It was evident that candidates with medium heavy to heavy calculus patients experienced far more difficulty than those with light calculus patients.

In order to compensate for the effects of patient difficulty on failure rates, it was recommended that the number of allowable errors for each patient be contingent on the number of calculus deposits. This means that as patients become more difficult, the minimum performance level expected of candidates is reduced. Patients with medium calculus deposits were allowed only one error, while those with medium heavy deposits were allowed two, and those with heavy deposits were allowed three. However, when this system was applied, confusing data was gathered that suggests further analysis of this procedure for equalizing patient differences is necessary.

Suffice it to say that differences in patient difficulty affect candidate results on the Periodontal Measurements section. More data needs to be collected in order to study true effects of patient difficulty on all charting sections.

Analysis of data collected in 1977 revealed that when patients with heavy calculus were treated, a high proportion of candidates failed but almost no failures resulted when patients with light calculus were treated. On the results of these findings the Steering Committee explicitly described patient acceptability requirements as well as adopted a contingency table for allowable errors: 4 allowable errors for medium patients; 5 for medium heavy; and 6 for heavy patients.

Examiner Variables to be Controlled

Any test in which the evaluation is conducted by examiners, is subject to examiner biases. In fact, the most critical source of potential bias concerns examiner variability. Opportunities for bias are described below with proposed methods for their control.

Opportunities for Bias — Methods of Control

- | | |
|--|--|
| A) Knowing the Candidate | <ul style="list-style-type: none"> 1) Use I.D. numbers. 2) Request candidates leave during patient check-in. 3) Use of examiner stations and assistants for Parts I and II. |
| B) Allowing examiners to proctor written tests | <ul style="list-style-type: none"> 1) Do not allow examiners to proctor written tests. |
| C) Recording written test grades | <ul style="list-style-type: none"> 1) Do not allow examiners to record or review written test grades until after clinical evaluation. |
| D) Knowledge of Part I grades when Part II is being evaluated. | <ul style="list-style-type: none"> 1) Examiner Assistant should fold the evaluated form so that Part I grades are hidden while Part II is being evaluated. |
| E) Conducting an examination for the graduates of a single school. | <ul style="list-style-type: none"> 1) Combine graduates of two or more schools, if possible. |

Although examiners may arrive with an open mind and remain unbiased throughout the test, there will always be variation in their clinical skills and personal standards of performance. To reduce this variability, the following steps have been taken: improvements in examining conditions by using assistants, improvements in performance criteria; and improvements in examiner preparation.

Based on excessive data analysis, the following recommendations are appropriate if an agency is seeking to balance all examiner teams and give the fairest possible examination:

- * pair dentist examiners with hygienist examiners
- * never pair two inexperienced examiners
- * when computer profiles of examiner performance are available as a basis for selecting examiner combinations, never pair two highly rigorous or two lenient examiners.
- * provide a ½ day standardization workshop for all teams prior to each examination.

Having prepared each examiner to the greatest extent currently practical and paired examiners in a balanced fashion, any critical differences in clinical judgements which arise between examiners must be resolved using a method of reconciliation called "validation".

The Validation Process

For those instances in which the examiners have disagreed on the number or location of errors, and when such disagreement makes a difference in whether the candidate passes or fails a given section, examiners must cross-validate each others findings and reach a decision. The situation could arise where two examiners will disagree on the presence of a candidate's error even after an attempted validation. If this happens, a third examiner should be asked to evaluate the situation and make a final decision.

Since the test is attempting to evaluate the candidate's true performance and since the examiners can immediately cross-validate the unconfirmed errors which are found, the validation process becomes a key factor in the assurance of a reliable and valid examination.

Standardizing Test Administration Variables

The Clinical Evaluation Study Steering Committee designed a number of printed manuals and audio-visual materials which can be modified and/or used by a testing agency to insure that all examiner teams of each site are equally prepared to conduct the examination. These materials include:

- * User Agency Guide
- * Examination Coordinator's Manual
- * Examiner's Preparation Manual
- * Examiner's Orientation (Slide-Tape)
- * Examiner's Standardization Workshop
- * Examiner's Evaluation Form
- * Examiner Assistant's Guidebook
- * Examiner Assistant Orientation (Slide-Tape)
- * Candidate's Guide
- * Candidate's Progress Folder
- * Radiographic Recognition Answer Sheet

When taken as a whole, these standardization procedures combine to produce a highly uniform clinical examination. Failure to adhere to the recommended standardization techniques would prohibit a testing agency from achieving a fair and reliable examination as easily as would allowing candidates to cheat or examiners to average their grades.

All of these contaminating variables have to be considered and controlled to produce a reliable and valid clinical exam. Candidate, patient, examiner, and test administration variables have been reviewed in this section. It is very important that testing agencies be aware of these variables and the steps that have been and should be taken to control them. It is also very important that data be collected and analyzed constantly to provide further information about the control of these contaminating variables.

Part III — Summary

Reliability and Validity

Extensive analysis of this test's reliability has shown that it is affected by several variables, all of which can be adequately controlled by the test design, examiner preparation, and examiner selection. Testing agencies must make rigorous attempts to control examiner variability since it is the most critical source of potential unreliability in this test. Considering that a test can be no more valid than it is reliable, the improvement and control of examiner performance plays a key role in establishing the test's credibility since all other threats to validity appear to be manageable.

More detailed information on validity and reliability measures is available upon request since quite an extensive set of data and graphs exist. The data is not presented in this report because of the complexity of the presentation.

Opportunities for Further Study

Significant questions were raised during the course of this study that warrant further study. A question was raised regarding partial credit for candidates who perform exceptionally on most sections, but who fail the test because of a few errors on critical sections. This situation was contrasted with that of a candidate who makes four or five times as many errors but, because of their wide distribution, passes the test. The strict interpretation of minimal competence used in this test allows this to occur and some examiners have suggested that because of this the test is unfair to a few candidates. The question deserves further study.

The collection of additional data is needed to study the adjustments in the test for varying patient difficulty. More information is needed on the effect of various strategies for examiner training and team composition. Similarly, the opportunities for analysis and control of examiner differences should be studied continually.

The study raised the question of performance standards. Perhaps the standards established by the study's Task Force are inappropriate. If so, the examination it has created is the best method for collecting the data which will help other agencies decide upon more appropriate standards of performance.

Of course, the opportunities this test provides for self-assessment, continuing education activities, and a vehicle for peer review are all worthy of further exploration. Many of these investigations are being carried out now.

Summary

All questions which needed to be asked about the design and administration of a clinical board examination in dental hygiene have been asked. The answers provided are not perfect and may not be the only answers which will lead to a credible examination; however, a testing agency whose test does not demonstrate adequate answers to these questions, must reconsider the validity and reliability of their current examination.

The performance levels which have been established by the Task Force appear to be reasonable. Examiners, practitioners and educators who have observed the test in progress consider it to be thorough, demanding and fair. This examination is now available to be adopted or adapted by a state board or regional testing agency. If the guidelines suggested in the **Testing Agency** are followed, a test of acceptable quality will result.

APPENDIX A

Listing of Examination Sections, Performance Levels, Allowable Errors, and Weights

Sections	Performance Levels	Allowable Errors	Weights
Part I - Data Gathering and Charting			
Oral Inspection	90%	1 of 10 oral inspection categories	5
Dental Charting	90%	1 of every 10 items charted	10
Periodontal	95%	1 of 24 measurements for patients with "Medium" Calculus	10
Measurement	90%	2 of 24 measurements for patients with "Medium/Heavy" Calculus	
	85%	3 of 24 measurements for patients with "Heavy" Calculus	
Section Weight			25
Part II - Oral Prophylaxis			
Subgingival	85%	4 of 28 surfaces for patients with "Medium" Calculus	25
	80%	5 of 28 surfaces for patients with "Medium/Heavy" Calculus	
	75%	6 of 28 surfaces for patients with "Heavy" Calculus	
Supragingival	95%	1 of 35 surfaces	20
Tissue	100%	no allowable errors on 28 tissue surfaces	5
Section Weight			50
Part III - Radiography			
Technique			10
Improper Mounting	100%	no allowable errors on 18 films	1
Cone Placement	95%	1 of 18 films	2
Film Placement	80%	3 of 18 films	2
Vertical Angulation	80%	3 of 18 films	2
Horizontal Angulation	80%	3 of 18 films	3
Recognition	85%	6 of 40 responses	15
Section Weight			25
Total Weight			100
Passing Grade			70

Appendix B

PERFORMANCE CRITERIA AND MINIMAL COMPETENCE LEVELS

Part I - Data Gathering and Charting - 25 points**Oral Inspection**

The candidate must assess and record the status of a board patient's oral and extra-oral structures using the format and following the instructions provided in the Candidate's Progress Folder. Acceptable performance will have been demonstrated if 90% of the candidate's findings are correct. This procedure must be completed in approximately 15 minutes.

Dental Charting - 10 points

Given approximately 15 minutes, the candidate must chart the status of the patient's dentition using the format and following the instructions provided in the Candidate's Progress Folder. With the aid of a dental light, mirror, and explorer, all restorations, missing teeth and obvious carious lesions should be identified. Obvious carious lesions should demonstrate a general lack of integrity in the enamel or cementum surface which can be determined either visually or by penetration with light pressure of a sharp #2 explorer followed by detection of a soft base to the defect or definite resistance upon withdrawal of the explorer.

Acceptable performance will have been demonstrated if 90% of the candidate's findings are correct.

Periodontal Measurements - 10 points

Given approximately 15 minutes, the candidate must chart the depth of the gingival sulcus for every tooth in an assigned quadrant using the format and following the instructions provided in the Candidate's Progress Folder. Using a mouth mirror and a color-coded periodontal probe divided into 3 millimeter bands, the candidate must record the depth of each sulcus/pocket to the nearest millimeter on six aspects (MF, F, DF, ML, L, DL) of each assigned tooth. Acceptable performance will have been demonstrated if 95% of all measurements are recorded accurately.

Part II - Oral Prophylaxis - 50 points

Given approximately one hour, the candidate must complete a thorough oral prophylaxis on a maximum of two assigned quadrants using appropriate hand instruments, prophylaxis handpiece, disclosing solution and a #2 (cowhorn or pigtail) explorer.

Subgingival Deposits - 25 points

Given approximately 45 minutes, the candidate must effectively remove subgingival calculus so that no deposits are detectable with a #2 (cowhorn or pigtail) explorer and no calculus is visible when the tissue is deflected with air. Acceptable performance will have been demonstrated if 85% of all subgingival tooth surfaces are free of deposits.

Supragingival Deposits - 20 points

Given approximately 15 minutes, the candidate must effectively remove calculus, soft deposits and extrinsic stains so that all non-decalcified surfaces are:

1. Visually clean when air-dried.
2. Tactilely smooth upon examination with a #2 cowhorn or pigtail explorer.
3. Free of plaque when examined after the application of a disclosing agent.

Acceptable performance will have been demonstrated if 95% of all supragingival tooth surfaces are free of deposits, plaque and extrinsic stains.

Tissue Condition - 5 points

The candidate must effectively utilize hand instruments, polishing cups or brushes, and dental floss so that no unwarranted soft tissue trauma (abrasions or lacerations) occurs as a result of the prophylaxis procedure. Acceptable performance will have been demonstrated if 100% of all proximal tissue surfaces exhibit no unusual mechanical damage. The unwarranted presence of grossly lacerated gingival tissues (four or more lacerations) will result in automatic failure of the entire Oral Prophylaxis section of the examination.

Part III - Radiography - 25 points**Radiographic Recognition (Slide Examination) - 15 points**

Given approximately one minute per slide, the candidate must complete a 24 slide, 40 question examination, which includes the recognition of normal and abnormal dental structures, carious lesions, calculus and anatomical landmarks. Acceptable performance will be demonstrated if the candidate correctly recognizes 85% of the radiographic structures.

Radiographic Technique - 10 points

Given approximately 30 minutes, either prior to or on the day of the clinical examination -(as specified by the testing agency) the candidate must expose, without assistance or retakes, a full mouth series of radiographs. After the radiographs have been developed by test-site staff, they must be properly mounted by the candidate in the accepted ADA method (dimple up) and must exhibit correct cone and film placement as well as correct vertical and horizontal angulation. Acceptable performance for each of the five skills to be tested will be assessed by computing the number of radiographs which demonstrate the correct application of the skill. The minimal competency level for each skill is listed below:

Mounting (1 point)	100%
Cone Placement (2 points)	95%
Film Placement (2 points)	80%
Vertical Angulation (2 points)	80%
Horizontal Angulation (3 points)	80%

Minimal Competency for the Entire Examination

The candidate must demonstrate minimal competency at the stated performance level for each component of the examination in order to receive a passing grade and be awarded the entire point value achieved for that component. A passing grade for the entire examination is achieved when the candidate accumulates at least 70% of the 100 total points when all components of the examination are combined. This means that even though a candidate may not have met the minimal performance standards in every component of the exam, overall competency has been demonstrated if a grade of 70% has been attained.

*TESTING AGENCY GUIDE
TO THE
DENTAL HYGIENE
CLINICAL BOARD EXAMINATION*



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January, 1978

TESTING AGENCY GUIDE
TO THE
DENTAL HYGIENE
CLINICAL BOARD EXAMINATION

INTRODUCTION

The purpose of the Clinical Evaluation Study was to develop an objective method to evaluate the skills of dental hygienists as a part of a licensure examination. State and Regional Boards or testing agencies that wish to utilize this examination format must fully understand the design and administration of the instrument before an effort is made to implement it.

This Guide has been created to offer examining boards and testing agencies detailed information regarding the development, performance and recommended use of this test. The Guide also outlines the decisions that a testing agency must consider prior to adapting the examination to its particular needs.

If further information is needed in addition to that which is provided in this Guide and the accompanying examination manuals, copies of the Clinical Evaluation Study's Final Report and consultation by the Study's Task Force members can be arranged by the American Dental Hygienists' Association upon request.

A. DEVELOPMENT OF THE TEST

1. Background

The Clinical Evaluation Study was initiated because of the need expressed by many examiners to define more objective performance criteria and relate these to an efficient method of measuring and documenting competency within the dental hygiene state board examination. The American Dental Hygienists' Association obtained funding to develop a prototype clinical dental hygiene examination based upon the following objectives:

- a. To define measurable, objective performance criteria for the evaluation of competency.
- b. To develop an efficient grading system that would:
 - (1) Measure performance according to criteria.
 - (2) Provide documentation of findings.
 - (3) Facilitate inter-examiner reliability.
- c. To make the results of the study available to state and regional boards.

The project has been developed and guided by a Task Force of examiners and educators from throughout the country, who chose to involve themselves in an effort to strengthen dental hygiene licensure

examinations. The Task Force members are committed to the principle that the evaluation of professional competency for licensure should be conducted by qualified dentists and dental hygienists.

In the process of developing and field testing the examination, 498 candidates have been examined utilizing 53 examiners from 26 different states. In addition, the instrument has been further evaluated during actual board examinations utilizing 348 actual board candidates and 20 examiners from 10 different states.

During the first phase of the Study, the Task Force identified and weighted the components of the examination, established criteria for each component, developed a pilot evaluation instrument, and field tested the examination six times. In the second phase of the Study, 13 field tests were conducted in seven states, with a board member from each state participating as part of the field test team. The primary objectives of these field tests were to: test the instrument in a realistic setting, clarify the examination forms, and refine the test administration process. During Phase III, the Task Force continued to modify those areas of the examination that needed greater standardization, while at the same time, analyzing its reliability and validity.

2. Principles of Test Design for Clinical Competency

In constructing any test, the goal of the test designers is to isolate the variable that is being evaluated from other extraneous variables which contaminate test results and then measure it as precisely as possible. The variable which is being measured in this examination is the candidate's performance of basic dental hygiene skills.

In order to measure this variable, the Task Force incorporated several important test design concepts and procedures into the development of the examination. It is as comprehensive as possible in order to reflect the scope of dental hygiene education; it is based on measurable performance criteria; it is designed to identify minimal competency so that a pass/fail decision can be made; and the passing score is established by predetermined performance levels for every function. Therefore, the examination can be said to be a criterion-referenced instrument because the evaluation of each skill is based on measurable performance criteria.

In determining the content of the examination, the Task Force recognized that in evaluating dental hygiene skills dentistry has traditionally placed the greatest importance on a hygienist's ability to perform the oral prophylaxis, and the Task Force believes this emphasis is appropriate to the current scope of

dental practice. However, they also agreed that hygienists should be examined over the entirety of their clinical education and the responsibilities that they will fulfill in practice to the degree that it is feasible on a state board examination. Consequently, an examination of basic dental hygiene skills was developed which consists of twelve skills organized in the following manner:

Part I - Data Gathering and Charting

Oral Inspection
Dental Charting
Periodontal Measurement

Part II - Oral Prophylaxis

Subgingival
Supragingival
Tissue

Part III - Radiography

Radiographic Technique

Improper Mounting
Cone Placement
Film Placement
Vertical Angulation
Horizontal Angulation

Radiographic Recognition

The evaluation of each of these skills is based on specific criteria that are defined in both the Examiner's and Candidate's Manuals. These criteria are included in this Guide as Appendix 1 and Appendix 2.

For further information about the features of this examination, potential users should thoroughly review the:

"Candidate's Guide"
"Examination Coordinator's Manual"
"Examiner Assistant Guidebook"
"Examiner's Manual"

It is clear that the purpose of clinical board examinations is to grant licensure only to those candidates who can demonstrate at least minimal competency. Therefore, the task of examiners is to discriminate between acceptable and unacceptable performance which will lead to pass/fail decisions. The significant feature

of a pass/fail evaluation system is that it will discriminate between acceptable and unacceptable performance, but it does not discriminate between acceptable performance and outstanding ability. Therefore, examiners should be aware of the fact that the candidate who makes errors, but consistently demonstrates minimal competency, will receive the same grade as the candidate who makes no errors at all since the purpose of the test is to differentiate between those dental hygienists who are minimally qualified to practice the profession and those who are not.

In order to make objective pass/fail decisions, the level at which the candidate is expected to perform must be clearly defined. Performance levels, therefore, become part of the examination criteria. For example: performance level might be stated so that the candidate will be expected to remove supragingival deposits from 35 surfaces with 95% accuracy. Once the performance level is clearly identified, it must then be translated into allowable errors, which probably have the greatest relevance to an examiner, because the number of allowable errors determines whether the candidate passes or fails the examination. This means that, if supragingival calculus is found on only one surface, the candidate will receive all of the points for that function. However, if the candidate exceeds these allowable errors, minimal competency has not been demonstrated and no points are received for this component of the exam. These principles of evaluation establish a format for the objective measurement of clinical performance. But, being objective is not as easy as these principles suggest; and every effort must be made to control extraneous variables which can impact upon the evaluation of candidate performance.

3. Controlling Contaminating Variables

During the course of the Clinical Evaluation Study, the Task Force identified a number of variables which interfere with the measurement of candidate performance. These contaminating variables were classified into two categories--those which could be prevented and those which had to be accommodated. Examiner bias and the fact that some candidates were able to prepare in advance for the examination so that they had an unfair advantage over others, are two examples of contaminating variables which can, for the most part, be prevented. Efforts to control such variables are discussed later in this Guide in a section titled "Test Security." Contaminating variables which are inherent in a clinical examination and which must be accommodated include: differences among patients, examiners, examiner teams, and examination sites. The methods for controlling their influence in the evaluation of clinical competency which have been recommended as a result of this study are described below.

a. Controlling Patient Differences

Three of the eight functions which are tested within this examination are affected by differences in patient difficulty. They include Dental Charting, Periodontal Measurements, and Subgingival Prophylaxis. The Dental Charting section is more likely to be failed when the candidate must record a high number of decayed, missing, or restored teeth than when there are only a few charting entries. To compensate for this, the performance level is established as 90% of the number of items a candidate has charted. The 10% allowance for errors permits one error on a patient with ten items charted and four errors for a patient with 40 recorded entries.

Both the Periodontal Measurement and Subgingival Prophylaxis sections of the examination are more likely to be failed when the patient has "heavy" calculus deposits present. To compensate for these differences, the performance levels are adjusted so that the number of allowable errors within these sections is increased as the calculus deposits become heavier. A further step to equalize patient difficulty in performing the Oral Prophylaxis is assigning candidates only one quadrant for patients with "heavy" calculus deposits, while two quadrants must be completed for patients with "medium" deposits. As a result of these efforts to equalize patient difficulty, the test now appears to be fair for all candidates.

b. Controlling Differences Between Examiners

Because of the inherent differences among individuals, it can be anticipated that differences among examiners will always exist. For the purposes of evaluation, these differences should be minimized; and when they occur, they must be resolved before a pass/fail decision can be made. Analysis of field test data shows that examiners initially identify the same errors approximately 30% of the time. Pass/fail disagreement can occur on as many as 20%-30% of the candidates, depending upon the section being evaluated. In those instances in which a pass/fail disagreement occurs, examiners must resolve this disagreement through a validation process to confirm each other's findings. As a result of the validation process, the examiners verify the existence of specific errors and resolve pass/fail disagreements. This assures a more accurate evaluation of the candidate than would have been achieved using only one examiner.

The importance of the validation process on pass/fail decision-making can be seen in the following example. The following example is taken from information obtained during the last two administrations of the test in actual board examinations:

During the evaluation of the 11 test sections for the 138 candidates by each examiner team, there were 65 section failures agreed to by both examiners and 114 sections in which the examiners differed in their initial pass/fail decisions. Of these 114 potential failures, if only one examiner had been used, 53 candidates were ultimately failed by the two examiners while 61 other candidates were passed. This represents an increase in the section failure rate of 42% as a result of the validation process to say nothing of the 61 initial decisions to fail candidates which can be later reversed. Between 10% and 12% of the time, pass/fail disagreements do occur and must be resolved. Therefore, the validation process becomes the key and provides accurate justifications for decisions which are made.

c. Controlling Differences Between Examiner Teams and Examination Sites

Data obtained during the Clinical Evaluation Study also indicated that there were significant differences between examiner teams. Careful selection of teams (See the section on "Team Selection" below) as well as conducting thorough examiner standardization workshops and thorough orientations are essential at each site to reduce such differences.

B. RECOMMENDED ADMINISTRATION OF THE TEST

At the conclusion of the Clinical Evaluation Study, a number of recommendations were developed regarding the effective administration of a clinical examination. An agency which adopts this test should carefully consider these findings before proceeding with the design and administration of its own dental hygiene examination.

1. Team Selection

Research conducted during the Clinical Evaluation Study pointed out the following facts regarding the ability and/or willingness of examiners to identify candidate errors when examining the same population of candidates:

- a. Some examiners tend to find very few errors while others find very many. This difference among examiners is significant.
- b. There are significant differences between dentist and hygienist examiners on several sections of the test.
- c. There are significant differences between experienced and inexperienced examiners on some sections of the test.

- d. Examiners tend to adjust to each other's level of error identification. For example, when an examiner who usually finds few errors is paired with an examiner who finds many errors, they both tend to become more consistent with each other as the examination progresses.

As a result of these findings, it is suggested that an agency select their examiner teams by following the guidelines for team composition provided below:

- a. Pair dentists with hygienists. By allowing their different professional skills to complement each other, a more thorough evaluation can be conducted.
- b. Pair experienced examiners with inexperienced examiners. This will assist new examiners in learning to apply evaluation standards without penalizing candidates in the process.
- c. Pair examiners who find an average number of errors but do not pair examiners who find far fewer or far more errors than the average. Instead, compose teams to include one of each in order to insure a balanced evaluation of candidates.
- d. Do not use examiners who, in relationship with other examiners testing the same population of candidates, consistently fail to find any candidate errors.

If a testing agency utilizes a process such as this in selecting those to be included on teams of examiners, it will be possible to more carefully control the reliability of the examination. Monitoring of examiner performance on an annual basis will enable an agency to make appropriate decisions regarding the last two recommendations. To assist in this process, the final section of this Guide outlines several methods of analyzing test performance.

2. Examiner Preparation

The Clinical Evaluation Study considered, designed, and utilized a number of strategies which are intended to prepare examiners for the demands of conducting an accurate clinical evaluation. Implementation of these strategies during field trials revealed the differences that exist between trained and untrained examiners. Therefore, it is recommended that the following steps be taken by an agency using this examination format in order to assure adequate examiner preparation:

- a. Presenting every board member or examiner with a copy of the Dental Hygiene Examiner Preparation Manual upon their appointment.
- b. Orienting any new dental hygiene examiners annually to the Dental Hygiene Board Examination. These examiners should be

required to complete the in-office preparation activities outlined in the Examiner's Preparation Manual as well.

- c. Providing a half-day (minimum) standardization workshop for examiner teams immediately prior to the first examination in each testing cycle.
- d. Holding a one to two hour orientation to the examination procedures at each site on the day prior to an examination.

3. Test Security

During the clinical trials which enabled the pre-testing of this examination, several potential test security problems were identified. Four of these involved situations in which some candidates could give themselves an unfair advantage over other candidates and four others involved situations in which examiners could bias their clinical evaluations. Brief descriptions of these potentially unfair practices and a recommended method of preventing their occurrence are listed below:

a. Controlling Opportunities for Candidate Cheating

<u>Methods</u>	<u>Control</u>
1) The most subtle form of candidate inequity occurs during their selection of patients. Some candidates try to select patients to sit for the examination who have almost no calculus deposits. When candidates are successful in utilizing such patients during a board examination, these candidates are almost assured of passing, while fellow candidates, with more difficult patients, are administered a fair test of their skills.	Strictly enforce the minimally acceptable patient requirements by dismissing unacceptable patients during patient check-in. Similarly dismiss patients who are too difficult for the purposes of a board examination.
2) A second unfair advantage occurs when candidates complete the Data Gathering and Charting sections of the test prior to the examination. Not only do they have additional time to check their work, but they can also have faculty, other candidates, or dental students check the accuracy of their records. The test then	It is recommended that all patients who are acceptable for the examination be posted and randomly assigned to each candidate at the beginning of the test. If this is done, all candidates will have an equal opportunity to demonstrate their data-gathering and charting skills. The top section of the Examiner's Form

becomes a copying exercise for these candidates and is obviously unfair to the public as well as other candidates who have either chosen not to record the patient's oral condition in advance or have not had access to their patients before the examination.

- 3) When radiographs are exposed prior to the examination, candidates could receive assistance from faculty who want them to do well on the examination.

- 4) Whether radiographs are exposed prior to or on the day of the clinical examination, they are returned to the candidate for mounting after they have been processed. A weak candidate would have ample time and privacy to simply switch the series which was submitted for the test with a film series of proven high quality. This would obviously be unfair to the public and other candidates who did not cheat.

provides a mechanism whereby this can be readily accomplished using the white page for the patient and the green one for the receptionist.

If the testing agency does not feel secure with the Program Director's certification of films, a board member or dental hygiene examination proctor should be assigned to monitor the exposure of board films to insure that no assistance has been given in their preparation and no retakes are allowed.

Testing agencies should distribute the required number of films to each candidate. These films should be marked so that after processing they can be readily identified as test films. For example, one corner can be cut off and a letter, number, or design can be coded on the film. No switching of films could then occur and the series could be returned to the patient's chart as long as a different code was used each year.

b. Controlling Opportunities for Examiner Bias

Methods

- 1) Bias as a result of knowing the candidate's age, sex, race, religion, physical appearance, personality, school, home state, or relatives in the dental profession can not be tolerated in a licensure examination.

Control

The use of examiner stations and assistants for Part I and Part II evaluations is designed to be a further control of examiner bias. If patients have already been screened and randomly assigned during patient check-in the previous day, the patient check-in procedure will

- 2) Bias as a result of examiners proctoring written tests taken before the clinical examination and seeing who finishes early or late. This could cause a "labelling" of candidates which could inappropriately carry over to the clinical examination.
- 3) Bias as a result of recording written test grades prior to the clinical tests. This could cause a "labelling" of candidates which could influence the way in which they are evaluated clinically.
- 4) Bias resulting from a knowledge of Part I grades when Part II is being evaluated. A "halo effect" could result for candidates who did very well or very poorly on Part I and this could influence the Part II evaluation. The same bias can occur while evaluating Part III if examiners are aware of the results of previous sections of the examination.

have already been completed and candidates can begin work immediately. If, however, the agency has decided to check patients in on the morning of the examination, it must separate examiners and candidates during this procedure by asking candidates to leave the operatory.

Do not allow examiners to proctor written tests.

Do not allow examiners to record or review written test results until the clinical examination has been completed and graded. A second alternative is to have examiners grade written tests and record results for candidates who are not assigned to their team for clinical examination.

Be sure that grades on all previously completed sections of the test are unavailable to examiners until all evaluations are completed. As a basic procedure, the examiner assistant should fold the evaluation form so that Part I grades are hidden while Part II is being evaluated. An even better alternative utilized by some jurisdictions is to rotate teams of examiners between evaluations of Part I, II, and III. Each group of candidates is then evaluated by a different team on each part of the examination.

- 5) Bias as a result of conducting an examination for the graduates of a single school. In the same way that knowing a candidate's identity or past performance can bias an examiner, the knowledge that all candidates are from a "new" or "weak" or "strong" school can easily bias all examiners at the test site either by passing candidates who would otherwise be failed or visa versa.

If possible, do not schedule examinations for a single school. Instead, combine the graduates of two or more schools into a test which is spread over several days. Be sure to randomly assign candidates from the different schools to be examined on each test day.

All of the above control measures can be implemented by the testing agency with a minimum of prior planning and will insure the administration of a fair and secure test.

4. Test Administration Format

The Examiner's Preparation Manual outlines in greater detail the recommended format for the administration of this test. Although an agency may wish to alter the predetermined performance levels and weights for the various sections, the administration of the test should closely adhere to the following recommendations:

- a. Examination orientations for candidates, examiners, and examiner assistants should be held at each site prior to the test.
- b. A standardization workshop for examining teams should be held prior to the test.
- c. Candidate to examiner team ratio can vary from 8:1 to 15:1, depending on the experience of examiners and time allotted for the test.
- d. Candidate identification badges containing only the candidate's identification number and photograph should be issued.
- e. Examiner stations and assistants should be used.
- f. Other routine procedures as outlined in the Examiner's Preparation Manual should be followed.

Assuming the Examination Coordinator's Manual is followed, these preparation activities can be carried out in advance and should lead to the smooth administration of this test.

C. MODIFYING THE EXAMINATION TO MEET STATE AND REGIONAL NEEDS

It is important that agencies realize that the Clinical Evaluation Study developed a method of constructing and administering a dental hygiene board examination that follows sound testing principles. It is possible to modify the test to meet local needs while at the same time adhering to these principles. For example, in states in which hygienists are legally permitted to perform functions that are not part of this test, an agency can add these functions to the test as long as they design and pretest such additions in a sound manner.

In addition, some jurisdictions may feel that the passing grade, section weights, and the predetermined performance levels developed in the model test do not reflect the professional judgements of their agency or state. Again, since these values are the product of Task Force judgements and clinical field trials, it is possible to reassess the conclusions which were reached to meet particular needs. For example, if it is the general consensus of examiners, practitioners, and educators in a given jurisdiction that the weights on the Radiography section should be decreased and replaced by a written test in jurisprudence or the weight of other components should be increased then such actions can be appropriately taken.

As a testing agency prepares to modify the examination for its particular needs, each agency should consider establishing a Dental Hygiene Examination Committee if such a structure does not already exist. A small working group is needed to carefully prepare the final examination and supportive materials. The remainder of this section outlines the modifications which such a committee may wish to consider prior to recommending that a testing agency implement this examination format.

1. Designing Additional Sections

The steps to be followed by the testing agency when it has been decided to add a new section to this examination are listed below:

- a. Describe the function to be tested in as much detail as possible.
- b. Decide on the criteria which will be used to judge whether or not the procedure has been competently performed.
- c. Assess the impact of variables beyond the candidate's direct control that can influence the examiners' ability to judge candidate performance such as patient differences and examiner agreement about criteria.
- d. Develop a standardized way of measuring the degree to which the performance criteria have been met.
- e. Establish the minimally acceptable performance level which will be used by examiners to make pass/fail decisions.

- f. Develop a method for recording and documenting findings that is consistent with the examination format.
- g. Establish the relative importance of the new section in comparison with all other sections of the test by assigning a weight or point score to the section while simultaneously adjusting point values on the other components of the test.
- h. Pretest the new section to determine:
 - 1) The accuracy and interpretation of the criteria.
 - 2) The ability of examiners to agree (inter-examiner reliability) on their application of these criteria.
 - 3) The failure rate when the established performance level is used.
 - 4) The probable impact of failing the section on total test performance.
 - 5) The amount of time required to perform and evaluate the new section.
- i. After pretesting, if the inter-examiner reliability is low, attempts should be made to improve the statement of performance criteria and further standardize the measurement technique being used. This should be done and the section pre-tested before a decision is made to modify the minimally acceptable performance level.
- j. If the failure rate does not reflect the professional judgements of the agency and its consultants after further pretesting, steps should be taken to then modify the performance level to achieve the desired results.
- k. Based on the impact which the resultant failure rate may have on the entire test, the weights of the new section should be reconsidered and, if necessary, adjusted.

2. Modifying the Difficulty of the Test

The purpose of the clinical board examination is to separate those individuals who are competent from those who are not yet competent. A good test will do so with a minimum of errors. The two types of testing errors which can occur involve the failing of candidates who should have passed and the passing of candidates who should have failed. Historically the failure rate on dental hygiene licensure examination has been negligible in many jurisdictions; therefore the failure of candidates who should have passed has been an unlikely occurrence. It is regrettable to unnecessarily fail a candidate and delay their entry into dental hygiene practice for several months; however this is far more acceptable from the point of view of protecting the public, than passing candidates who should have failed.

Task Force members who assisted in the development of this test have suggested that, in their professional judgement, as many as 10% of all dental hygiene graduates are not yet competent to practice dental hygiene upon completion of their program. Therefore, it has been the aim of the Clinical Evaluation Study to set the performance levels on each section so that between 5% and 15% of all candidates will fail the section. However, it should be pointed out that only when a consistently weak candidate fails several sections will a test failure result.

The Task Force has, therefore, designed the test so that between 5% and 10% of the candidates tested will fail the examination. However, since it is a criterion-based test assessing the competence of a dental hygienist to practice rather than a norm-referenced test, this percentage can vary considerably depending upon the competence of candidates at any given site. The key point in this discussion is that the testing agency must make a professional judgement regarding acceptable performance on the examination and each of its parts; test that judgement by administering a pretest; adjust it to conform to actual findings; and then rigorously enforce the standards which have been established.

3. Precautions Which Must Be Observed

The Task Force realizes that this test, being a prototype examination designed for use throughout the country, may be adapted in many different ways to meet the individual needs of a state board or testing agency. It must be remembered, however, that the data which are presented in support of the test's reliability apply only to the published test. Agencies which modify the test must be forewarned that changes in the test's basic parameters necessitate the collection of new baseline data so that the revised test's performance can be analyzed.

Moreover, it must be realized that this test was constructed using test design principles which build and rely upon each other. The use of one or two new concepts such as making allowances for patient difficulty while using an old testing format, no criteria, one examiner, the averaging of grades or other inappropriate performance testing concepts, totally defeats the purpose of the examination. No other selective adaptations of the test beyond the addition of new sections or changes in performance parameters should be made unless a testing agency is confident that the impact of each modification will not impair the reliability of the examination.

In summary, it is the agency's responsibility to:

- a) Establish performance levels which are considered to be reasonable for each section of the examination. These performance standards can be raised from time to time to reflect or stimulate improvements in dental hygiene education and practice.

- b). Assign appropriate weights for each section. These weights can be modified from time to time as the function and scope of dental hygiene practice evolves and the test is modified to reflect such changes in education or practice.
- c) Establish an appropriate overall passing grade. In some states this grade is specified in the Dental Practice Act.
- d) Agree not to deviate from any of the established performance testing concepts which are currently used in the test.
- e) Develop a data base using the revised examination content and/or parameters which can be used to assess the test's performance and to make further modifications in the test as are necessary.

By continuously monitoring test performance and dental hygiene practice, an agency can be assured that it is offering a fair and meaningful licensure examination.

D. PREPARING THE TEST FOR AGENCY USE

When the Examination Committee has made its determinations regarding the inclusion of new test sections or reweighting of the examination, the examination and all supportive materials must be finalized for use by the individual testing agency. This section of the Guide will describe the necessary steps to modify the prototype examination for agency use.

1. Examiner/Candidate Ratio and Time

When it has been decided what modifications, if any, will be made in the examination, the testing agency must determine the examiner/candidate ratio and the time frame for administration. In the final field trials, the examination took 5-5½ hours to administer, using one examining team for every 10 candidates. This did not include the evaluation of radiographic skills.

In all likelihood, the clinical portion of the examination could be administered in four hours using one examining team for every 6 or 8 candidates. The use of this ratio would ~~permtt~~ permit the evaluation of one group of candidates in the morning and another group in the afternoon. The test has also been administered within a seven hour time frame, using one examining team for every 15 candidates.

It is obvious that the time allotted for the clinical portion of the examination is contingent upon the examiner/candidate ratio. The testing agency may find that after examiners have gained experience in the administration of this examination less time will be required for the clinical evaluation procedures. The time schedule for the examination, orientations and written examinations must be determined by the testing agency and outlined in their Manuals and Guidebooks.

2. Random Assignment of Patients

The Task Force has strongly recommended the pooling and random assignment of patients in order to maintain the security of the examination as described in Section B 3 of this Guide. This controls the potential variability caused by the candidate's familiarity with the patient and the opportunity which they may have to complete data gathering

and charting procedures prior to the examination.

All candidates must present a patient to be screened for acceptability. Acceptable patients are pooled and only candidates who have provided an acceptable patient are eligible for the examination. At the beginning of the clinical examination, acceptable patients are randomly redistributed to candidates, so that they will have no prior knowledge of their patient's condition.

The screening process may be conducted the day prior to the examination or redistribution of patients can occur after the patient check-in procedure is completed. The NCR Evaluation Form lends itself well to this procedure. Copies of the top portion of the form may be detached and the record of patient condition and candidate assignments distributed to patients or candidates to facilitate the redistribution procedure.

When the testing agency has determined the necessary time and logistics for this random redistribution, the process must be described in the examination Manuals. All candidates and potential patients must be made aware of the redistribution procedure as well.

3. Selection of Radiographic Technique Module

The Clinical Evaluation Study identified three different alternatives for the administration of the radiographic technique section. They include:

- Module #1. A full-mouth survey previously exposed without assistance as certified by each Dental Hygiene Program Director, which is developed, mounted and critiqued during the examination.
- #2. A full-mouth survey which is exposed, developed, mounted and critiqued at the examination site.
- #3. A partial survey for which all procedures are completed at the examination site.

If the agency chooses to use a partial survey, the allowable errors in each category must be adjusted to reflect the lower number of measurements from the radiographs on which the evaluation will be based.

4. Preparing the Radiographic Recognition Test

The testing agency must also select and prepare radiographs for the radiographic recognition slide examination. Radiographs must be carefully screened to assure that the structures to be identified are accurate representations. For example, if a film is selected to depict the mental foramen, it is important that the foramen appear without distortion in its proper anatomical relationship to the mandibular bicuspsids.

In order to identify the structures to be recognized, circles and arrows which can be obtained from suppliers of graphic art materials should be utilized. These symbols can be placed on the slide by burnishing them from the transfer sheet onto the radiograph. If placed incorrectly, they are easily removable by lifting them off with tape. The circles and arrows must be carefully placed to ensure that they are pinpointing structures accurately. Screening of the slides by the Examination Committee and pretesting the examination will help to identify the slides which are inadequate as testing devices. When the usable slides have been prepared for projection, they should be consecutively numbered in a visible location on each radiograph, using graphic transfer numbering sets.

Exactly 24 slides should be prepared, 16 of which depict 32 different normal or abnormal structures, caries, calculus and anatomical landmarks. Multiple circles or arrows will be placed on a number of the first 24 films so that the candidates can be directed to identify a structure to coincide with each circle or arrow. The last eight slides should each depict one correct or incorrect radiographic technique. On the 24 slides, a total of 40 test items should be identified in order to provide a valid examination of the candidate's radiographic recognition ability. Two sample slides accompany this Guide, one which identifies several structures for recognition, the other displaying a single technique error. They have been placed in a library card pocket inside the back cover of this Guide.

The answer sheet provides the candidate with an alphabetical listing of appropriate responses for identifying each structure. The candidate is to select the best answer (s) for each slide and pencil it in the appropriate box (es) in the column number corresponding to the slide number. A template should be prepared as a grading key so that it displays the correct answers when superimposed upon the answer sheet.

5. Selection of Standardized Instruments

Field tests have clearly demonstrated that the wide variations in instruments adversely affected the reliability of the examination. Candidates who present coarse, dull or difficult to adapt explorers have a definite advantage over candidates who were examined with sharp, fine explorers. In addition to these measurement problems, the use of bulky probes or probes with varied or illegible markings creates unnecessary strain and fatigue for examiners. Clinical experience has also indicated that examiners must use the same probes as the candidates in order to achieve the most consistent results. The Task Force, therefore, determined that standardized examining instruments were essential to the administration of a reliable examination. The instruments selected which best fulfilled the necessary examination requirements were a Periodontal Probe, color-coded in 3-mm. increments, and a #2 explorer, commonly called a "cowhorn" or "pigtail" explorer.

It is the responsibility of the testing agency to select the standardized periodontal probes and explorers to be used for the examination. They must also identify the method by which the instruments will be provided. There are four alternatives:

- a. Instrument specifications can be sent to the candidate who will be responsible for purchasing the instruments and bringing them to the examination site.
- b. The testing agency can purchase a supply of instruments, make them available to candidates and collect them at the conclusion of the examination.
- c. The testing agency can purchase the required instruments and supply them to the candidates and include the cost in the examination fee.
- d. The testing agency can give the candidate the option of purchasing the instruments from the agency at cost or securing the specified instruments from commercial sources.

6. Modifying Forms and Manuals

The Examination forms for both Examiners and Candidates have been designed to precisely accommodate the format of this examination. Comprehensive manuals have been developed to prepare all participants for their role in the examination process. These materials may be utilized exactly as written if the testing agency wishes to adopt the examination without modifications. It is more likely, however, that the testing agency will want to utilize the materials as a prototype for the preparation of their own individualized forms and manuals. If new sections are to be added, performance levels revised, or the examination reweighted, these modifications must be reflected in the forms and manuals. Examination Committees should note that there is no such thing as a minor examination revision. The interdependent relationship of one aspect of the examination to another necessitates careful follow-through to insure that each revision is incorporated into every relevant form and manual.

Particular attention should be paid to the preparation of the Examiner's Evaluation Form. The chemically treated pages must be arranged so that page 1 does not copy onto page 2, while both pages 1 and 2 copy onto page 3. Special care must be taken to assemble the forms so that the examiner's recordings are precisely superimposed in the appropriate spaces on the third page of the form so that a master grade sheet is prepared for each candidate.

7. Organizing Examination Procedures

a. Selection of Assistants

As the Clinical Evaluation Study focused on improving the thoroughness, efficiency and reliability of examiners, efforts were made to reduce the distractions to which examiners are subjected. Since the benefits of chairside assistants to practitioners have been well established, it was concluded

that the same benefits should be available to examiners. By using assistants to manage the patient flow to examiners, maintain aseptic technique at examiner stations, provide chairside assistance and record the examiners' findings, the administration of the examination as well as the accuracy of the results could be enhanced. Not only has the use of examiner assistants improved the flow of the examination during both clinical field trials and actual board examinations but examiners have also responded very enthusiastically to their involvement.

The testing agency must establish guidelines for the selection of assistants by the Examination Coordinator at each site. Having given considerable thought to the question of who should serve as assistants and the effect of their selection on the security of the examination, it is recommended that assistants be recruited from the following groups, listed in order of preference:

1. Dental hygiene faculty members -- they are usually available at the site, are interested in the evaluation and accustomed to maintaining the security of examinations. If several schools are located near the testing site, each faculty should be given the opportunity to be represented. This arrangement can bring with it some specific benefits to a testing agency. Many educators who had an opportunity to be involved in field tests were impressed by the thoroughness of the evaluation and felt that they were better able to prepare students for the examination as a result of their first-hand observations. This can have a positive influence on the relationship between Boards and Educators.
2. Testing site staff assistants -- they are frequently available at the site if a dental examination is not being conducted simultaneously. They are competent for the responsibilities which must be assumed and are not likely to have a personal interest in the candidate's performance.
3. Practicing hygienists -- part-time practicing hygienists can be recruited through the local dental hygiene association. This could provide an opportunity for a positive interface between practicing hygienists and the testing agency.
4. Junior dental students -- they are usually readily available at dental school sites and fully capable of providing the required assistance. However, careful direction should be given to them regarding examination security.
5. Junior dental hygiene students -- they should be readily available, capable and undoubtedly eager to assist. Because of the obvious advantage this experience would give them during their own examination the following year, their selection is the least desirable alternative.

The examiner assistants will participate only in Part I and Part II evaluations. To help maintain the security of candidates' results, the scores for the written portion of the examination and Part III evaluations should not be made available to the assistants.

b. Selecting Examining Teams and Coordinators

The Examination Coordinator is the key to well organized and properly executed examination. The testing agency should identify those to serve as coordinators who are most experienced with the examination format and capable of organizing the logistics of the entire test administration process. The examining teams should be paired according to the guidelines provided in Section B of this Guide.

c. Organizing Orientations and Workshops

The importance of orientations and examiner workshops to improve the reliability of examiners has been consistently stressed throughout the Clinical Evaluation Study. The Examination Coordinator's Manual provides resource material for preparing these activities. The testing agency should provide for the careful development of orientations and clinical participation workshops on a schedule that will most effectively prepare the participating examiners.

E. COST OF TEST ADMINISTRATION

It is not possible to project whether or not there will be increased cost in using this examination without having specific knowledge of a testing agency's current dental hygiene testing activity. The time schedule for the examination and the examiner/candidate ratio will dictate the required number of examiners and the direct cost involved. Because of the comprehensive nature of these examination materials, some additional printing costs can be anticipated. The agency may also need to plan for the cost of examination instruments, depending on the method selected for providing them. Further costs may also be incurred to prepare and conduct Examiner Workshops.

Since the use of NCR Evaluation forms is not a customary procedure for most agencies, this is another cost which can be incurred. The Clinical Evaluation Study forms were produced in bulk of 1,000 sets at a cost of approximately \$.20 per set as additional expense for art work and printing plates was also necessitated. If only minor revisions are warranted once the forms are produced, the cost of art work and plates should not reoccur.

Therefore, the ultimate cost of administering an examination of this type is largely dependent upon the present practices of the testing agency. Every effort has been made to ensure the cost-effective operation of these clinical evaluation procedures. The initial costs for the development of this type of an examination have been underwritten by

the funding agency. However, a number of costs are ongoing no matter what type of examination is administered. Numbers of examiners, candidate to examiner ratios, examination length, and the extent of examiner workshops as well as efforts to evaluate and improve examination performance are all factors which can substantially affect the cost of conducting a clinical evaluation of this type.

F. METHOD AND COST OF PERIODIC COMPUTERIZED TEST ANALYSIS

An agency which adopts or adapts this test can not ignore the benefits which periodic analysis of the test will bring. Not only can the failure rates on each section be analyzed from school to school, site to site and year to year, the performance of examiners can be assessed so that team composition is done as fairly as possible on an annual basis. As a result of its efforts during the three years of the Clinical Evaluation Study the American Dental Hygienists' Association has begun to develop a substantial data base from which subsequent evaluation of clinical examinations can be made.

The Examiner's Evaluation Form and its method of recording errors have been specifically designed for easy coding and computer analysis. The cost of such analysis will vary according to the total population tested; fee quotation will be made available from the American Dental Hygienists' Association upon request. For agencies which have test analysis capabilities, a computer program which uses a statistical program entitled Statistical Package for the Social Sciences is available at cost for their use. Appendix III provides a sample Data Processing Information Form which is to be completed after every test administration for purposes of examination analysis.

The benefit of undertaking such an analysis for both the candidate and testing agency is clear. To expedite such a process, the computer analysis of all test results is recommended. Since conducting such an analysis is critical to the ongoing development and further improvement of the examination and its results, the costs of such examination evaluation procedures should be included as a part of testing fees.

Appendix I

Listing of Examination Sections, Performance Levels, Allowable Errors, and Weights

Sections	Performance Levels	Allowable Errors	Weights
<u>Part I - Data Gathering and Charting</u>			
Oral Inspection	90%	1 of 10 oral inspection categories	5
Dental Charting	90%	1 of every 10 items charted	10
Periodontal Measurement	95%	1 of 24 measurements for patients with "Medium" Calculus	10
	90%	2 of 24 measurements for patients with "Medium/Heavy" Calculus	
	85%	3 of 24 measurements for patients with "Heavy" Calculus	25
<u>Part II - Oral Prophylaxis</u>			
Subgingival	85%	4 of 28 surfaces for patients with "Medium" Calculus	25
	80%	5 of 28 surfaces for patients with "Medium/Heavy" Calculus	
	75%	6 of 28 surfaces for patients with "Heavy" Calculus	
Supragingival	95%	1 of 35 surfaces	20
Tissue	100%	no allowable errors on 28 tissue surfaces	5
			50
<u>Part III - Radiography</u>			
Technique			
Improper Mounting	100%	no allowable errors on 18 films	10
Cone Placement	95%	1 of 18 films	1
Film Placement	80%	3 of 18 films	2
Vertical Angulation	80%	3 of 18 films	2
Horizontal Angulation	80%	3 of 18 films	3
Recognition	85%	6 of 40 responses	15
Total Weight			25
Passing Grade			100
			70

Appendix II

PERFORMANCE CRITERIA AND MINIMAL COMPETENCE LEVELS

Part I - Data Gathering and Charting - 25 points

Oral Inspection - 5 points

The candidate must assess and record the status of a board patient's oral and extra-oral structures using the format and following the instructions provided in the Candidate's Progress Folder. Acceptable performance will have been demonstrated if 90% of the candidate's findings are correct. This procedure must be completed in approximately 15 minutes.

Dental Charting - 10 points

Given approximately 15 minutes, the candidate must chart the status of the patient's dentition using the format and following the instructions provided in the Candidate's Progress Folder. With the aid of a dental light, mirror, and explorer, all restorations, missing teeth and obvious carious lesions should be identified. Obvious carious lesions should demonstrate a general lack of integrity in the enamel or cementum surfaces. This can be determined either visually or by the penetration, with light pressure, of a sharp, #2 explorer, followed by detection of a soft base to the defect or definite resistance upon withdrawal of the explorer.

Acceptable performance will have been demonstrated if 90% of the candidate's findings are correct.

Periodontal Measurements - 10 points

Given approximately 15 minutes, the candidate must chart the depth of the gingival sulcus for every tooth in an assigned quadrant using the format and following the instructions provided in the Candidate's Progress Folder. Using a mouth mirror and a color-coded periodontal probe divided into 3 millimeter bands, the candidate must record the depth of each sulcus/pocket to the nearest millimeter on six aspects (MF, F, DF, ML, L, DL) of each assigned tooth. Acceptable performance will have been demonstrated if 95% of all measurements are recorded accurately.

Part II - Oral Prophylaxis - 50 points

Given approximately one hour, the candidate must complete a thorough oral prophylaxis on a maximum of two assigned quadrants using appropriate hand instruments, prophylaxis handpiece, disclosing solution and a #2 (cowhorn or pigtail) explorer.

Subgingival Deposits - 25 points

Given approximately 45 minutes, the candidate must effectively remove subgingival calculus so that no deposits are detectable with a #2 (cowhorn or pigtail) explorer and no calculus is visible when the tissue is deflected with air. Acceptable performance will have been demonstrated if 85% of all subgingival tooth surfaces are free of deposits.

Supragingival Deposits - 20 points

Given approximately 15 minutes, the candidate must effectively remove calculus, soft deposits and extrinsic stains so that all non-decalcified surfaces are:

1. Visually clean when air-dried.
2. Tactilely smooth upon examination with a #2 cowhorn or pigtail explorer.
3. Free of plaque when examined after the application of a disclosing agent.

Acceptable performance will have been demonstrated if 95% of all supragingival tooth surfaces are free of deposits, plaque and extrinsic stains.

Tissue Condition - 5 points

The candidate must effectively utilize hand instruments, polishing cups or brushes, and dental floss so that no unwarranted soft tissue trauma (abrasions or lacerations) occurs as a result of the prophylaxis procedure. Acceptable performance will have been demonstrated if 100% of all proximal tissue surfaces exhibit no unusual mechanical damage. The unwarranted presence of grossly lacerated gingival tissues (four or more lacerations) will result in automatic failure of the entire Oral Prophylaxis section of the examination.

Part III - Radiography - 25 pointsRadiographic Recognition Slide Examination - 15 points

Given approximately one minute per slide, the candidate must complete a 24 slide, 40 question examination, which includes the recognition of normal and abnormal dental structures, carious lesions, calculus and anatomical landmarks. Acceptable performance will be demonstrated if the candidate correctly recognizes 85% of the radiographic structures.

Radiographic Technique - 10 points

Given approximately 30 minutes, either prior to or on the day of the clinical examination, as specified by the testing agency, the candidate must expose, without assistance or retakes, a full-mouth

series of radiographs. After the radiographs have been developed by test-site staff, they must be properly mounted by the candidate in the accepted ADA method, dimple up, and must exhibit correct cone and film placement as well as correct vertical and horizontal angulation. Acceptable performance for each of the five skills to be tested will be assessed by computing the number of radiographs which demonstrate the correct application of the skill. The minimal competency level for each skill is listed below:

Mounting (1 point)	100%
Cone Placement (2 points)	95%
Film Placement (2 points)	80%
Vertical Angulation (2 points)	80%
Horizontal Angulation (3 points)	80%

Minimal Competency for the Entire Examination

The candidate must demonstrate minimal competency at the stated performance level for each component of the examination in order to receive a passing grade and be awarded the entire point value which can be achieved for that component. A passing grade for the entire examination is achieved when the candidate accumulates at least 70% of the 100 total points when all components of the examination are combined. This means that even though a candidate may not have met the minimal performance standards in every component of the examination, overall competency has been demonstrated if a grade of 70% has been attained.

Appendix III

Dental Hygiene Board Examination Analysis

Data Processing Information Form

This form must be completed for each test administration before being forwarded to the Test Evaluation Consultant. An original Page 3 (or copies, if necessary) of the Examiner Evaluation Form for each candidate must accompany this Information Form.

1. Name of Board or Testing Agency _____
2. Testing Site _____ 3. Date of test _____
4. Number of candidates taking examination _____
5. Please list the examiners used at this test site by name (or a code number for later reference) and provide the requested information for each one.

Name or ID #	Dentist or Hygienist	# of D.H. Board exams given previously	Specialty (if any) of Dentists
a.			
b.			
c.			
d.			
e.			
f.			
g.			
h.			

6. Please list each examiner team (by names or code numbers) and provide the requested information for each team.

Names or ID #'s		Number of times team has examined together before	Candidates (ID#'s) examined
Examiner A	Examiner B		
a.			
b.			
c.			
d.			

7. Please identify any revisions in the suggested sample size (number of measurements), number of allowable errors, and section weights used by your agency by correcting the format as presented below. (If a copy of the Examiner's Evaluation accurately displays this information, simply attach it to this survey form.)

	# of items measured	# of allowable errors	section weights
<u>PART 1 - Charting</u>			
Oral Inspection	10	1	5
Dental Charting	0-10	1	10
	11-20	2	
	21-30	3	
	31-40	4	
	> 40	5	
Periodontal Measurements	24 surfaces	medium calculus = 1 medium/heavy = 2 heavy calculus = 3	10

Part 11 - Prophylaxis

Subgingival	28 surfaces	medium calculus = 4 medium/heavy = 5 heavy calculus = 6	25
Supragingival	35 surfaces	1	20
Tissue	28 surfaces	0	5

PART 111 - Radiography

Technique			
Improper mounting	18	0	1
Cone Placement	18	1	2
Film Placement	18	3	2
Vertical Angulation	18	3	2
Horizontal Angulation	18	3	3
Radiographs	40	6	15

Other written Tests (Please forward the final grade sheet with all candidate grades and ID #'s for each written test.)

1. _____	_____	_____	_____
2. _____	_____	_____	_____
3. _____	_____	_____	_____
Total Points			100
Passing Grade			70

8. If your agency would like to review candidate results by school of graduation, please provide the following information:

School A	School B	School C	School D
Candidate ID Numbers	Candidate ID Numbers	Candidate ID Numbers	Candidate ID Numbers
=====	=====	=====	=====
1. _____	_____	_____	_____
2. _____	_____	_____	_____
3. _____	_____	_____	_____
4. _____	_____	_____	_____
5. _____	_____	_____	_____
6. _____	_____	_____	_____
7. _____	_____	_____	_____
8. _____	_____	_____	_____
9. _____	_____	_____	_____
10. _____	_____	_____	_____
11. _____	_____	_____	_____
12. _____	_____	_____	_____
13. _____	_____	_____	_____
14. _____	_____	_____	_____
15. _____	_____	_____	_____
16. _____	_____	_____	_____
17. _____	_____	_____	_____
18. _____	_____	_____	_____
19. _____	_____	_____	_____
20. _____	_____	_____	_____
21. _____	_____	_____	_____
22. _____	_____	_____	_____
23. _____	_____	_____	_____
24. _____	_____	_____	_____
25. _____	_____	_____	_____

9. If your agency would like to assess the validity of this examination by comparison of test results with clinic and radiology grades, please provide the following information.

Candidate's School name or code	Candidate's ID #	Clinic Grades (% only)	Radiology Grades (% only)
1. _____	_____	_____	_____
2. _____	_____	_____	_____
3. _____	_____	_____	_____
4. _____	_____	_____	_____
5. _____	_____	_____	_____
6. _____	_____	_____	_____
7. _____	_____	_____	_____
8. _____	_____	_____	_____
9. _____	_____	_____	_____
10. _____	_____	_____	_____
11. _____	_____	_____	_____
12. _____	_____	_____	_____
13. _____	_____	_____	_____
14. _____	_____	_____	_____
15. _____	_____	_____	_____
16. _____	_____	_____	_____
17. _____	_____	_____	_____
18. _____	_____	_____	_____
19. _____	_____	_____	_____
20. _____	_____	_____	_____
21. _____	_____	_____	_____
22. _____	_____	_____	_____
23. _____	_____	_____	_____
24. _____	_____	_____	_____
25. _____	_____	_____	_____

*EXAMINATION COORDINATOR'S MANUAL
FOR THE
DENTAL HYGIENE
CLINICAL BOARD EXAMINATION*



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EXAMINATION COORDINATOR'S MANUAL
FOR THE DENTAL HYGIENE
CLINICAL BOARD EXAMINATION

I. Introduction

The role of the Examination Coordinator is the key to an efficiently administered examination. It is the responsibility of the Coordinator to ensure that the physical facilities, equipment, forms and procedures as well as candidates and examiners are thoroughly prepared to conduct an examination that is a reliable measure of clinical competency. It is essential that facilities, procedures and examiners are as standardized as possible in their evaluative efforts so that there will be consistency not only within a given examination, but also from examination to examination, as administered by a particular testing agency. This manual, which is designed to facilitate the achievement of this objective, outlines long range, short range and on-site preparations which are the responsibility of the Examination Coordinator.

II. Long-Range Preparations (4-6 months in advance of examination)
Approximately 4 to 6 months prior to the examination, the testing site should be contacted and a Site Coordinator identified. The Site Coordinator is usually a member of the staff at the test site and is to work with the Examination Coordinator to provide the following clinical facilities, testing site requirements and local arrangements:

1. Reserve an adequate number of operatories for applicants.
2. Reserve two to three operatories per examiner team for examiners' stations in reasonably close proximity to each group of 10 candidates' operatories.
3. Secure adequate supplies such as gauze sponges, bracket covers, headrest covers, patient napkins, and paper towels.
4. When the policy of the testing agency permits, provide a supply of standardized examining instruments for candidates and examiners.
5. Provide a supply of sterile examining instruments (mirrors, explorers and probes) at examining stations in case of breakage or contamination.
6. After determining the radiographic module to be required by the testing agency, prepare adequate radiographic units, films and mounts for candidates who will be using the facility for their radiographic procedures. If possible, cones of different lengths and a variety of film holders should be made available for use by the candidates.
7. If pre-examination radiographic procedures are authorized, give the candidates, currently enrolled in dental hygiene programs, instructions and a standardized envelope for the certification of the films by the program director prior to the examination.
8. Provide adequate staff personnel to process films.
9. Provide area with viewboxes for examiners to evaluate radiographs.

10. Provide a slide projector and room which will accommodate all candidates for both the orientation session and the radiology recognition test.
 11. Provide a slide projector and room for Examiner's Orientation.
 12. Determine what testing site requirements, if any, must be fulfilled by the candidate, such as the use of school health histories, pre-examination sterilization of candidate instruments, and rental fees.
 13. Determine testing site fee to be charged candidates for disposable items, film, mounts and equipment.
 14. Determine the availability of "back-up" patients at the site in the event that some patients are dismissed because they are unacceptable.
111. Short-Range Preparations (4-6 weeks in advance of examination).
- A. Test Site Preparations
 1. The testing site should provide candidates with the following information at least four weeks in advance of the examination:
 - a. Time and location of check-in procedures.
 - b. Testing site fee.
 - c. Testing site procedures for receiving patients and operatory assignments.
 - d. Testing site forms to be completed other than examination forms.
 - e. Specifications for attachable handpieces, or the availability of rental handpieces and the fee for their use.
 - f. Sterilization procedures.
 - g. Availability of hotel accommodations in close proximity to the test site.
 - h. Testing site check-out procedures.

Such a mailing should also reaffirm the candidate's responsibility for patient selection while reminding candidates that obtaining back-up patients is not the test site's responsibility.

2. The Examination Coordinator should arrange for:
 - a. Meals for examiners. Breakfasts will need to be early and prompt and lunches should be brought to the testing site.
 - b. Transportation for examiners from the hotel to the testing site.
 - c. Guaranteed reservations for examiners at a conveniently located hotel.
 - d. Notification to examiners well in advance of hotel arrangements, availability of transportation between terminals and hotel, and the time and place to convene for the orientation session.

- e. Selection of an assistant for each examiner and development of a schedule for their orientation and assignments as well as a list of their responsibilities.
- f. Delivery of all examination forms, materials and slides to the testing site.

B. Candidate Preparation

At least 4-6 weeks in advance of the examination, the Examination Coordinator should ensure that Candidates' Guides have been distributed to the candidates. This Guide and accompanying forms provide the candidate with a detailed overview of the examination, expected performance levels, guidelines for patient selection and recommended procedures for candidate preparation.

C. Examiner's Preparation

The Examiner's Manual should be distributed well in advance of the examination. The Manual orients the examiners to their responsibilities in the administration of the examination, defines performance criteria as well as describing the way in which they should be applied in the detection of errors. The examiners should be urged to follow recommended procedures for preparation prior to the examination.

D. Procedures to Maintain Anonymity

It is essential that the examination results reflect a measurement of competency that is not biased by other considerations such as race, sex, age, personal appearance or previous performance. The Examination Coordinator can minimize the potential bias through organization of the examination.

1. Candidate forms and grade sheets are identified by number or a code so that examiners are not aware of the identity of the candidate when evaluating their performance. The Coordinator should insure that the identity of the candidates is not revealed to the examiners until the completion of the examination and the submission of all grades.
2. If Candidate identification pictures are used, they should be placed on the candidates' badges instead of the Candidate Progress forms. During the examination, the Examination Coordinator should randomly check identification badges to ascertain that the candidate taking the examination is, indeed, the same person who submitted the credentials on the application form.

3. If a written examination is administered prior to the clinical examination, examiners should not have access to the results or proctor the examinations of candidates assigned to their team. Prior knowledge of who scored either well or poorly on a written examination, or the opportunity to observe which candidates finish first or last, could subjectively prejudice an examiner's evaluation of clinical performance. Similarly, examiners should not be aware of candidates who are retaking the examination because of previous failure.
4. The Examiner Assistant should receive and seat patients who are presented for evaluation so that the examiners do not have the opportunity to associate candidates with patients.
5. If a jurisdiction feels that examiner bias is a significant concern, a further strategy is to rotate teams of examiners between Part I, Part II and Part III Evaluations. Each team would evaluate Part I for one group of candidates and Part II and III for different groups, thereby eliminating the possibility of allowing a candidate's performance in one section of the examination to influence the evaluation of a subsequent section. If such a strategy is to be employed, the Examination Coordinator should determine the appropriate organization of examiner teams and evaluation forms to facilitate its implementation.

IV. On-Site Preparations

A. Examination Materials

At the examination site, the Coordinator should insure that all necessary forms, materials and instruments are provided. The facilities for the slide examination should be prepared, and the radiographic slides should be previewed to assure they are correctly placed for projection.

B. Examiner's Orientation

1. Approximately 2 to 3 hours should be scheduled at an appropriate time, for the examiners' orientation. A slide projector and screen will be necessary for the projection of Orientation slides. The Coordinator should review and respond to questions regarding the examiner's previous analysis of the Examiner's Manual. Using the Orientation slide presentation, a step-by-step review of procedures for the examination should be conducted. During this procedural orientation, the Examination Coordinator should be sure to include a discussion of:

- a. Patient acceptability.
- b. Classification of the patient difficulty level.
- c. Assignment of a quadrant for periodontal charting.
- d. Assignment for the oral prophylaxis.
- e. Selection of the tooth sample for the prophylaxis.
- f. Review of the candidates' forms.
- g. Procedures for recording errors and computing grades.
(Sample exercises for use with the Examiner's Evaluation form are included as an appendix to this manual).
- h. Validation procedures.
- i. Use of examiner stations and assistants.
- j. Description of emergency procedures at the testing site.

The Site Coordinator should familiarize examiners with information that has been provided to candidates about site requirements and clearance procedures for the release of candidates by the testing site at the conclusion of the examination. The Site Coordinator should also familiarize the examiners with the clinical facilities.

- 2. If the testing agency has determined that more in-depth preparation of examiners is appropriate, then the Coordinator should organize a four-hour clinical participation workshop for examiners. While the Examiner's Orientation will necessarily focus on procedures for the administration of the exam, a clinical participation workshop will concentrate on clarification of performance criteria and the examining techniques required to correctly apply the criteria. This will result in greater standardization of examiners. An outline is included in the appendix to this Manual to assist the Examination Coordinator in organizing clinical standardization exercises.

C. Candidate's Orientation

A 60 minute orientation for candidates should be scheduled at an appropriate time and should include:

- 1. The distribution of Examination Packages including identification Badges, Candidate Forms, receipts, and X-ray mounts.
- 2. A review of the Examination format.
- 3. A review of the forms and progress chart indicating that candidates must:
 - a. Have the examiner assign quadrants for periodontal charting and the oral prophylaxis, and
 - b. Have the examiner initial progress sheet after each check.
- 4. An emphasis on the need to:
 - a. Prepare Data Gathering and Charting Section (Part I) immediately.
 - b. Complete all blanks on the Oral Inspection Form and Health History
 - c. Correctly record dental findings. (This portion of the presentation should be diagrammed on a chalkboard.)
 - d. Use red and blue pencil for dental charting.

- e. Measure six aspects for every tooth when completing periodontal charting, recording only those measurements of 3 mm. or more.
5. Establish a method for the flow of patients to examiners.
 - a. Forms (and instruments if necessary) to be presented with the patient.
 - b. Release of patients from the examining station.
6. Review Prophylaxis Procedures for:
 - a. Completing prophylaxis assignment;
 - b. Disclosing patient;
 - c. Completing entire prophylaxis, if time permits;
 - d. Dismissing patient.
7. Review Radiographic Procedures:
 - a. Scheduling radiographic units for on-site radiographic procedures;
 - b. Collecting pre-exposed radiographs for processing;
 - c. Numbering mounted films from 1-18, and recording patient's name and candidate number on mount.
8. Review candidate check-out procedures and necessary clearance from testing site.
9. Inform candidates of procedures for reclaiming radiographs following finalization of examination results.
10. Discuss utilization of time so that all procedures are completed within the time frame allotted for the examination.
11. Ascertain that all candidates have the required probes and explorers. Arrange loan of instruments to any candidate who needs them.
12. Describe emergency procedures for the testing site.
13. Familiarize candidates with facilities.
14. Administer Radiology Recognition Slide Examination and other written examinations as may be required by the testing agency.

D. Examiner Assistants' Orientation

A 45 minute Orientation of examiner assistants should be scheduled at an appropriate time. An approach which has worked well is to orient examiner assistants while the clinic is first being set up and patients are being seated and checked-in. The Examination Coordinator should assign the recorders to specific examiners and then review the procedures for the following:

1. Presenting patients at examining stations in the order of the candidates' requests for evaluation on sign-up sheet.
2. Providing chairside assistance.
3. Recording examiner findings.
4. Comparing results of both examiners.
5. Requesting validation of findings when the total number of different errors recorded by examiners exceeds the allowable errors.
6. Maintaining observer status.
7. Releasing the patient from the examiner station when the examiners have agreed upon and recorded a pass or failure or have completed their validation procedures.
8. Preparing the operatory for the next patient.

V. Examination Coordination and Follow-up Procedures.

If a policy of pooling and random redistribution of patients among candidates has been adopted by the testing agency as a measure of insuring an equal amount of prior patient exposure, the examination coordinator must supervise this activity either the day before or at the beginning of each test administration. After supervising the Patient Check-in procedures and conducting the Examiner Assistant Orientation, the Examination Coordinator should remain available throughout the examination to assist examining teams. The Coordinator may be asked to render a third opinion for an evaluation if agreement cannot be reached through validation. At the conclusion of the examination, the Coordinator should collect all candidates' and examiners' forms and ensure that documentation is provided for all failures as required by the testing agency. Clearance of all candidates from the testing site should be confirmed. Arrangements should be made for distribution of radiographs, if any, following finalization of examination results. All examination materials should be forwarded to the office in charge of permanent records.

Supplementary Materials

Included in the remainder of this Manual are outlines to assist the Coordinator in conducting two different kinds of exercises.

1. Two "mock" Examiner's Evaluation Forms have been prepared with narratives for each one. After the Examination Coordinator has explained the use of the Evaluation Form, the examiners can be divided into teams and an Examiner A and B identified for each team. The Coordinator can then read the exercise narrative while the examiners fill out an Evaluation Form according to the directions. This will provide practice through a simulation of the examination procedures. The examiners' results can be compared to the correctly completed example form. These exercises will be helpful in orientation for both examiners and examiner assistants.
2. An outline has been prepared to assist the Examination Coordinator in developing a clinical participation workshop for examiners, if the testing agency has determined that such standardization exercises are to be conducted. The outline includes the content, clinical facilities, patients, supplies and method of organization that would be necessary to implement such a workshop.

OUTLINE OF EXAMINER STANDARDIZATION EXERCISES

- A. Review of Orientation's Purpose
 - 1. Purpose of examination: evaluate students for minimal clinical competency
 - 2. Reliability: consistency between teams and sites
 - 3. Test standardization: now only two major variables - examiners and candidates. Standardization exercises minimize examiner variability.
 - 4. Orientation will - review each section
 - discuss performance criteria
 - demonstrate examiner procedures
 - practice examiner procedures
 - compare and discuss results, measuring differences against performance criteria
- B. Patient Classification
 - 1. Review the importance of having a reliable patient classification (Performance levels are determined by patient classification)
 - 2. Review of criteria for Patient Classification
 - a. Unacceptable patients
 - 1) Insufficient deposits
 - 2) Periodontal patients
 - 3) Adverse medical or soft tissue conditions
 - b. Acceptable patients
 - 1) Medium
 - 2) Heavy
 - 3) Medium-Heavy
 - 3. Review recording of patient conditions and candidate assignments (Demonstrate how examiners should work together for patient check-in)
- C. Part I - Data Gathering and Charting
 - Review role of hygienist - to screen patients and call the dentist's attention to conditions needing definitive diagnosis

Oral Inspection

- 1. Review purpose, candidate instructions, and performance criteria
 - 2. Describe and demonstrate Examiner Procedures
 - a. Order: extra-oral, intra-oral, gingiva, teeth
 - b. Thoroughness: Comprehensive but equal emphasis
 - c. Questioning of patients when necessary: (TMJ pain)
 - d. Examples of common errors:
 - miss crepitus
 - overzealous (chart insignificant conditions)
 - incorrectly describe gingival characteristics
 - miss abrasion or crossbite
 - misclassify occlusion
- Demonstration includes
- Walk-through of procedures using examiner assistant and stresses communicating with assistants
- Materials include:
- 2x2 Gauze Sponges
 - Mirror (for retraction)
 - Candidate Progress Folder
 - Examiner Evaluation Form
 - Examiner Assistant

Dental Charting

1. Review purpose, candidate instructions, and performance criteria
(Demonstrate on blackboard correct examples of charting)
2. Describe and demonstrate Examiner Procedures
 - a. Order: follow tooth numbering system
 - b. Thoroughness: tooth by tooth
 - c. Use of air: must be consistent
 - d. Review of caries detection criteria
 - e. Examples of common errors: miss silicates, miss caries, chart on wrong tooth or wrong tooth or wrong surface, chart wrong missing tooth, transpose teeth (count 1 error for every transposed tooth)

Demonstration includes:

 - focusing light
 - air drying teeth
 - exploring teeth in order, noting extractions, restorations, and caries
 - using examiner assistant to read charting to examiner
 - completing of Examiner Evaluation Form

Resources include:

 - patient, dental operatory with air syringe and light
 - mirror, explorer
 - 2x2 Gauze squares, patient napkin and clips
 - Candidate's Progress Folder
 - Examiner Evaluation Form
 - Examiner assistant
3. Standardization Exercise
 - a. Materials needed:
 - one complete operatory per examiner team
 - one patient who has been charted (perhaps with one or two errors on the Progress Folder) per team
 - mirror, explorer, patient napkin and clips
 - completed Progress Folder
 - Examiner Evaluation Forms
 - b. Tasks:
 1. Each examiner team completes a half mouth dental charting evaluation using examiner from another team as their assistant. (See the last page of the instructions for organizing teams for exercises)
 2. Each team is to compare and discuss their performance, validating, differences when necessary, in an attempt to standardize their interpretation and application of the evaluation criteria.
 3. Tasks 1 and 2 are repeated for other half mouths (optional: as time permits)

Periodontal Measurements

1. Review of purpose, candidate instructions and performance criteria
2. Description and Demonstration of examiner procedure
 - a. Identify quadrant and tooth sample
 - b. Measure locations on tooth
 - c. Probe angulation (long axis) and position (2 + 3 contact points)
 - d. Ensure clear readings: (Use of air when necessary)
 - e. Determine error ($\pm$ 1 mm.)
 - f. Identify examples of common errors

- g. Explain the use of examiner assistants (read periodontal measurement to examiner)
- h. Complete Examiner Evaluation Form

Demonstration includes: Identifying and probing 4 teeth on patient using an examiner assistant

Materials needed: Same as for Dental Charting demonstration with the addition of the standardized periodontal probes

3. Standardization Exercise

- a. Materials needed:
 - One patient per examiner team, each of whom has two quadrants charted (perhaps with errors) on the Candidate's Progress Folder
 - Other materials should be used for the Dental Charting standardization exercise with the addition of the standardized periodontal probe

b. Tasks:

- 1. Each examiner team completes a periodontal measurement evaluation of the same four tooth samples using examiners from another team as their assistants.
- 2. Each team is to then compare and discuss their performance, and to validate differences when necessary, in an attempt to standardize their interpretation and application of evaluation criteria and procedures.
- 3. Tasks 1 and 2 are repeated for the second sample of four teeth in remaining quadrant (Optional: as time permits.)

D. Part II - Oral Prophylaxis

- 1. Review of purpose, candidate instructions and performance criteria
- 2. Description and demonstration of Examiner procedure
 - a. Tooth Sample Identification
 - b. Use of Air
 - c. Examining Technique
 - 1) Instrument grasp and lightness of touch
 - 2) Angulation and position of explorer tip
 - 3) Location and frequency of strokes
 - d. Use of disclosing agent to confirm suspect supragingival plaque
 - e. Tissue examination
 - f. Examples of Common Errors: subgingival calculus, facial calculus, failure to air-dry, crescent of stain on line angle of tooth, soft deposits on occlusal surfaces
 - h. Use of Examiner Assistants
 - 1. Completion of Examiner Evaluation Form

Materials include: are the same as for previous demonstrations

Demonstration includes: Evaluation of one quadrant using examiner assistant to dry the tooth surfaces being examined and fill out the Examiner's Evaluation Form

3. Standardization Exercise

- a. Materials:
 - 2 patients with a few deposits only
 - other materials as in previous standardization exercises including the standardized "#2" explorer

b. Tasks:

- 1. Each examiner team does an oral prophylaxis evaluation of the same seven tooth samples using examiners from another team as their assistant.
- 2. Each team compares and discusses their performance, validating differences when necessary, in an attempt to standardize their interpretation and application of the evaluation criteria and procedures.
- 3. Tasks 1 and 2 are repeated using the other two quadrants and switching patients.

E. Part III - Radiography Technique

- 1. Review purpose, candidate instructions, and performance criteria
- 2. Describe and demonstrate Examiner Procedures including:

- a. Numbering of radiographs
- b. Options within the sequence of examination procedures
 - one film at a time using all five criteria, or
 - one criteria at a time for all films

3. Standardization Exercise

- a. Materials needed:
 - 2 numbered full-mouth radiographic series per team
 - Two x-ray viewboxes per team
 - Examiner Evaluation Form
 - Radiographic performance criteria and examples from Examiner Preparation Manual

b. Tasks:

- 1. Each examiner is to individually evaluate a full-mouth radiographic series noting the number of each radiograph demonstrating a technique error on the appropriate grid on the Examiner's Evaluation Form, removing the top page of form when completed.
- 2. The examiners are then to trade radiographs and forms and individually evaluate the second full-mouth series.
- 3. Each team is to compare and discuss their performance and validate errors when necessary, in an attempt to standardize their interpretation and application of the evaluation criteria and procedures.

F. Summary

- 1. Review reliability concepts and the importance of patient classification and independent evaluation followed by validation when necessary
- 2. Questions
- 3. Further standardization exercises as time and energy permit

ORGANIZING TEAMS FOR STANDARDIZATION EXERCISES

The examiners can be organized for clinical exercises so that they have an opportunity to gain experience serving as both an examiner and an assistant. They should be paired with an examining partner exactly as they would be for an examination. However, they should assist an examiner who is evaluating a different patient from the one for whom they are responsible. In this manner, their evaluation will not be influenced by having assisted someone else to evaluate that same patient.

For example, if six examiners are going to participate in clinical exercises, organize them into three teams, with a patient assigned to each team:

Team 1
Examiner A-1
Examiner B-1

Team 2
Examiner A-2
Examiner B-2

Team 3
Examiner A-3
Examiner B-3

Begin the clinical exercises with the examiners distributed in the following way:

Team 1 Patient
A-1 Examines
B-2 Assists

Team 2 Patient
A-2 Examines
B-3 Assists

Team 3 Patient
A-3 Examines
B-1 Assists

SWITCH STATIONS AND CONTINUE EVALUATION

B-1 Examines
A-3 Assists

B-2 Examines
A-1 Assists

B-3 Examines
A-2 Assists

SWITCH STATIONS FOR VALIDATION

A-1 and B-1
Validate Together

A-2 and B-2
Validate Together

A-3 and B-3
Validate Together

Required Resources for the Examiner Standardization Exercises

1. The Examination Coordinator.
2. One Examiner Assistant, if assistants are to be used.
3. One complete operatory for each examiner team including chair, light, air, operator, and assisting stools.
4. Several mirrors, cow-horn or pigtail explorers, color-coded periodontal probe, patient napkins and clips, and 2 X 2 gauze squares for each operatory.
5. One patient along with their radiographs, who has had a recent prophylaxis for each examiner team. A Candidate Progress Folder must have been previously completed for each patient. One or two errors per section (on the folder) would be desirable.
6. Several Examiner Evaluation Forms.
7. Two viewboxes for each examiner team.

PRACTICE EXERCISES TO BE UTILIZED
WITH EXAMINER'S EVALUATION FORM

Take a sample evaluation form and fill in your findings for each exercise. As you complete each Part, you may refer to the example showing the correctly completed form.

EXERCISE #1

Fill in the following information at the top of the page:

Candidate #84
Patient Condition: Calculus - Medium
 Stain - Light
 Tissue - Irritated (firm)
Assign: Periodontal Quadrant - LL
 Prophylaxis - UL and LR

PART I

Examiner A is first examiner - Record Candidate number
Oral Inspection - Errors on B and E
Dental Charting - Record 29 Items charted - Errors on 10, 15 and 30
Periodontal Probing - Record Teeth ID #18, 19, 20, 21
 Errors on #20-DF

Count and record number of errors A found in A's column of circles
Tear off the white sheet for Part I and transfer onto the green sheet the
Candidate's number, the number of the items on the dental chart, and the
ID numbers for the Periodontal Teeth

Examiner B Findings

Oral Inspection - Errors on B and I
Dental Charting - Record 29 Items charted - Error on #10
Periodontal Probing - Error on #18 - ML

Count and record the number of errors B found in B's column of circles
Tear off the green sheet for Part I and assess the need for validation

Does Oral Inspection need validation?	YES:	1 Allowable error	
A validates B's error on I		Examiners found 1 identical error	
B denies A's error on E			2 unconfirmed errors
Candidate FAILS with 2 confirmed errors			

Does Dental Charting need validation?	NO:	29 Items = 3 allowable errors	
Candidate PASSES		Examiners found 1 identical error	
			2 unconfirmed errors

Does Periodontal Probing need validation:	YES:	Medium Patient = 1 Allowable error	
A validates B's error on #18-ML		Examiners found 2 unconfirmed errors	
B validates A's error on #20-DF			
Candidate FAILS with 2 confirmed errors			

PART II

Examiner B is first examiner - Record Candidate number
 Examiner B records Tooth ID numbers for the prophylaxis sample. They are:
 #15, 13, 11, 9, 26, 28, 30
 Subgingival - Errors on #26 - M and D
 Supragingival - Errors on #15 -F, #9 -L, #30 - Occlusal
 Tissue - Error on #15-F

Count and record the number of errors B found in B's column of circles
 Tear off the white sheet for Part II and transfer onto the green sheet the
 Candidate's number and the ID number for the teeth in the prophylaxis sample

Examiner A's findings

Subgingival - Errors on #15-M and D
 Supragingival - Error on #30-Occlusal
 Tissue - Errors on #15-F, #9-L

Count and record the number of errors A found in A's column of circles
 Tear off the green sheet for Part II and assess the need for validation

Does Subgingival need validation? NO: Medium Patient = 4 Allowable errors
 Examiners found 4 unconfirmed errors

Does Supragingival need validation? YES: 1 Allowable Error
 A validates B's error on #9-L & #15-F Examiners found 1 identical error
 Candidate FAILS with 3 confirmed errors 2 unconfirmed errors

Does Tissue need validation? NO: 0 Allowable Errors
 CANDIDATE FAILS Examiners found 1 identical error
 1 unconfirmed error

PART III

Examiner A records Candidate #84
 Mounting - Errors on films 3 and 5
 Cone Cut - Errors on film 7
 Film Placement - Errors on films 1, 6, 8, 15
 Vertical Angulation - Errors on films 1, 2, 7
 Horizontal Angulation - Errors on films 2, 9, 16, 17

Count and record the number of A's errors in A's column of circles
 Tear off the white sheet and transfer the Candidate number onto the green sheet

Examiner B Findings

Mounting - Errors on films 3 and 5
 Cone Cut - No Findings
 Film Placement - Errors on films 1, 6, 13, 15
 Vertical Angulation - Errors on films 2, 7
 Horizontal Angulation - Errors on films 9, 16, 17, 18

Count and record the number of B's errors in B's column of circles
 Tear off the green sheet and assess the need for validation

Does Mounting need validation?
Candidate FAILS

NO: 0 Allowable Errors
Examiners found 2 identical errors

Does Cone Cut need validation?
Candidate PASSES

NO: 1 Allowable Error
Examiners found 1 unconfirmed error

Does Film Placement need validation?
A validates B's error on 13
B validates A's error on 8
Candidate FAILS with 5 confirmed errors

YES: 3 Allowable Errors
Examiners found 3 Identical errors
2 unconfirmed errors

Does Vertical Angulation need validation? NO: 3 Allowable Errors

Candidate PASSES

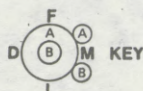
Examiners found 2 Identical errors
1 unconfirmed error

Does Horizontal Angulation need validation? YES: 3 Allowable Errors
A denies B's error on 18
B denies A's error on 2
Candidate PASSES

Examiners found 3 identical errors
2 unconfirmed errors

CLINICAL TOTALS:

Record total scores at the top of the form and compare your Exercise Sheet with the Example for Exercise #1.



EXAMINER'S EVALUATION FORM

Exercise 1

 Total Possible Points: 100
 Passing: 70
Candidate's Number 84
 Examiner A _____
 Examiner B _____

Patient Condition (Circle):

CALCULUS: Medium Med/Hvy HeavyStain: Light Medium Heavy
 Gingiva: Normal Irritated (but firm) Irritated (spongy & hemorrhagic)

Candidate Assignments (circle)

Periodontal Measurements: UR UL LL LRProphylaxis Quadrants: UR UL LL LR
 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
 32 31 30 29 28 27 26 25 24 23 22 21 20 19 18 17

TOTALS

PART I 10PART II 85

PART III _____

Technique 7

Recognition _____

Candidate's Score: _____

PART III RADIOGRAPHS (10 points)

Candidate Number 84, 84

TECHNIQUE Record in the appropriate grid the identification number of unacceptable radiographs for each category. Record validated errors with an X.

A	1	3	5			
	2	7				
	3	1	6	8	15	
	4	1	2	7		
	5	2	9	16	17	

- Improper mounting
- Cone cut
- Improper film placement
- Elongation or foreshortening
- Interproximal overlapping

B	1	3	5			
	2					
	3	1	6	8	15	
	4	2	7			
	5	9	16	17	18	

A	B	AE	V	Points
2	2	0	0	X
1	0	1	0	2
4	4	3	5	X
3	2	3	0	2
4	4	3	3	3
Total Technique				7

PART II ORAL PROPHYLAXIS (50 points)

Candidate Number 84, 84

Record errors by placing a dot on the appropriate tooth surface. Record validated errors with an X.

SUBGINGIVAL

15/15 # 13/13 # 11/11 # 9/9 # 26/26 # 28/28 # 30/30

A	B	AE	V	Points
2	2	0	0	25
M = 4 MH = 5 H = 6				

SUPRAGINGIVAL



A	B	AE	V	Points
1	3	1	3	X

TISSUE



A	B	AE	V	Points
2	1	0	0	X

Total Part II 25

PART I CHARTING (25 points)

Candidate Number 84, 84

Record errors by circling item letter or tooth number. Record validated errors with an X.

ORAL INSPECTION

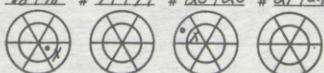
A	A	B	C	D	E	F	G	H	X	J
B	A	B	C	D	E	F	G	H	1	J

DENTAL CHARTING

Items Charted 29, 29

A	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
	32	31	30	29	28	27	26	25	24	23	22	21	20	19	18	17
B	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
	32	31	30	29	28	27	26	25	24	23	22	21	20	19	18	17

PERIODONTAL MEASUREMENTS:

 Record errors by checking tooth sextant on which error is located.
 Record validated errors with an X.


A	B	AE	V	Points
2	2	1	2	X

A	B	AE	V	Points
3	1	3	0	10
0 - 10 = 1 21 - 30 = 3				
11 - 20 = 2 31 - 40 = 4				

A	B	AE	V	Points
1	1	1	2	X
M = 1 MH = 2 H = 3				

Total Part I 10

EXERCISE #2

Fill in the following information at the top of the page:

Candidate #16

Patient Condition: Calculus - Heavy
Stain - Medium
Tissue - Irritated and Hemorrhagic

Assign: Periodontal Quadrant - LR
Prophylaxis - LL

PART I

Examiner B is first examiner - Record Candidate number

Oral Inspection - Error on H

Dental Charting - Record 14 Items Charted - Errors on # 13, 15, 26

Periodontal Probing - Record Teeth ID #31, 30, 29, 28. Error on #30-MF

Count and record the number of errors B found in B's column of circles

Tear off the white sheet for Part I and transfer onto the green sheet the
Candidate's number, the number of items on the dental chart and the tooth
ID numbers to be checked on Periodontal Measurements

Examiner A's Findings

Oral Inspection - Error on H

Dental Charting - Errors on 2, 13 and 26

Periodontal Probing - Errors on #31-F, #28-DL

Count and record the number of errors A found in A's column of circles

Tear off the green sheet for Part I and assess the need for validation

Does Oral Inspection need validation? NO: 1 Allowable Errors

Candidate PASSES

Examiners found 1 identical error

Does Dental Charting need validation? YES: 14 items = 2 allowable errors

B validates A's error on #2

Examiners found 2 identical errors

A denies B's error on #15

2 unconfirmed errors

Candidate FAILS with 3 confirmed errors

Does Periodontal Probing need validation? NO: Heavy Patient = 3 Allowable errors

Candidate PASSES

Examiners found 3 unconfirmed errors

PART II

Examiner A is first examiner - Record Candidate number

Examiner A records Tooth ID number for prophylaxis sample: #18,19,20,21,22,23,24

Subgingival - Errors on #18-D, #19-M, #21-D, #22-F, #24-M and D

Supragingival - Error on #23-L

Tissue - No Findings

Count and record the number of errors A found in A's column of circles

Tear off the white sheet for Part II and transfer onto the green sheet the

Candidate number and the ID number for the teeth in the prophylaxis sample

Examiner B's Findings

Subgingival - Errors on #18-D and L, #19-M, #22-F, #24-D

Supragingival - Errors on #23-L, #24-F

Tissue - No Findings

Count and record the number of errors B found in B's column of circles

Tear off the green sheet for Part II and assess the need for validation

Does Subgingival need Validation? YES: Heavy Patient = 6 Allowable Errors
 Examiner B validates A's error #24-M Examiners found 4 Identical Errors
 Examiner B denies A's error #21-D 3 Unconfirmed Errors
 VALIDATION CAN STOP BECAUSE TOTAL WILL NOT EXCEED 6
 Candidate PASSES

Does Supragingival need validation? YES: 1 Allowable Error
 A validates B's error on #24-F Examiners found 1 Identical Error
 Candidate FAILS 1 Unconfirmed Error

Does Tissue need validation? NO: 0 Allowable Errors
 Candidate PASSES Examiners found no errors

PART III

Examiner A records Candidate #16
 Mounting - No findings
 Cone Cut - Errors on films 1, 2, 15
 Film Placement - Errors on films 6, 9, 18
 Vertical Angulation - Error on film 5
 Horizontal Angulation - Errors on films 15, 16, 17, 18
 Count and record the number of A's errors in A's column of circles
 Tear off the white sheet and transfer the Candidate number onto the green sheet

Examiner B Findings

Mounting - No findings
 Cone Cut - Errors on films 1, 2, 15, 17
 Film Placement - Error on film 16, 17, 18
 Vertical Angulation - Error on film 7
 Horizontal Angulation - Errors on films 3, 5, 17
 Count and record the number of B's error in B's column of circles
 Tear off the green sheet and assess the need for validation.

Does Mounting need validation? NO: 0 Allowable errors
 Candidate PASSES Examiners found no errors

Does Cone Cut need validation? NO: 1 Allowable Error
 Candidate FAILS Examiners found 3 Identical Errors
 1 Unconfirmed Error

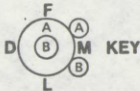
Does Film Placement need validation? YES: 3 Allowable Errors
 B validates A's errors on 6 and 9 Examiners found 1 Identical Error
 A denies B's error on 17 and 16 4 Unconfirmed Errors
 Candidate PASSES

Does Vertical Angulation need validation? NO: 3 Allowable Errors
 Candidate PASSES Examiners found 2 Unconfirmed errors

Does Horizontal Angulation need validation? YES: 3 Allowable Errors
 A validates B's errors on 3 and 5 Examiners found 1 Identical Error
 B validates A's error on 15 and 18 5 Unconfirmed Errors

Candidate FAILS with 5 confirmed errors

RECORD TOTAL SCORES AND COMPARE YOUR EXERCISE SHEET WITH THE EXAMPLE.



EXAMINER'S EVALUATION FORM

Exercise 2

 Total Possible Points: 100
 Passing: 70

 Candidate's Number 16 Examiner A _____
 Examiner B _____

TOTALS

PART I 15PART II 30

PART III _____

Technique 5

Recognition _____

Candidate's Score: _____

Patient Condition (Circle):

CALCULUS: Medium Med/Hvy HeavyStain: Light Medium Heavy

Gingiva: Normal Irritated (but firm) Irritated (spongy & hemorrhagic)

Candidate Assignments (circle)

Periodontal Measurements: UR UL LL LRProphylaxis Quadrants: UR UL LL LR

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

32 31 30 29 28 27 26 25 24 23 22 21 20 19 18 17

PART III RADIOGRAPHS (10 points)

Candidate Number 16, 16

If validated errors exceed circled amount, deduct all points for that category.

TECHNIQUE Record in the appropriate grid the identification number of unacceptable radiographs for each category. Record validated errors with an X.

1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5

- 1 Improper mounting
- 2 Cone cut
- 3 Improper film placement
- 4 Elongation or foreshortening
- 5 Interproximal overlapping

1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5
1	2	3	4	5

A	B	AE	V	Points
0	0	0	0	1
0	0	0	0	2
0	0	0	0	3
0	0	0	0	4
0	0	0	0	5
0	0	0	0	6
0	0	0	0	7
0	0	0	0	8
0	0	0	0	9
0	0	0	0	10
0	0	0	0	11
0	0	0	0	12
0	0	0	0	13
0	0	0	0	14
0	0	0	0	15
0	0	0	0	16
0	0	0	0	17
0	0	0	0	18
0	0	0	0	19
0	0	0	0	20
0	0	0	0	21
0	0	0	0	22
0	0	0	0	23
0	0	0	0	24
0	0	0	0	25
0	0	0	0	26
0	0	0	0	27
0	0	0	0	28
0	0	0	0	29
0	0	0	0	30
0	0	0	0	31
0	0	0	0	32
0	0	0	0	33
0	0	0	0	34
0	0	0	0	35
0	0	0	0	36
0	0	0	0	37
0	0	0	0	38
0	0	0	0	39
0	0	0	0	40
0	0	0	0	41
0	0	0	0	42
0	0	0	0	43
0	0	0	0	44
0	0	0	0	45
0	0	0	0	46
0	0	0	0	47
0	0	0	0	48
0	0	0	0	49
0	0	0	0	50
0	0	0	0	51
0	0	0	0	52
0	0	0	0	53
0	0	0	0	54
0	0	0	0	55
0	0	0	0	56
0	0	0	0	57
0	0	0	0	58
0	0	0	0	59
0	0	0	0	60
0	0	0	0	61
0	0	0	0	62
0	0	0	0	63
0	0	0	0	64
0	0	0	0	65
0	0	0	0	66
0	0	0	0	67
0	0	0	0	68
0	0	0	0	69
0	0	0	0	70
0	0	0	0	71
0	0	0	0	72
0	0	0	0	73
0	0	0	0	74
0	0	0	0	75
0	0	0	0	76
0	0	0	0	77
0	0	0	0	78
0	0	0	0	79
0	0	0	0	80
0	0	0	0	81
0	0	0	0	82
0	0	0	0	83
0	0	0	0	84
0	0	0	0	85
0	0	0	0	86
0	0	0	0	87
0	0	0	0	88
0	0	0	0	89
0	0	0	0	90
0	0	0	0	91
0	0	0	0	92
0	0	0	0	93
0	0	0	0	94
0	0	0	0	95
0	0	0	0	96
0	0	0	0	97
0	0	0	0	98
0	0	0	0	99
0	0	0	0	100

Total Technique

PART II ORAL PROPHYLAXIS (50 points) Candidate Number 16, 16

Record errors by placing a dot on the appropriate tooth surface. Record validated errors with an X.

SUBGINGIVAL

18, 18 # 19, 19 # 20, 20 # 21, 21 # 22, 22 # 23, 23 # 24, 24

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

A	B	AE	V	Points
0	0	0	0	1
0	0	0	0	2
0	0	0	0	3
0	0	0	0	4
0	0	0	0	5
0	0	0	0	6
0	0	0	0	7
0	0	0	0	8
0	0	0	0	9
0	0	0	0	10
0	0	0	0	11
0	0	0	0	12
0	0	0	0	13
0	0	0	0	14
0	0	0	0	15
0	0	0	0	16
0	0	0	0	17
0	0	0	0	18
0	0	0	0	19
0	0	0	0	20
0	0	0	0	21
0	0	0	0	22
0	0	0	0	23
0	0	0	0	24
0	0	0	0	25
0	0	0	0	26
0	0	0	0	27
0	0	0	0	28
0	0	0	0	29
0	0	0	0	30
0	0	0	0	31
0	0	0	0	32
0	0	0	0	33
0	0	0	0	34
0	0	0	0	35
0	0	0	0	36
0	0	0	0	37
0	0	0	0	38
0	0	0	0	39
0	0	0	0	40
0	0	0	0	41
0	0	0	0	42
0	0	0	0	43
0	0	0	0	44
0	0	0	0	45
0	0	0	0	46
0	0	0	0	47
0	0	0	0	48
0	0	0	0	49
0	0	0	0	50

M = 4 MH = 5 H = 6

SUPRAGINGIVAL

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

TISSUE

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Total Part II 30

PART I CHARTING (25 points)

Candidate Number 16, 16

Record errors by circling item letter or tooth number. Record validated errors with an X.

ORAL INSPECTION

A	A	B	C	D	E	F	G	H	I	J
B	A	B	C	D	E	F	G	H	I	J

A	B	AE	V	Points
1	1	1	0	5

DENTAL CHARTING

Items Charted 14, 14

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

3	3	2	3	X
---	---	---	---	---

0 - 10 = 1 21 - 30 = 3

11 - 20 = 2 31 - 40 = 4

PERIODONTAL MEASUREMENTS:

 Record errors by checking tooth
 sextant on which error is located.
 Record validated errors with an X.

*CANDIDATE'S GUIDE
TO THE
DENTAL HYGIENE
CLINICAL BOARD EXAMINATION*



*American Dental Hygienists' Association
Clinical Testing Evaluation Service
211 East Chicago Avenue, Suite 1616
Chicago, Illinois 60611*

January, 1978

CANDIDATE'S GUIDE TO THE DENTAL HYGIENE
CLINICAL BOARD EXAMINATION

A. GENERAL INFORMATION

This pamphlet has been designed to assist you in your preparation to be a participant in a dental hygiene clinical board examination. The examination is based on specific performance criteria which will be used to measure your clinical competency in three basic dental hygiene functions: Data Gathering and Charting, the Oral Prophylaxis and Radiographic Technique. The examination also includes a Radiographic Recognition Slide examination which is scheduled separately from the clinical portion of the examination.

1. Candidates must furnish their own patients, prophylactic instruments, mouth mirrors, a red and blue pencil and a handpiece compatible with testing center attachments. Arrangements for rental handpieces can be made through the testing site. The use of ultrasonic instruments will not be permitted. Instruments required for the examination are: a periodontal probe, color-coded in 3 millimeter increments, and a double-ended #2 explorer, sometimes referred to as a "pigtail" or "cowhorn" explorer. These instruments and all necessary forms for the examination will be supplied at the testing site.
2. Candidates should bring with them to the examination cash or a check, as may be required by the respective testing center, made payable to that center for materials and equipment used during the examination.
3. Candidates may not use dental assistants.
4. Each candidate will be assigned a specific team of two examiners who will evaluate all of the procedures performed by that candidate.
5. As a participant is participating in an examination to assess professional competency, each candidate is expected to maintain professional standards in the following areas:
 - a. Suitable operating attire.
 - b. Consideration for patients and cooperation with examiners, testing site personnel and other candidates.
 - c. Aseptic technique and general cleanliness of operatory during all procedures and the condition of instruments.
 - d. Protection of and concern for tooth structure and supporting tissues during patient's treatment.

B. PATIENT SELECTION

Patient selection is probably the single most important factor in preparation for the examination. Unacceptable patients will be dismissed and another patient must be provided if the candidate is to continue the examination. Therefore, obtaining a "back-up" patient is advisable. The patient's acceptability will be evaluated on the basis of: (1) health condition; (2) dentition requirements; and (3) adequate deposits.

1. Health Condition - The patient's health condition must be acceptable for prophylactic treatment. If conditions indicate an alteration in treatment procedures or a need to consult the patient's physician, the candidate must obtain the necessary written clearance before the patient will be accepted. There should be no soft tissue lesions that contraindicate dental hygiene instrumentation.
2. Dentition Requirements - The clinical patient must have a minimum of 14 natural teeth with at least two molars which are in contact with adjoining teeth since molars are often the most difficult to instrument and provide a reasonable test of the candidate's skill.

Radiographic patients must have at least 22 natural teeth. Care should be taken in the selection of the patient needing radiographs in order to avoid those patients with extensive overlapping or crowding since the evaluation of horizontal angulation is based, in part, on the presence of clear interproximal contacts.

3. Adequate Deposits - Visible supragingival deposits or stain and medium-to-heavy subgingival calculus must be present. A minimally-acceptable board patient would be one with supragingival calculus visible on at least the mandibular anteriors, explorer-detectable subgingival calculus throughout at least two other quadrants of the mouth, and minimal gingival inflammation. From this minimally-acceptable baseline, the degree of patient difficulty can vary substantially. Stain is not essential to qualify a patient as acceptable. However, a patient with minimally-acceptable subgingival calculus and moderate-to-heavy stain on the gingival third of almost all surfaces would provide ample opportunity for the candidate to demonstrate competency.

The candidate should not select advanced periodontal cases, such as an ADA Type IV patient which is defined as:

- (IV) Advanced Periodontitis: severe pocket depth, deeper than 7 millimeters; severe crestal bone resorption ($\frac{1}{2}$ or more crestal bone resorption); advanced mobility patterns.

It is imperative that all assigned procedures be completed. Incomplete procedures, for example in the area of gross scaling, cannot be evaluated. Therefore, another consideration in patient selection is the cooperative attitude of the patient. Patients should not be selected who are apprehensive, hypersensitive, or cannot remain until the examination is completed.

C. PATIENT DIFFICULTY

After it has been determined that the patient is acceptable, the examiner team will classify the patient according to the amount of calculus present in the patient's mouth. This classification of patient difficulty becomes a guide for the number of teeth or quadrants assigned for the oral prophylaxis. Most candidates will be assigned a two-quadrant prophylaxis. However, it is quite likely that candidates with "heavy" patients will be assigned only one quadrant, while candidates with minimally-acceptable patients may be assigned three or four quadrants. This assignment is for examination purposes only. The patient should be presented for examination when the assignment is completed. The candidate may then proceed with the remaining portions

of the mouth so that all patients, except those who would normally require more than one appointment, can be completed within the examination period.

The level of patient difficulty also becomes a guide in determining the level of performance expected from each candidate for periodontal measurements and the oral prophylaxis sections of the examination. Candidates whose patients are "minimally acceptable" will be expected to attain higher performance levels than those candidates whose patients are classified as "heavy." These adjustments in the amount of work to be completed and the minimal performance level to be demonstrated enable the examiners to equalize the performance expectations for all candidates.

D. SUGGESTED PREPARATION PROCEDURES

Familiarity with Forms and Instruments - Candidates should study this booklet carefully to familiarize themselves with the examination format. The candidate should practice using a color-coded periodontal probe for charting and the #2 explorer to check for deposits, since these are the instruments the examiners will utilize to evaluate the candidate's performance. The sample examination forms, which accompany this Candidate's Guide, should be used on at least one patient prior to the examination so that every candidate will have the opportunity to become thoroughly familiar with them. The forms to be used for the examination will be provided during the Candidate's Orientation Session.

E. RADIOGRAPHIC PROCEDURES

The testing agency will determine the radiographic requirements for the examination. They may require that a full-mouth or partial survey be exposed, processed and mounted at the examination site; or the candidate may be directed to expose a partial or full-mouth survey prior to the examination and bring the undeveloped films to the examination for processing and mounting.

1. Pre-exposed radiographic procedures:

If authorized by the testing agency, candidates currently enrolled in a dental hygiene program must expose a partial or full-mouth series of radiographs prior to the examination. The program director must certify that the radiographs have been exposed by the candidate without assistance. The candidate must bring the exposed, undeveloped radiographs in a sealed, certified envelope to the candidate's orientation where they will be submitted to examiners for development. The special envelopes will be provided by the testing agency. An 18 film survey is preferred. The mount will be provided by the testing site if a full-mouth series is required.

2. On-site radiographic procedures:

When pre-exposed radiographs are not authorized, candidates will be scheduled for radiographic procedures on the day of their clinical examination. The candidate may expose radiographs on their prophylaxis patient (if there are 22 natural teeth) or on a separate radiology patient. The mount will be provided by the testing site.

Candidates who are not enrolled in a dental hygiene program must expose a radiographic survey at the examination site.

F. PERFORMANCE EXPECTATIONS

This clinical dental hygiene examination has three parts. A description of the performance criteria and minimal competency levels for each part is offered below:

1. Part I - Data Gathering and Charting - 25 points

a. Health History

The candidate must obtain an accurate health history and utilize the information to plan dental hygiene care which prevents harm to the patient, operator and/or others. This is a required, non-graded section of the examination.

b. Oral Inspection - 5 points

(1) Performance Criteria and Minimal Competency Level

The candidate must assess and record the status of a board patient's oral and extra-oral structures using the format and following the instructions provided in the Candidate's Progress Folder. Acceptable performance will have been demonstrated if 90% of the candidate's findings are correct. This procedure must be completed in approximately 15 minutes.

(2) Candidate Instructions

For each item on the Oral Inspection Form, record the condition of any tissue or feature which demonstrates those significant findings that are identified on the form and described below:

EXTRA-ORAL

- (a) Inspect and palpate the FACE and NECK for any lesions, moles or birthmarks.
- (b) Palpate LYMPH NODES for any evidence of hardness, non-mobility or enlargement.
- (c) Examine the function of the TEMPOROMANDIBULAR JOINT for evidence of pain, restricted opening or crepitation.

INTRA-ORAL

Soft Tissue

- (d) Inspect and palpate the ORAL MUCOSA and all soft tissue structures which follow for lesions, chemical or physical irritation and palpable nodules. In addition, the other soft tissues must be examined for specific findings described below:

- (e) Examine and palpate the PALATE for the presence of tori.
- (f) Examine and palpate the TONGUE for symptoms of black hairy tongue, geographic tongue, glossitis or loss of papilla.
- (g) Inspect and palpate the FLOOR OF THE MOUTH for ankylo-glossia, tori and ranula.
- (h) Inspect and palpate the GINGIVA for fibrosis, edema, hyperemia, severe recession or hemorrhagic conditions.

Dentition

- (i) Examine the TEETH for evidence of abrasion, attrition and erosion.
- (j) Examine the teeth in OCCLUSION for evidence of crossbite, openbite or malocclusion, noting only those cases which demonstrate Angles Class II or III.

Note: Any significant findings as described above should be described in a one-line comment. If the tissue or feature demonstrates no significant findings, place a check mark in the column headed "NONE."

c. Dental Charting - 10 points

(1) Performance Criteria and Minimal Competency Level

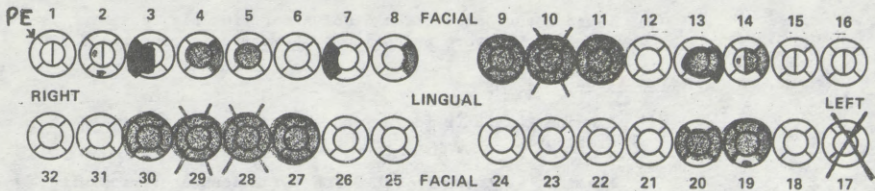
Given approximately 15 minutes, the candidate must chart the status of the patient's dentition using the format and following the instructions provided in the Candidate's Progress Folder. With the aid of a dental light, mirror, and explorer, all restorations, missing teeth and obvious carious lesions should be identified. Obvious carious lesions should demonstrate a general lack of integrity in the enamel or cementum surface which can be determined either visually or by penetration with light pressure of a sharp #2 explorer followed by detection of a soft base to the defect or definite resistance upon withdrawal of the explorer.

Acceptable performance will have been demonstrated if 90% of the candidate's findings are correct.

(2) Candidate Instructions

The candidate must accurately record the location and extent of dental restorations, missing teeth and fixed prostheses in blue pencil. Fractured, missing, loose or temporary restorations should be shown in blue and outlined in red. The presence of supernumerary, deciduous or partially erupted teeth should be noted in writing. Obvious caries should be charted in red. The charting does not need to differentiate between restorative materials such as gold, alloy or composite. (Please note that the candidate must count and record the number of items charted in the space provided on the dental chart in the Candidate's Progress Folder).

An example of correct charting is shown below. Each item is counted separately. Two separate restorations on one tooth are counted as two items. Bridges are counted as one item per unit. The example has been color-coded with the red areas denoting caries and the blue areas denoting restorations. # Items 23



<u>Tooth No.</u>	<u>Description</u>	<u>No. Items</u>
1	Partially Erupted	1
2	Occlusal and lingual fillings	2
3	Distal-occlusal caries	1
4	MO restoration	1
5	Occlusal restoration	1
7	Distal caries	1
8	Mesial restoration	1
9 - 11	3 Unit Bridge, #10 missing and replaced by a pontic	3
13	Defective DO restoration - may be fractured, missing, loose or temporary	1
14	Occlusal and DO restorations	2
17	Missing	1
19	3/4 Crown and facial restoration	2
20	MOD restoration	1
27 - 30	4 Unit Bridge, #28, 29 missing and replaced by pontics; #30 is a 3/4 crown and facial restoration	5

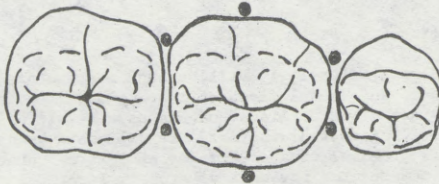
d. Periodontal Measurements - 10 points

(1) Performance Criteria and Minimal Competency Level

Given approximately 15 minutes, the candidate must chart the depth of the gingival sulcus for every tooth in an assigned quadrant using the format and following the instructions provided in the Candidate's Progress Folder. Using a mouth mirror and a color-coded periodontal probe divided into 3 millimeter bands, the candidate must record the depth of each sulcus/pocket to the nearest millimeter on six aspects (MF, F, DF, ML, L, DL) of each assigned tooth. Acceptable performance will have been demonstrated if 95% of all measurements are recorded accurately.

(2) Candidate Instructions

Only measurements of 3 millimeters or more are to be recorded. The measurements should be recorded at precisely those locations diagrammed in the example provided here.

2. Part II - Oral Prophylaxis - 50 points

Performance Criteria and Minimal Competency Levels

Given approximately one hour, the candidate must complete a thorough oral prophylaxis on a maximum of two assigned quadrants using appropriate hand instruments, prophylaxis handpiece, disclosing solution and a #2 (cowhorn or pigtail) explorer.

a. Subgingival Deposits - 25 points

Given approximately 45 minutes, the candidate must effectively remove subgingival calculus so that no deposits are detectable with a #2 (cowhorn or pigtail) explorer and no calculus is visible when the tissue is deflected with air. Acceptable performance will have been demonstrated if 85% of all subgingival tooth surfaces are free of deposits.

b. Supragingival Deposits - 20 points

Given approximately 15 minutes, the candidate must effectively remove calculus, soft deposits and extrinsic stains so that all non-decalcified surfaces are:

- (1) Visually clean when air-dried.
- (2) Tactilely smooth upon examination with a #2 (cowhorn or pigtail) explorer
- (3) Free of plaque when examined after the application of a disclosing agent.

Acceptable performance will have been demonstrated if 95% of all supragingival tooth surfaces are free of deposits, plaque and extrinsic stains.

c. Tissue Condition - 5 points

The candidate must effectively utilize hand instruments, polishing cups or brushes, and dental floss so that no unwarranted soft tissue trauma (abrasions or lacerations) occurs as a result of the prophylaxis procedure. Acceptable performance will have been demonstrated if 100% of all proximal tissue surfaces exhibit no unusual mechanical damage. The unwarranted presence of grossly lacerated gingival tissues (four or more lacerations) will result in automatic failure of the entire Oral Prophylaxis section of the examination.

3. Part III - Radiographs - 25 points

a. Radiographic Recognition (Slide Examination) - 15 points

Performance Criteria and Minimal Competency Level

Given approximately one minute per slide, the candidate must complete a 24 slide, 40 question examination, which includes the recognition of normal and abnormal dental structures, carious lesions, calculus and anatomical landmarks. Acceptable performance will be demonstrated if the candidate correctly recognizes 85% of the radiographic structures.

b. Radiographic Technique - 10 points

Performance Criteria and Minimal Competency Level

Given approximately 30 minutes, either prior to or on the day of the clinical examination (as specified by the testing agency) the candidate must expose, without assistance or retakes, a full mouth series of radiographs. After the radiographs have been developed by test-site staff, they must be properly mounted by the candidate in the accepted ADA method (dimple up) and must exhibit correct cone and film placement as well as correct vertical and horizontal angulation. Acceptable performance for each of the five skills to be tested will be assessed by computing the number of radiographs which demonstrate the correct application of the skill. The minimal competency level for each skill is listed below:

Mounting (1 point)	100%
Cone Placement (2 points)	95%
Film Placement (2 points)	80%
Vertical Angulation (2 points)	80%
Horizontal Angulation (3 points)	80%

c. Candidate Instructions

The candidates should obtain their developed radiographs from the testing site staff and mount them at their earliest convenience. The candidate must number the radiographs on the mount as follows: 1) starting in the upper left hand corner of the mount, number maxillary films from 1-7; 2) number mandibular films from 8-14, starting in the lower right hand corner of the mount; and 3) bite-wings should be numbered 15-18, starting from the left side of the mount. The patient's name and candidate's name and number should be written on the mount.

4. Minimal Competency for the Entire Examination

The candidate must demonstrate minimal competency at the stated performance level for each component of the examination in order to receive a passing grade and be awarded the entire point value achieved for that component. A passing grade for the entire examination is achieved when the candidate accumulates at least 70 of the 100 total points when all components of the examination are combined. This means that even though a candidate may not have met the minimal performance standards in every component of the exam, overall competency has been demonstrated if a grade of 70% has been attained.

G. CONDUCT OF THE EXAMINATION

1. Orientation - Prior to the beginning of the clinical examination, the Examination Coordinator will convene the candidates, distribute all necessary forms and explain the procedures for the examination. An opportunity will be provided for questions and answers.
2. Progress Folder - The candidate will be provided a progress folder with space for examiners to initial each portion of the evaluation as it is completed. It is the responsibility of the candidate to ensure that examiners initial the progress record after each check. The candidate will be asked to step away from the cubicle during all checks. If examining stations are used, instructions will be given to the candidate at the orientation session on how to present the patient at the examination

station. Radiographs will be retained until all examination results are verified and recorded. After that time, dissemination of the radiographs will be as directed by the testing agency.

3. Examination Sequence

There are four stages to the clinical examination. They include:

a. Patient Check-In

As soon as the candidate has seated the patient and completed a health history, the examining team will evaluate the patient's acceptability to determine:

- (1) Oral and systemic conditions acceptable for treatment
- (2) Proper number of teeth (14 or more)
- (3) Adequate deposits (medium to heavy subgingival calculus)
- (4) Quadrant assigned for periodontal measurements
- (5) Oral Prophylaxis assignment

If the patient is acceptable, the candidate may immediately begin to perform the assigned clinical procedures. If the patient is dismissed as unacceptable, the candidate must provide another patient and repeat the patient check-in.

b. Part I Evaluation: Data Gathering and Charting

The candidate will complete the Oral Inspection, Dental Charting of the entire mouth and Periodontal Measurements in an assigned quadrant. The candidate should request that an examiner check these sections as soon as the information is recorded. If it is necessary to wait for an examiner to evaluate Part I, the candidate should sign the appropriate waiting list and begin the oral prophylaxis in any assigned quadrant at once, except for the quadrant in which the periodontal charting has been completed.

c. Part II Evaluation: Oral Prophylaxis

The candidate will complete the prophylaxis assignment and immediately present the patient for evaluation. If it is necessary to wait for an examiner, the candidate should sign the appropriate waiting list and then continue with the remaining (unassigned) portion of the prophylaxis.

The profession has a responsibility to provide complete treatment to patients. The candidate should complete the entire prophylaxis if possible in the remaining time or advise the patient of the necessity and availability of services to obtain further treatment.

The patient may be dismissed after being released by the examiners.

d. Candidate Check-Out

- The candidate will present the required radiographs and entire

progress folder to examiners along with the candidates' badge and all necessary receipts and/or institutional check-out forms. When all release requirements have been cleared with the testing site, the candidate will be dismissed.

4. Time Utilization - The clinical portion of the examination (excluding radiographic procedures) must be completed in 5-5½ hours. Time should be carefully utilized because not only must the candidate have sufficient time to competently complete the examination requirements, but also the examiners must have time to complete their evaluations within the time provided for the examination process. Examiners cannot give candidates the fair, thorough evaluations that their professional skills deserve if all patients are presented for evaluation at the last minute.

It is possible that examiners may not be immediately available when the candidate is ready for evaluation. If so, the candidate should sign a waiting list and continue with other procedures until examiners are available. Effective utilization of the candidate's time while the patient is undergoing evaluation by the examiners would be to mount the developed radiographs in preparation for their final check-out.

To assist the candidates in pacing their activities, the following time frames are recommended:

30 minutes into the examination - all patient check-ins should be completed. The candidate should have the patient ready for check-in as soon as possible but may not proceed until authorized to do so by the examiner.

45 minutes after your patient has been accepted - data gathering and charting (Part I) should be ready for evaluation. As soon as this section is completed, the candidate should sign the waiting list and then proceed with the oral prophylaxis assignment until called by the examiners. You should anticipate that your patient will be at the examiner station approximately 20-30 minutes.

1-1½ hours after your Part I evaluation is completed - the prophylaxis assignment should be ready for evaluation. As soon as the specific prophylaxis assignment is completed, the candidate should sign the waiting list and then proceed with those quadrants which were not assigned. You should anticipate that your patient will be at the examiner station approximately 15-20 minutes.

Any remaining time should be used to complete the unassigned portions of the prophylaxis, mount and number radiographs and prepare all examination materials for Candidate Check-Out.

H. SUMMARY

This Manual has described general directives for the conduct of the clinical examination, guidelines for patient selection, suggestions for candidate preparation, performance expectations as well as clinical and radiographic procedures. It is your responsibility to come to the examination fully prepared to demonstrate your competency in clinical dental hygiene skills. Any questions you may have can be addressed during the Candidate Orientation Session.

EXAMINER'S MANUAL
FOR THE
DENTAL HYGIENE
CLINICAL BOARD EXAMINATION



American Dental Hygienists' Association
Clinical Testing Evaluation Service
211 East Chicago Avenue, Suite 1616
Chicago, Illinois 60611

January, 1978

DENTAL HYGIENE EXAMINER'S MANUAL

I. Introduction

This Manual is one of the keys to conducting a successful clinical board examination. It is designed to help all examiners - the experienced as well as the inexperienced - become more familiar with the problems inherent in clinical evaluation and to provide the information and guidance needed by conscientious dental hygiene examiners.

It has long been known that sound examinations are difficult to construct. Ideally, examinations should have high levels of reliability and validity while at the same time being practical to administer and grade. To be reliable a test must provide consistent results each time it is utilized, regardless of who administers it. Otherwise, an agency may actually be giving many different tests instead of giving many administrations of the same test. This is a cause for concern since some test administrations may be more difficult or some examiners may be more lenient than others and the result is that candidates may not be treated equally.

To be valid, a test needs to accomplish the task for which it was designed. Since a clinical board examination is designed to distinguish between those candidates who are competent to practice dental hygiene and those who are not yet competent to do so, it should be able to accurately identify those who perform satisfactorily and those who do not.

In constructing the best possible clinical board examination, one should seek to reduce and/or standardize the variables that interfere with the one variable being measured - the competency of the candidate. Some of the extraneous or contaminating variables which can affect the results of a clinical examination and which should be taken into consideration when designing the examination are listed below:

1. Student Variables
 - a. Familiarity with examination procedures and materials
 - b. Familiarity with testing site facilities and requirements
 - c. Familiarity with patient
2. Patient Variables
 - a. Oral Conditions
 - b. Cooperativeness

3. Examination Procedures Variables
 - a. Facilities and test-site preparations
 - b. Number of examiners per team
 - c. Number of examiner teams per candidate
 - d. Length of time for the examination
 - e. Degree of standardization of procedures and instruments
 - f. Anonymity of candidates
 - g. Potential for examiners to evaluate non-identical samples
 - h. Potential for students to correct suspected errors between examiner evaluations
 - i. Independence of examiner evaluations
 - j. Cross validation or confirmation of examiner differences
4. Examiner Variables
 - a. Examiner biases, background, individual competence, and familiarity with examination
 - b. Individual examiner consistency and accuracy
 - c. Inter-examiner consistency and accuracy
 - d. Consistency between examiner teams
 - e. Consistency of examiner performance from one examination site to another

This examination has been designed to eliminate or control as many of these variables as possible. Some of the inherent features of the examination that serve to control variables will be described throughout the remainder of the Manual.

A. CANDIDATE PREPARATION

When each candidate's application is received, the candidate will be provided with a brochure entitled "Candidate's Guide to the Dental Hygiene Clinical Board Examination", copies of the examination forms, and a description of the instruments which are required for the examination. The Guide includes the following:

1. General directions on examination requirements such as instruments, attire, conduct and testing site procedures.
2. Patient selection guidelines.
3. Suggested preparation procedures to assist Candidates to become familiar with examination forms and required instruments.
4. Performance criteria and minimum competency levels for each section of the examination.
5. An outline of procedures, sequence and expected utilization of time when the examination is being conducted.

A copy of the Candidate's Guide and the Candidate's Progress Folder should accompany this manual even though this Manual includes many of the pertinent sections of the Candidate's Guide. In this way, examiners can become more familiar with each step of the examination and aware of the instructions and information that have been provided to the candidate. At their orientation, the candidates will also receive a Progress Folder which directs them through each part of the exam and contains all the forms for their charting procedures. A copy of the Progress Folder should also accompany this manual.

B. CANDIDATE ANONYMITY

The reliability and validity of the exam is best assured by maintaining the anonymity of candidates so that extraneous factors such as age, sex, race and appearance do not subjectively influence the evaluation. It is best that examiners not have access to the candidate's person, name, background information or previous performance record. It is the examiner's task to evaluate only the result of the candidate's performance. Therefore, you should conscientiously avoid individual conversation with candidates so that personal variables do not influence your decisions. If written exams are administered prior to the clinical exam, you should not serve as a proctor and you must not have access to the candidate's written examination scores prior to the clinical portion of the examination.

C. EXAMINING TEAMS

Examiners will be paired in teams of two and be assigned approximately 10 candidates per day for whom they are responsible. Each team will usually consist of one dentist examiner and one dental hygienist examiner.

D. EXAMING STATIONS

Whenever facilities permit, examiners will be assigned two operatories or stations at which they will remain while patients are brought to them for evaluation. This helps maintain candidate anonymity, improves examiner efficiency and allows you and your examining partner to easily confirm your pass/fail decisions.

E. EXAMINER ASSISTANTS

Whenever possible, you will be provided with an assistant for the clinical examination. You will find that utilizing an assistant will save you time and greatly improve your ability to examine thoroughly. The basic responsibilities of an Examiner Assistant are:

1. Managing patient flow to examiner stations. The assistant should post sign-up sheets in an appropriate area for candidates to sign when they are ready for their patient to be evaluated. The assistant will call the patients following the order of the sign-up sheet and will escort them to the examiner stations along with the Candidate's Progress Record and instruments.
2. Sanitizing the examiner's units and maintaining asepsis.
3. Maintaining Examiner Evaluation Forms so they are readily available.
4. Assisting the examiner at the chairside and recording the findings.

As different sections of the examination are described in subsequent sections of this manual, further suggestions will be made regarding the use of the assistant. However, it is important to remember that the assistant must never become involved in judgments about the candidate's competency and that only you and the other member of your examining team make the decisions regarding a candidate's performance. For instance, you should always have the assistant read the candidate's charting to you as you inspect the mouth so that you are in the position of determining its accuracy. Do not forget to communicate with your assistants and direct them as to how they can help you in the best possible way. This is an essential element in assuring that you utilize your assistant effectively and efficiently.

F. STANDARDIZED INSTRUMENTS

Candidates are required to have periodontal probes which are color-coded in 3 mm. increments and a #2 explorer. This helps to assure that all candidates receive the same evaluation. Additional sets of sterilized instruments should be kept at examiner's stations in case instruments are broken or contaminated.

G. SAMPLING PROCEDURES

In order to permit examiners to conduct a thorough and precise evaluation, only samples of the candidate's performance are assessed. Selection of the samples must be standardized so that both examiners evaluate exactly the same teeth; therefore it is essential that examiners correctly follow the sampling techniques

which have been specified. To ensure that this is being done accurately, you should ask that examiner assistants consistently call out the number of the tooth which is to be examined. It should be noted that the size of the sample is also standardized so that every candidate receives the same evaluation.

H. PASS/FAIL EVALUATION

This examination is designed to isolate several skills which are felt to be critical aspects of dental hygiene practice. Each of these skills is described in such a way that both candidates and examiners understand what constitutes acceptable performance for each skill. If the acceptable performance level is achieved, the candidate passes the examination in a particular skill area. If enough skills are successfully completed so that an overall grade of 70% or greater is achieved, the candidate passes the exam. Thus, this is a pass-fail examination based on measurable performance criteria.

You are expected to verify whether or not acceptable performance has been achieved in each skill by calculating the number of candidate errors for any given section. When the number of allowable errors has been exceeded, minimal competency has not been demonstrated for that skill and the candidate does not receive points for that particular component of the examination. Since candidate errors are validated by a second examiner, the result is a performance based, pass-fail examination that relieves you of the responsibility for making subjective decisions about the quality of the candidates' work. You should keep in mind that a grade of 100% does not mean the candidate has made no mistakes; it only means that minimal competency has been consistently demonstrated.

I. VALIDATION PROCEDURES

The validation process is the key to maintaining the reliability of the examination. You must independently evaluate the candidate's performance and record your individual findings. When both examiners have separately evaluated a given section of the exam, you must compare your results. When differing evaluations occur and when the potential for failing a section is evident, you must validate your findings with the other examiner on your examining team. This validation procedure is more fully explained in Part V of this Manual.

J. EXAMINER'S EVALUATION FORMS

A triplicate NCR form, which accompanies this manual, has been designed to precisely fit the examination procedures. The first page, on which the first examiner to see the patient records their findings, is not carboned, and is removed by the first examiner when the initial evaluation is completed. The second page, on which the second examiner to see the patient records their findings, is carboned on the back side and transfers the findings of both examiners onto the third, master copy.

When the second examiner completes the initial evaluation and tears off the copy of the form, the master copy will display an immediate comparison of both examiners findings. The need to validate each other's findings can therefore be immediately assessed.

II. CONTROLLING EXAMINER VARIABLES

The primary purpose of this Manual is to control variables among examiners by describing in detail your responsibilities in the administration of the examination. While it is essential for you to understand how to record grades and calculate scores, research has shown that the greatest variable, other than student performance, is the variability in examiner performance. The following examples show how differences in technique, tactile sensitivity, and judgment can lead two examiners to widely differing evaluations of a single candidate's performance.

1. Technique variations which could result in significantly different examiner evaluations include:
 - the degree of thoroughness demonstrated by the examiner when performing the oral inspection
 - the angulation of the periodontal probe when measuring sulcus depths
 - the angulation of the explorer tip on the tooth during calculus detection strokes
 - the distance between and, therefore, the number of exploratory strokes used on each tooth during calculus detection procedures
 - the willingness and/or ability of the examiner to use the air syringe to assist in plaque and calculus detection.
2. Tactile sense variations which could lead to significantly differing examiner evaluations include:
 - measuring sulcus depths to the depth of a ledge of calculus rather than to the level of the gingival attachment
 - assuming that fine, smooth calculus is well polished tooth structure
 - assuming the cemento-enamel junction or a gingival margin of a restoration is calculus.

3. Variations in judgment which could lead to significantly differing examiner evaluations can be demonstrated by asking the following questions:

- when is a deep occlusal pit considered to be a carious lesion?
- when does a less than perfect radiograph become unacceptable?
- when is a minor candidate error significant enough to record?

The correct use of an explorer, probe, or air syringe are basic skills for all dental professionals. Although it may seem elementary, it is lack of consistency in the application of these basic skills that results in discrepancies in examiners' findings and leads to low levels of examiner reliability. Therefore, each description of your examining procedures will contain sections written in special type face to call your attention to correct examining technique and mechanisms for determining levels of examiner errors.

There are several pre-examination activities that examiners may undertake to improve their proficiency as an evaluator of dental hygiene competency.

A. Knowledge of Dental Hygiene Education

A newly selected examiner might consider a visit to one or more dental hygiene programs. The curriculum of all programs throughout the country is continually being revised and strengthened. Such a visit would allow the new examiner to become as familiar as possible with the scope of current dental hygiene instruction.

B. Knowledge of Evaluation Criteria and Procedures

All examiners should carefully review this Manual to develop a thorough understanding of the performance criteria and evaluation procedures utilized to assess candidate performance

C. In-Office Preparation

During routine office procedures, you have ample opportunity to become thoroughly familiar with the examination. Please take the examination several times by yourself, using the Candidate's Progress Folder, and evaluate your own performance using the Examiner Evaluation forms and instruments provided. Having taken and evaluated the examination beforehand, you will be able to function more confidently, efficiently, and of greatest importance, more reliably, during an examination. Since this aspect of your advanced preparation is so critical, it is suggested that you bring at least two completed Candidate's Progress Folders and two completed Examiners Evaluation forms to the Examiner Orientation. The following suggestions are provided to help you take each section of the examination.

1. Data Gathering and Charting

The health history, oral inspection, dental and periodontal charting forms in the Candidate's Progress Folder should be used during the examination of several patients. The color-coded periodontal probe that has been provided, will be used by candidates and examiners during all examinations. This probe should be used for sulcus measurement.

Examiners who are dentists should complete the forms, or ask their hygienists to do so, for several patients. Then the charting portion should be evaluated as would be done during a board examination, using the Examiner's Evaluation form to record any errors which are identified. Examiners who are hygienists should ask a dentist or another hygienist in the dental office to similarly evaluate the charting components of the examination.

2. Prophylaxis

After completing several routine prophylaxes, utilize the standardized #2 explorer provided for all Candidates and examiners to check for any remaining deposits. Following the recommended examination procedure, evaluate your own and/or your hygienist's prophylaxis by carefully air-drying teeth and exploring for subgingival and supragingival deposits. To practice utilizing the evaluation form, record any deposits which are found on the grade sheet as errors.

3. Radiography

Select four or five full-mouth surveys from your files. These surveys should be evaluated according to the radiography criteria and your evaluation should be recorded on the grade sheet. It would be helpful to ask a second evaluator, a dentist or hygienist colleague, to individually evaluate the same radiographs. Then their results can be compared with yours and you can discuss any differing observations, using the stated performance criteria as your standard.

Your in-office preparations serve a greater purpose than giving you a better understanding of what is expected of both the candidate and the examiner. Your personal experiences will undoubtedly raise several questions of judgment, interpretation or procedure which should be clarified during the Examiner Orientation Session held just prior to each examination, rather than on the clinic floor during your first administration of the examination. These in-office preparations are invaluable and must be completed, even by experienced examiners, prior to your first scheduled board examination.

D. Standardization Exercises

At the examination site, you and your teammates will have the opportunity to participate in a half-day clinical workshop given by the Examination Coordinator. For each part of the examination, correct examining technique must be demonstrated and criteria reviewed for the determination of errors. Patients whose mouths have already been charted will be examined during the workshop. Examiners will be able to practice each examining procedure, compare their findings with those of their partner and discuss any variations in their results using the stated performance criteria to guide their discussions and final decisions.

III. EXAMINATION SCHEDULE

First DayTime

(schedule to be
determined by
Testing Agency)

Examiner's Orientation and Standardization
Exercises
Examiner Assistant's Orientation
Candidates' Orientation
Radiographic Written Examination (Slide)
(and other written examinations as
determined by the testing agency)
Tour of the site for those candidates
wishing to familiarize themselves with
with the clinical facility.

Clinical Days

(schedule to be
determined by
Testing Agency)

Roll Call
Clinical Procedures as assigned to candidates
On-site radiology procedures as assigned to
candidates
Evaluation of Radiographs and Posting of Grades

IV. ORIENTATIONS

A. EXAMINER'S ORIENTATION

As outlined in the above schedule, orientations will be conducted by the Dental Hygiene Examination Coordinator on the day prior to the examination. The Coordinator will review the performance criteria and the procedures for detecting errors in each section of the exam so that examiners will have a mutual understanding of the correct application of instruments and criteria to determine what does or does not constitute an error. At this time, you should be prepared to discuss any questions regarding the administration of the test which a thorough reading of this Manual and review of the forms may have raised.

B. CLINICAL WORKSHOP FOR EXAMINERS

Upon the approval of each testing agency, the Examination Coordinator will organize a clinical demonstration and participation workshop for examiners. Utilizing clinical patients, examiners will practice examining procedures to further standardize their evaluative skills.

C. CANDIDATES ORIENTATION

The Dental Hygiene Examination Coordinator will convene the candidates, call roll, make introductions, distribute candidate packets, describe procedures for handling patient emergencies, and review all examination procedures. The radiographic recognition slide examination will then be administered to all candidates.

D. EXAMINER ASSISTANTS' ORIENTATION

The Dental Hygiene Examination Coordinator will arrange a time, possibly while written exams are being administered, to orient the examiner assistants to their role and responsibilities.

V. CONDUCTING THE CLINICAL EXAMINATION

The remainder of the Manual describes each section of the examination and details what the candidate is expected to do, how they have been instructed to do it, examining procedures, the utilization of the assistant, how to determine candidate errors and how to record them. It will be helpful for you to refer to the Candidate's Progress Folder and the NCR Examiner's Evaluation Form as you study each step of the examination process.

A. PATIENT CHECK-IN AND CLASSIFICATION

The examiners should check patients in as rapidly as possible so that the review of patient acceptability can be completed within 30-45 minutes. It has proved most effective for both examiners to work as a team to evaluate patient acceptability, and move together from operator to operator. While one examiner inspects the patient's oral condition, the other can review the health history and record the candidate's assignments. The candidate should be excused from the area while the examiners are in the operator. During the check-in, you must determine whether:

1. the health condition contraindicates treatment as assessed by the health history
2. the soft-tissue condition is free from lesions which would contraindicate prophylaxis
3. the proper number of teeth (14 or more) are present

4. adequate deposits (visible supragingival deposits and medium to heavy subgingival calculus) exist.

If the patient is unacceptable, the candidate should be so informed and asked to present a second patient. If the patient is accepted, you must identify:

1. the quadrant to be assigned for periodontal measurements, and
2. the oral prophylaxis assignment.

Each step of the Patient Check-In and Classification procedure is fully described below.

HEALTH HISTORY

At least one examiner must review the health history. This is a required, non-graded section of the examination. The patient should be questioned regarding specific conditions, if necessary. Be alert for conditions that might contraindicate treatment or require alteration of procedures, such as blood dyscrasias, heart conditions, valvular infections, rheumatic fever, uncontrolled diabetes, hepatitis, or venereal disease.

If any systemic conditions indicate that the patient's, operator's, or examiner's health could be jeopardized, you should require the candidate to present a written clearance from the patient's physician before accepting the patient for treatment. If conditions indicate an alteration in treatment procedures, such as taking special precautions against the transmission of infectious disease, ascertain that the candidate has recognized and implemented the appropriate procedures before proceeding. The patient should be dismissed if the health history contraindicates treatment or if appropriate precautions have not been taken.

Soft-Tissue Condition

Ascertain that the tissue is free of lesions that would contraindicate treatment in a board examination, such as multiple ulcerations, carcinomas, dilantin hyperplasia, active venereal lesions or pathologic proliferation of tissue. The patient may be dismissed if the soft tissue examination reveals a candidate which contraindicates treatment.

Dentition Requirements

You must confirm that a minimum of 14 natural teeth are present, at least two of which are molars in contact with adjoining dentition.

Adequate Deposits

The candidate has been given guidelines for patient selection in order to reduce the variations in patient difficulty. There must be visible supragingival deposits as well as medium to heavy subgingival calculus to provide an acceptable test of the candidate's ability. It is critical to the administration of the examination that examiners dismiss un-

acceptable patients; otherwise the objective evaluation of all candidates will be impaired. Conditions which make a patient unacceptable for the purposes of this examination are described below:

1. "Light" deposits - deposits of subgingival calculus are not heavy enough to fulfill the criteria for patient selection. The patient may, indeed, need a prophylaxis, but does not offer a sufficient opportunity for the candidate to demonstrate competency.
2. Periodontal Patients - Patients with advanced periodontal disease must be dismissed when they exhibit deposits at the depths of pockets that cannot be reasonably instrumented without laying gingival flaps. The ADA Type IV periodontal condition defines such a patient:
Advanced Periodontitis: severe pocket depth, deeper than 7 mm; severe crestal bone resorption (1/2 or more crestal bone resorption); advanced mobility patterns.

Quadrant to be assigned for Periodontal Measurements

Research has demonstrated that some quadrants are more difficult than others to accurately probe. Since the upper right quadrant is particularly difficult to probe, it should be avoided for the periodontal assignment. If possible, the quadrant for periodontal probing should not be the same as those assigned for the prophylaxis.

Oral Prophylaxis Assignment

The prophylaxis assignment is determined by the amount of deposits present in the patient's mouth. In evaluating the patient's acceptability, you must determine not only that there are adequate deposits, but also how heavy the deposits are. Your classification of the amount of deposits determines the performance level expected of the candidate and the extent of treatment to be provided. There are basically two classifications of acceptable patients, "medium" or "heavy". Conditions in a range between these two classifications can be categorized as "medium-heavy". Guidelines for the classification of patients are provided below:

1. Medium - The Medium patient is the minimally acceptable patient, since a patient with "light" deposits cannot be accepted. This patient should exhibit visible supragingival calculus on the mandibular anteriors, with explorer-detectable subgingival calculus throughout at least two other sextants of the mouth. Extrinsic stain may or may not be present nor is it required. A "medium" patient would probably exhibit more deposits than a typical routine recall patient in the dental office, but would be a patient that could reasonably be completed in one appointment. For medium patients, candidates are assigned two quadrants for the prophylaxis. Research has demonstrated that the assignment of diagonally opposing quadrants (UR-LL or UL-LR) best equalizes the difficulty of all candidates' assignments. Therefore, if the distribution of teeth permits it, the examiner should assign two diagonally opposed quadrants instead of the upper or lower arch or right or left half of the mouth.

2. Heavy - A heavy patient may exhibit gross deposits of supragingival calculus, with subgingival calculus generalized throughout the mouth. When subgingival calculus can be detected on at least 3 out of 4 surfaces of most teeth (typically the lingual, mesial and distal surfaces), the patient would be classified as heavy. "Heavy" patients would generally require more than one appointment to be completed in the dental office. Patients with advanced periodontal disease should not be accepted since they are too difficult for the purposes of this examination.

Candidates presenting patients with heavy deposits are assigned only one quadrant for completion; but the assignment must include at least seven teeth. These seven teeth should include two molars, two premolars and three anterior teeth in order to properly balance the difficulty of the candidate's task.

3. Medium Heavy - The patient whose deposits vary between the two categories of "medium" and "heavy" should be classified as "medium-heavy". It is here that you must exercise some judgment in assigning either a one or two quadrant prophylaxis. Most medium-heavy patients will indicate a two-quadrant assignment. Factors that might be considered in determining the prophylaxis assignment include:

a. Calculus

Amount - If subgingival calculus is detectable in more than two sextants, but not generalized throughout the mouth as in a "heavy" patient, the patient should be classified as "medium-heavy" and two quadrants assigned.

Type - Some types of calculus are more difficult to instrument than others. Substantial deposits of black, flat and very tenacious calculus would justify a classification of medium-heavy and the assignment of one quadrant.

b. Stain

Amount and Type - Medium subgingival calculus with generalized stain certainly increases the difficulty of the candidate's task. If the calculus is only medium but the stain is so heavily generalized that it must be scaled off instead of merely polished (such as in a heavy pipe-smoker with black, "baked-on" stain), the patient should be classified as medium-heavy and one quadrant assigned.

If you are in doubt about the classification of patient difficulty, give the candidate the benefit of the doubt and use the heavier classification.

Even though the format of the examination necessitates the assignment of partial prophylaxis, it is recognized that as a profession, dentistry is committed to providing comprehensive oral health care to patients. The candidate has been instructed to complete the prophylaxis, if time permits, after the examiners have evaluated the patient. However, only the assigned quadrants will be evaluated. If insufficient time remains for completion of the prophylaxis, the candidate must inform the patient of the necessity for and the availability of further treatment.

Recording Patient Conditions

It is essential for both examiners to consult and agree on the classification of patient difficulty because the performance levels for certain components of the examination are contingent upon this decision. Having agreed upon the patient classification, examiners are to circle the appropriate category at the top of the Examiner's Evaluation Form under Patient Condition in the following manner:

- Classify the calculus by clearly circling one of the three categories, with no overlapping between the categories.
- Classify the stain as light, medium or heavy and circle the appropriate category. This can be used to help decide the extensiveness of the prophylaxis assignment.
- Circle the appropriate description of gingival condition. This can be used as the basis for comparison of the condition of the tissue following instrumentation.

Example of
Grade Sheet:

Patient Condition (Circle):

CALCULUS:	Medium	Med/Hvy	Heavy
Stain:	Light	Medium	Heavy
Gingiva:	Normal	Irritated (but firm)	Irritated (spongy & hemorrhagic)

Recording Candidate Assignments

When the examiners have determined the quadrant to be assigned for periodontal measurements and prophylactic treatment, both must be recorded at the top of the Examiners Evaluation Form by circling the assigned quadrants(s). For the prophylaxis assignment, if the distribution of the dentition or deposits does not lend itself to the assignment of specific quadrants, you may assign specific teeth (always at least seven) and circle the appropriate tooth numbers.

Example of
Grade Sheet:

Candidate Assignments (circle)

Periodontal Measurements:	UR	UL	LL	LR
Prophylaxis Quadrants:	UR	UL	LL	LR

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
32 31 30 29 28 27 26 25 24 23 22 21 20 19 18 17

Completing Candidate's Progress Folder, Patient Check-In:

On the progress sheet, record the following:

- Circle the quadrant assigned for periodontal measurements.
- Circle the prophylaxis assignment exactly as recorded on the grade sheet.

- c. Place your initials in the boxes for Patient Acceptability, Assignments and Health History.

Patient Check-In

Both members of your examining team must evaluate your patient's acceptability to determine:

1. Oral and systemic conditions acceptable for treatment
 2. Proper number of teeth (14 or more)
 3. Adequate deposits (medium to heavy subgingival calculus)
 4. Assigned quadrant for Periodontal Measurements: UR UL LL LR
 5. Oral Prophylaxis assignment: UR UL LI LR
- | | | | | | | | | | | | | | | | |
|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| 32 | 31 | 30 | 29 | 28 | 27 | 26 | 25 | 24 | 23 | 22 | 21 | 20 | 19 | 18 | 17 |

Examiner's Initials

HEALTH HISTORY
PATIENT ACCEPTABILITY

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Utilizing the Assistant For Patient Check-In

While examiners are conducting the patient check-ins, one assistant should be setting up and supplying the examiner stations and posting the candidates' sign-up sheet. The other assistant can follow the examiners, keeping track of the Examiner's Evaluation Forms and recording assignments as they move from operatory to operatory.

B. EVALUATION OF PART I - DATA GATHERING AND CHARTING

As you review the charting section of the examination, keep in mind the role of the hygienist which is to screen patients and call the dentist's attention to conditions for purposes of diagnosis.

1. Oral Inspection - 5 Points
- a. Performance Criteria and Minimal Competency Level

The candidate must assess and record the status of the patient's oral and extra-oral structures using the format and following the instructions provided on the Candidate's Progress Folder. Acceptable performance will have been demonstrated if 90% of the candidate's findings are correct.

- b. Candidate Instructions

For each item on the Oral Inspection Form, record the condition of any tissue or feature which demonstrates those significant findings that are identified on the form and described below:

EXTRA ORAL

- (a) Inspect and palpate the FACE and NECK for any lesions, moles or birthmarks.

- (b) Palpate LYMPH NODES for any evidence of hardness, non-mobility or enlargement.
- (c) Examine the function of the TEMPOROMANDIBULAR JOINT for evidence of pain, restricted opening or crepitation.

INTRA-ORAL

Soft Tissue

- (d) Inspect and palpate the ORAL MUCOSA and all soft tissue structures which follow for lesions, chemical or physical irritation and palpable nodules. In addition, the other soft tissues must be examined for specific findings described below:
- (e) Examine and palpate the PALATE for the presence of tori.
- (f) Examine and palpate the TONGUE for symptoms of black hairy tongue, geographic tongue, glossitis or loss of papilla.
- (g) Inspect and palpate the FLOOR of the MOUTH for ankyloglossia, tori and ranula.
- (h) Inspect and palpate the GINGIVA for fibrosis, edema, hyperemia, severe recession or hemorrhagic conditions.

Dentition

- (i) Examine the TEETH for evidence of abrasion, attrition and erosion.
- (j) Examine the teeth in OCCLUSION for evidence of crossbite, openbite or malocclusion, noting only those cases which demonstrate Angle's Class II or III.

Any significant findings as described above are to be described in a one-line comment. If the tissue or feature demonstrates no significant findings, place a check mark in the column headed "NONE."

c. Examiner Procedure

The oral inspection form follows a logical progression of observations from extra-oral to intra-oral, gingival and dental findings. Conduct a brief but thorough oral inspection, giving equal emphasis to each item to determine whether you can confirm the candidate's findings.

d. Determination of Errors

Each lettered item requires a "none" response in the appropriate column if none of the significant findings identified for each structure are evident. When any of the specified conditions are observed, a short written description must be entered in the appropriate column. The comment must be kept within the single line provided for each item. The following examples

of candidate performance are not acceptable:

- (a) Any item not marked with a response
- (b) Any incorrect response

e. Examples of Common Errors

- (1) undetected crepitation
- (2) incorrect description of gingival characteristics
- (3) undetected abrasion or crossbite
- (4) misclassification of occlusion
- (5) overlooked tori

f. Use of Assistant

You can review the oral inspection form faster than the assistant can read it aloud to you. Therefore, the assistant should hold the chart so that you can readily refer to it as you compare your findings to the candidate's, and record any errors that you identify.

g. Recording Errors

Direct the assistant to circle the item letter on the evaluation form corresponding to the item on the oral inspection form when an error is noted using the line designated for you as Examiner A or B. The example shows that Examiner A recorded one error.

ORAL INSPECTION	A	A	B	C	D	E	F	G	H	I	J	A /	B
	B	A	B	C	D	E	F	G	H	I	J		

2. Dental Charting - 10 Points

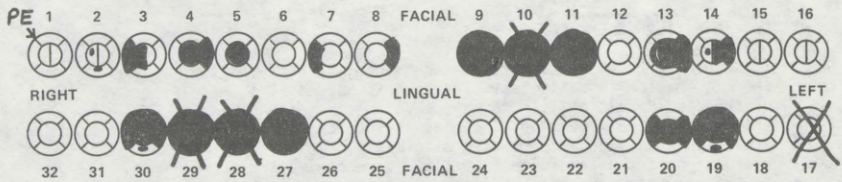
a. Performance Criteria and Minimal Competency Level

Given approximately 15 minutes, the candidate must chart the status of the patient's dentition using the format and following the instructions provided in the Candidate's Progress Folder. With the aid of a dental light, mirror and sharp #2 explorer, all restoration, missing teeth and obvious carious lesions should be identified. Obvious caries should demonstrate a general lack of integrity in the enamel or cementum surface which can be determined either visually or by penetration with light pressure on the explorer to detect: 1) a soft base to the defect or 2) definite resistance upon withdrawal of the explorer. Acceptable performance will have been demonstrated if 90% of the candidate's findings are correct.

b. Candidate Instructions

The candidate must accurately record the location and extent of dental restoration, missing teeth and fixed prostheses in blue pencil. Fractured, missing, loose or temporary restoration should be shown in blue and outlined in red. The presence of supernumerary, deciduous or partially erupted teeth should be noted in red. The charting does not need to differentiate between restorative materials such as gold, alloy or composite. (Please note that the candidate must count and record the number of items charted in the space provided on the dental chart in the Candidate's Progress Folder.)

An example of correct charting is shown below. Each item is counted separately. Two separate restorations on one tooth are counted as two items. Bridges are counted as one item per unit. The example has been color-coded with the red areas denoting caries and the blue areas denoting restorations. # Items 23



<u>Tooth No.</u>	<u>Description</u>	<u>No. Items</u>
1	Partially Erupted	1
2	Occlusal and lingual fillings	2
3	Distal-occlusal caries	1
4	MO restoration	1
5	Occlusal restoration	1
7	Distal caries	1
8	Mesial restoration	1
9 - 11	3 Unit Bridge, #10 missing and replaced by a pontic	3
13	Defective DO restoration - may be fractured, missing, loose or temporary	1
14	Occlusal and DO restorations	2
17	Missing	1
19	3/4 Crown and facial restoration	2
20	MOD restoration	1
27 - 30	4 Unit Bridge, #28, 29 missing and replaced by pontics; #30 is a 3/4 crown and facial restoration	5

c. Examiner Procedure

Although each examiner has a personalized system for dental charting, perhaps the simplest procedure is to follow the tooth numbering system and thoroughly inspect the dentition tooth by tooth. The findings are charted from visual observations and explorer examination, without the use of radiographs.

d. Determination of Errors

It should be noted that charting techniques may vary and that the examination is not a test of art-work; nor is it a test of the candidate's ability to make a definitive diagnosis. Criteria for the detection of caries is subject to interpretation even among experienced clinicians. This is an evaluation of the candidate's ability to recognize and accurately record dental conditions, and note areas which should be called to the dentist's attention. However, a candidate error should be recorded when:

- a) Restored or carious surfaces are either not recorded, recorded on the wrong surface, or recorded on the wrong tooth. (A separate error is recorded for each tooth that is transposed)
- b) Restoration or caries have been recorded, but are not present.
- c) Missing teeth are either not recorded or are incorrectly recorded.

Note: Performance levels have been adjusted to reflect the complexity of the dental chart. The candidate is to record the number of separate chart entries in the space provided. The number of errors identified by the examiner must remain less than 10% of the number of items recorded, otherwise the candidate fails this section of the examination.

e. Use of the Assistant

Perhaps the most commonly made error by both candidates and examiners is failure to air dry the teeth. Direct the assistant to follow you consistently with the air syringe as you progress around the mouth. The assistant should read the charting to you and record any errors you identify.

f. Recording Errors

- (1) Have the assistant transfer the number of items that have been charted from the dental chart to the designated space on the evaluation form. (See illustration.)

- (2) Direct the assistant to circle the tooth number on the evaluation form for any tooth on which an error is identified, using the line designated for you as Examiner A or B. In the example below, Examiner B has identified a total of two errors on tooth number 7 and 20.

DENTAL CHARTING

Items Charted

19

A	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
	32	31	30	29	28	27	26	25	24	23	22	21	20	19	18	17
B	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
	32	31	30	29	28	27	26	25	24	23	22	21	20	19	18	17

○ 2

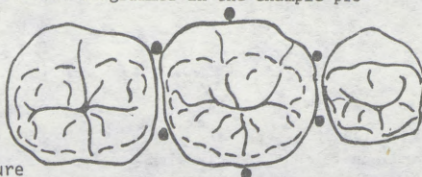
3. Periodontal Measurements - 10 Points

a. Performance Criteria and Minimal Competency Level

Given approximately 15 minutes, the candidate must chart the depth of the gingival sulcus for every tooth in an assigned quadrant using the format and following the instructions provided in the Candidate's Progress Folder. Using a mouth mirror and a color-coded periodontal probe divided into 3 millimeter bands, the candidate must record the depth of each sulcus/pocket to the nearest millimeter on six aspects (MF, F, DF, ML, L, DL) of each assigned tooth. Acceptable performance will have been demonstrated if 95% of all measurements are accurately recorded.

b. Candidate Instructions

Only measurements of 3 millimeters or more are to be recorded. The measurements should be recorded at precisely those locations diagrammed in the example provided below.



c. Examiner Procedure

Only four (24 measurements) in the assigned periodontal quadrant will be evaluated by the examiners; these are the four most posterior teeth (excluding third molars). You must use the candidate's color-coded probe calibrated into 3 mm. bands to make this evaluation. There are

three criteria for the correct use of the probe:

- 1) The probe must always be parallel to the long axis of the tooth
- 2) The upper portion of the probe must be stabilized in contact with the greatest convexity of the coronal portion of the tooth, and
- 3) Using light pressure, the tip must be positioned at the depth of the sulcus at the soft-tissue attachment.

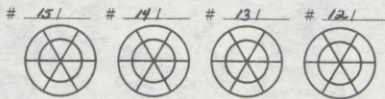
The examiner should carefully determine that the probe tip is, in fact, at the depth of the sulcus and not resting on a ledge of calculus. The candidate is expected to have estimated the sulcus depth to the nearest millimeter.

d. Determination of Errors

The majority of your judgments will focus around the 3 mm. marking. If the measurement is on the line, the candidate should have recorded it as 3 mm. If nothing is recorded, the candidate has read the measurement as less than 3 mm. The measurement of the examiner and candidate must be exact within 1 mm., otherwise an error has been made and must be recorded.

e. Use of the Assistant

- 1) Identify the four most posterior teeth in the assigned periodontal quadrant (excluding the third molar if all three molars are present) and call off their numbers for the assistant to record in the place above the circles and the top of the evaluation form. In the example below, the assistant has identified at the top of the form, teeth #'s 15, 14, 13 and 12 for periodontal measurements, and recorded those tooth numbers above the wheel grids:



- 2) Establish a pattern for checking periodontal measurements and use it consistently with your assistant. For instance, always begin on the distal-facial of the most posterior tooth and progress mesially, checking all the facial measurements. Then move to the mesial-lingual of the most anterior tooth and progress distally to check all the lingual measurements. Have the assistant call off the candidate's recordings as you confirm the measurements.

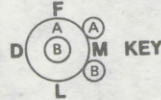
f. Recording Errors

- 1) The key to recording errors on the wheel grids is in the upper left hand corner of the evaluation form.

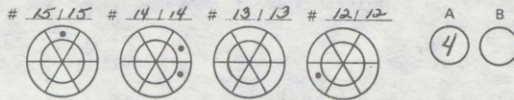
Examiner A always records in the outside circle

Examiner B always records in the inside circle

The mesial, distal, facial and lingual surfaces are consistently recorded as designated on the key.



- 2) To record an error, a distinct dot (•) should be placed on the appropriate surface of the Examiner's space. An example is shown below of four errors identified by Examiner A on teeth #'s 15, 14, 13 and 12.

4. Totalling Recorded Errors

1. Make sure that the assistant has counted the number of recorded errors for each component of Part I and written the total in the appropriate circle of the right-hand column designated for Examiner A or B.
2. Tear off the Part I portion of the grade sheet on which you have recorded your findings and keep it with you until all Part I evaluations are completed.
3. Ask the assistant to transfer the candidate number and the tooth identification numbers above the wheel grids onto the green sheet of the evaluation form so that the second examiner will check the same teeth.

5. Validation of Part I

- a. When both examiners have completed their evaluation of Part I of the examination and torn off their individual pages, the second examiner should compare the findings as recorded on the third page (master copy).
- b. The third column of circles, titled "AE", shows the allowable number of errors for each component of the exam. For the Dental Charting and Periodontal Measurements sections the allowable errors are contingent upon the patient's oral condition and must be computed as shown in boxes on the form.

- 1) Dental Charting - Compare the number of items charted with the numerical table to determine the allowable errors. For instance, if 14 items have been charted, it would appear as shown below and two errors would be allowed.

DENTAL CHARTING

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
A	32	31	30	29	28	27	26	25	24	23	22	21	20	19	18	17
B	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
	32	31	30	29	28	27	26	25	24	23	22	21	20	19	18	17

Items Charted 14

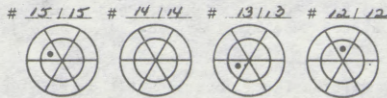
A	B	AE	V	
				10
$\begin{array}{l} 0 \cdot 10 = 1 \quad 21 \cdot 30 = 3 \\ 11 \cdot 20 = 2 \quad 31 \cdot 40 = 4 \end{array}$				

- 2) Periodontal Measurements - The allowable errors are determined by the classification of patient difficulty recorded during Patient Check-In. The example shows Examiner B found 3 errors on a "heavy" patient, and 3 errors are allowed.

Medium Patients	- 1 allowable error
Medium/Heavy Patients	- 2 allowable errors
Heavy Patients	- 3 allowable errors

PERIODONTAL MEASUREMENTS:

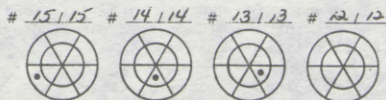
Record errors by checking tooth sextant on which error is located.
Record validated errors with an X.



A	B	AE	V
$M = 1 \quad MH = 2 \quad H = 3$			

- c. Add the total number of errors recorded by Examiners A and B and determine the need for validation using the following guidelines:

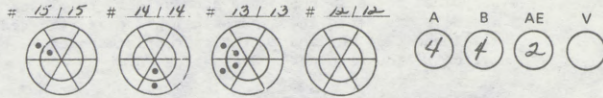
- 1) If the total number of Examiner A's and B's errors is equal to or less than the allowable errors, the candidate has passed that section, and no validation of errors is required.



Example:
Candidate Passes

- 2) If the total number of identical errors (recorded by both examiners) is more than the allowable errors, the candidate has failed that section. In the example below: Examiners A and B have both recorded 4 identical errors for periodontal

measurements on a MH patient, and only 2 errors are allowed. The candidate has failed and no further validation is required.



3. If the total number of unconfirmed errors (recorded by only one examiner) and identical errors exceeds the allowable errors, then the unconfirmed errors must be validated to determine whether the candidate has passed or failed the component. To do this, the examiners must return to the patient and confirm each other's findings. In the Dental Charting example below, Examiners A and B have identified one identical error and 2 unconfirmed errors. Their total exceeds the allowable number of errors and must be validated.

DENTAL CHARTING

		# Items Charted <u>20</u>																A	B	AE	V	
A	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16		2	2	2		10
	32	31	30	29	28	27	26	25	24	23	22	21	20	19	18	17						
B	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16						
	32	31	30	29	28	27	26	25	24	23	22	21	20	19	18	17						

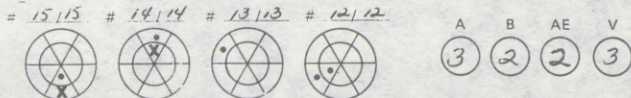
0 · 10 = 1 21 · 30 = 3

11 · 20 = 2 31 · 40 = 4

0 - 10 = 1	21 - 30 = 3
11 - 20 = 2	31 - 40 = 4

All validated errors are recorded on the master copy with an X. Any error initially recorded by one examiner that is not validated by an X in the corresponding space for the second examiner, is unvalidated and will not be counted in the final total. In the event that both examiners cannot agree on the presence of an error, the opinion of another examiner must be obtained.

4. All identical and validated errors are added and recorded in the final column of circles titled "V". The example below illustrates one identical error, two validated errors and one unconfirmed error, making a total of three validated errors.



5. Whenever the second examiner determines that validation is necessary, the results of that validation must be recorded in the last circle titled "V", no matter how many errors are finally confirmed. If no validation is necessary, the "V" circle is left blank.

- d. If the candidate has exceeded the allowable number of errors for any component, no points are awarded for that component. The points for all components successfully completed by the candidate are added and a numerical grade is recorded for Part I and also entered in the appropriate space in the top section of the Examiner's Evaluation Form.

The example shows that no validation was needed for Oral Inspection. The validation for Periodontal Measurements resulted in only one confirmed error, while the true validated errors in the Dental Chart indicates that the candidate has failed to successfully complete Dental Charting and receives 15 out of a possible 25 points for PERIODONTAL MEASUREMENTS: Part I.

	A	B	AE	V	Points
ORAL INSPECTION	(1)	(1)	(1)	()	5
DENTAL CHARTING	(3)	(2)	(2)	(3)	10
	0 - 10 = 1 21 - 30 = 3 11 - 20 = 2 31 - 40 = 4				
PERIODONTAL MEASUREMENTS:	(2)	(1)	(2)	(1)	10
	M = 1 MH = 2 H = 3				
	Total Part I				<u>15</u>

C. EVALUATION OF PART II - ORAL PROPHYLAXIS

For this evaluation, you are thoroughly inspecting exactly seven of the teeth in the prophylaxis assignment. For a one quadrant assignment, examine the seven most posterior teeth in the quadrant excluding third molars when all three molars are present. For a two quadrant contract, begin on either one of the two most posterior teeth in the upper quadrant which has been assigned. Examine this starting tooth and proceed to examine every other tooth (changing to the opposite lower quadrant at the midline) until seven teeth have been evaluated.

1. Subgingival Deposits - 25 Points

a. Performance Criteria and Minimal Competency Level

Given approximately 45 minutes, the candidate must effectively remove calculus so that no deposits are detectable with a #2 (cowhorn or pigtail) explorer and no calculus is visible when the tissue is deflected with air. Acceptable performance will have been demonstrated if 85% of all subgingival tooth surfaces are free of deposits.

b. Examiner Procedure

You must use an air syringe and a #2 explorer (commonly called a "pig tail" or "cowhorn" explorer) for detection of calculus. With adequate light and a clear visual field, you should air dry the tooth, deflecting the free gingiva to determine whether or not calculus is visible beneath the margin. Using a stable fulcrum, the modified pen grasp and a wrist-rock motion, the examiner should make short overlapping, light exploratory strokes from the soft tissue attachment on each of the four surfaces of the teeth which have been designated for examination. The number of strokes will vary according to the type and size of tooth being examined. As a rule, however, strokes should not be more than one to two millimeters apart as the explorer moves around the circumference of the tooth.

Rough areas should be carefully explored, always with a light touch, and the tip of the explorer properly adapted to the tooth. You may have to determine if the explorer is catching onto a piece of calculus or into a decalcified area or defect in the cementum. Overhanging margins of restorations or rough cemento-enamel junctions (CEJ) can frequently be confused with calculus. Ideally, a root surface that has been well scaled and planed will feel smooth and hard.

c. Determination of Errors

The presence of any unremoved calculus constitutes a subgingival error. Having made the determination that a rough area is, indeed, calculus, you are to record the error according to the surface of the tooth involved. Please note that as many as four separate errors could be recorded for a single tooth

since the unit of measurement for this section of the examination is tooth surfaces. However, the presence of two or more deposits on any one surface is only counted as one surface error.

2. Supragingival Deposits - 20 Points

a. Performance Criteria and Minimal Competency Level

Given approximately 15 minutes, the candidate must effectively remove calculus, soft deposits and extrinsic stains so that all non-decalcified surfaces are:

- 1) Visually clean when air-dried.
- 2) Tactilely smooth upon examination with a #2 (cowhorn or pigtail) explorer.
- 3) Free of plaque when examined after the application of disclosing agent.

Acceptable performance will have been demonstrated if 95% of all supragingival tooth surfaces are free of deposits, plaque and extrinsic stains.

b. Examiner Procedure

You are inspecting for supragingival calculus, extrinsic stains, materia alba and plaque. Adequate lighting and clear access to the field are again essential. Probably the most important instrument you have at your disposal is the air syringe. The teeth to be examined should be thoroughly dried, and all five coronal surfaces (M,D,B,L, and O) inspected using the #2 explorer. After air-drying, you should lightly explore the surfaces to determine that non-decalcified surfaces are:

- Clean, smooth and lustrous
- Free from soft deposits and extrinsic stains
- Free of tarnish on surfaces of metallic restorations.

Areas of stain should be explored to determine whether or not enamel decalcification or defects make the stain unremovable. Similarly, tarnished restorations should not be counted as an error if the restoration is so severely corroded that pumice polishing will not suffice.

c. Determination of Errors

All extrinsic deposits on any coronal surface are errors and should be recorded by the examiner. If there is any doubt regarding the presence of plaque or soft deposits, disclosing agents should be applied. Again, it should be noted that

the unit of measurement is tooth surfaces and in this case, as many as five errors could be recorded on any one tooth.

3. Tissue Condition - 5 Points

a. Performance Criteria and Minimal Competency Level

The candidate must effectively utilize hand instruments, polishing cups or brushes, and dental floss so that no unwarranted soft tissue trauma (abrasions or lacerations) occurs as a result of the prophylaxis procedure. Acceptable performance will have been demonstrated if 100% of all proximal tissue surfaces exhibit no unusual mechanical damage. The unwarranted presence of grossly lacerated gingival tissues (three or more lacerations) will result in automatic failure of the entire Oral Prophylaxis section of the examination.

b. Examiner Procedure

You should inspect the supporting soft tissues on all four surfaces of each tooth to be examined. It will be helpful in making comparisons for you to refer to the tissue condition as recorded when the patient was accepted or to compare it to other quadrants which have not received any treatment. You should be alert for any trauma, such as lacerations from instrumentation, improper flossing procedures, and abrasion as a result of polishing procedures.

c. Determination of Errors

A patient with deposits heavy enough to qualify as a board patient can be expected to present a poor gingival condition. The candidate should not be penalized for inflamed, hemorrhagic tissue that is the result of poor oral hygiene and chronic disease. However, any obvious mutilation of tissue should be recorded as a definitive error.

4. Use of the Assistant

In addition to recording any errors you identify, the most important function of the assistant for these evaluative procedures is to air-dry the teeth as you examine. The importance of the air syringe cannot be overemphasized as a key to a consistently accurate examiner evaluation.

5. Recording Errors

The first examiner to see the patient should call out the numbers of the teeth being examined so the assistant can write the identification number above each "wheel grid" as shown below.

Record errors by placing a dot on the appropriate tooth surface. Record validated errors with an X.
SUBGINGIVAL
14 # 12 # 10 # 25 # 27 # 29 # 31



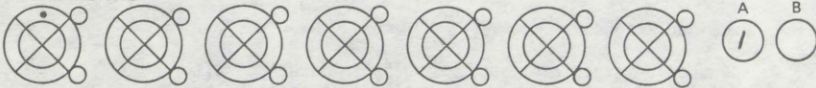
a. Subgingival Calculus

For any surface on which you detect calculus, call out the location and direct the assistant to mark a dot (•) on the appropriate ring and surface of the wheel grid, as described under Evaluation Procedures for Part I.

b. Supragingival Deposits

The small outside circles attached to the wheel grid represent the occlusal surface. Examiner A should always record occlusal errors in the upper circle, Examiner B in the lower one. For any supragingival calculus, stain or plaque that is detected on the seven examined teeth, a dot (•) should be recorded on the corresponding surface of the wheel grid.

SUPRAGINGIVAL



c. Tissue Condition

Record the location of lacerations in the appropriate space on the Tissue wheel grid with a dot (•). More than three mechanical lacerations constitute failure of the entire prophylaxis section of the examination.

6. Totalling Recorded Errors

Add the number of recorded errors for each component of the prophylaxis and enter them in the appropriate column for Examiner A or B. Tear off your copy of the evaluation form and keep it with you until the Part II evaluations are completed. The assistant for the first examiner should transfer onto the green sheet the candidate number and the tooth identification numbers above the wheel grids so that the second examiner will evaluate the same teeth.

7. Validation of Part II

- The allowable errors for subgingival calculus are determined by the original classification of patient difficulty. The example shows that for this medium-heavy patient, 5 errors are allowed.

Medium patients	=4 errors	A	B	AE	V	Points
Medium/Heavy patients	=5 errors					25
Heavy patients	=6 errors	M = 4 MH = 5 H = 6				

2. On the master copy, compare the total number of errors to the allowable number of errors, as explained under validation procedures for Part I.
3. If validation of unconfirmed errors is necessary, return to the patient and confirm or deny each other's findings.
4. Record the total of all identical and validated errors in the final column, titled "V". (If validation was not necessary, be sure to leave the circle empty.)
5. Delete the point value for any component in which the candidate has exceeded the allowable number of errors. Add the point value for all successfully completed components and record a numerical grade for Part II, following the same procedures described for Part I.

The example shows that for this "heavy" patient, no validation was necessary for subgingival scaling. Validation of the supragingival component resulted in failure and the loss of 20 points. Validation of the tissue section of the examination indicates that examiners agreed that there was no unwarranted tissue laceration. Therefore, the candidate receives 30 points for the prophylaxis.

	A	B	AE	V	Points
Subgingival	(5)	(3)	(6)	()	25
	M = 4 MH = 5 H = 6				
Supragingival	(3)	(1)	(1)	(3)	20
Tissue	(0)	(1)	(0)	(0)	5

D. EVALUATION OF PART III - RADIOGRAPHS (10 points)

Total Part II 30

1. Candidate Procedures for Exposing Radiographs

a. Pre-exposed radiographic procedures:

If authorized by the testing agency, candidates currently enrolled in a dental hygiene program will expose a partial or full-mouth series of radiographs prior to the examination. The dental hygiene program director must certify that the radiographs have been exposed by the candidate without assistance. The candidate must bring the exposed, undeveloped radiographs in a sealed, certified envelope to the candidate's orientation. At that time they will be given in to examiners for development. The special envelopes for certification purposes will be provided by the testing agency. The mount will be provided at the testing site if a full-mouth series are required.

b. On-site radiographic procedures:

Candidates who are not enrolled in a dental hygiene program will be assigned a time to expose a radiographic survey at the examination site. Radiographic procedures will be completed on the candidate's assigned day for clinical examination.

The candidate may expose radiographs on their prophylaxis patient (if there are 24 natural teeth) or on a separate radiology patient. The mount will be provided at the testing site.

2. Performance Criteria and Minimal Competency Levels

Given approximately 30 minutes, the candidate must expose, without assistance or retakes, a full mouth series of radiographs to be developed by test-site staff. The radiographs must be properly mounted by the candidate in the accepted ADA method (dimple up) and must exhibit correct cone and film placement as well as correct vertical and horizontal angulation. Acceptable performance for each of the five skills to be tested will be assessed by computing the number of radiographs which demonstrate correct application of the skill. The minimal competency level for each skill is listed below:

Mounting (1 point)	100%
Cone Placement (2 points)	90%
Film Placement (2 points)	80%
Vertical Angulation (2 points)	80%
Horizontal Angulation (3 points)	80%

3. Candidate Instructions

The candidates should obtain their developed radiographs from the testing site staff, and mount them at their earliest convenience. The candidate must number the radiographs on the mount in the following manner: starting in the upper left hand corner of the mount, number maxillary films from 1-7; number mandibular films from 8-14 starting in the lower right hand corner of the mount; bite-wings should be numbered from 15-18 starting at the left side of the mount. For proper identification it is essential that the patient's name and the candidate's name and number be written on the mount.

4. Examiner Procedures

When time is available and mounted radiographs are submitted for evaluation, you should obtain a viewbox and begin to evaluate the radiographic surveys according to the guidelines listed below. Use the film numbers from 1 to 18 that the candidate has placed on the mount to identify any errors, and place these numbers in the grid on the evaluation form.

a. Improper Mounting:

To determine if a film is properly mounted, examine each radiographic series to see whether each radiograph is placed so that the raised portion of the dimple is toward you. In addition, each radiograph within the series should be mounted so that each film is arranged in proper anatomic relationship to all of the other radiographs.

b. Cone Cut

A cone cut must affect the diagnostic quality of the film to be recorded as an error

c. Improper Film Placement

A film has been improperly placed when it does not incorporate completely those structures appropriate for the area of exposure. In order for a film to exhibit proper horizontal placement:

- 1) The molar films must show the distal of the most posteriorly erupted tooth.
- 2) The bicuspid films must include the mesial of the first bicuspid and should include the distal of the cuspids unless this is well defined in the cuspid film.
- 3) The anterior films must show that the appropriate teeth are reasonably centered on the film.

In order for a film to exhibit proper vertical placement:

- 1) All periapical films must show the entire crown as well as 2-3 mm. of bone around the apex.
- 2) All bite wing films must have a centered occlusal plane.

d. Vertical Angulation (Elongation and Foreshortening)

Periapical films should show the entire tooth from crown to apex with a minimum of distortion and 2-3 mm. of bone should show clearly around the apex. Periapical films can be of acceptable diagnostic quality even though there is moderate elongation or foreshortening present.

e. Horizontal Angulation (Interproximal Overlapping)

In order for periapical film to be acceptable, every contact must be open and clearly defined on at least one periapical film in the survey. On bite wing films all contacts must be open between the bicuspid on the pre-molar bite wings and all contacts must be open between the molars on the molar bite wings. No errors should be recorded when overlapping obviously is a result of malpositioned teeth.

NOTE: Any one film may demonstrate several different technique errors. A film that is improperly mounted, cone cut, improperly placed in the mouth, elongated and overlapped would be counted as an error in each of the five categories.

5. Recording Errors

- a. There is an error grid for recording the film number of radiographs that exhibit any of the five categories of technical errors. Examiner A's grid is on the left, Examiner B's grid is on the right.
- b. In your error grid, record in the appropriate category, the film number of any radiographs that exhibit technical error. For instance, on the grid below, films numbers 5 and 8 are shown as cone cut and number 2, 9, 15 and 18 are foreshortened.

- 1) Improper mounting
- 2) Cone Cut
- 3) Improper Film Placement
- 4) Elongation or Foreshortening
- 5) Interproximal Overlapping

1					
2	5	8			
3					
4	2	9	15	18	
5					

- c. Count the total number of errors in each category and record that number in your appropriate column. Tear off your individual evaluation page.
- d. When both examiners have individually evaluated the films, you should immediately work together to assess your findings on the master copy.
- 1) If the combined total of errors entered in columns A and B is less than or equal to the allowable errors, the candidate has successfully passed the examination in that category.
 - 2) If the combined total of columns A and B exceeds the number of allowable errors in a given category, you must re-examine the films recorded on your error grids and reach an agreement on the number of validated errors for that category.

Mark an X over the film numbers when one examiner validates the other's findings.

Count the number of initially identical errors and the number of validated errors and record the total in the final column entitled "v".

- e. For any category in which the candidate has exceeded the number of allowable errors, delete the point value. Add the point values for the categories successfully completed by the candidate and record a numerical grade for Part III. An example of a completed radiographic evaluation is shown below:

PART III RADIOGRAPHS (10 points)

Candidate Number _____/_____

If validated errors exceed circled amount, deduct all points for that category.

TECHNIQUE Record in the appropriate grid the identification number of unacceptable radiographs for each category. Record validated errors with an X.

	A				
1					
2	5	8			
3	7	10			
4	2	18			
5	3	7	X	X	

- 1 Improper mounting
2 Cone cut
3 Improper film placement
4 Elongation or foreshortening
5 Interproximal overlapping

	B				
1					
2	5	8			
3					
4	3	X	X	18	
5	3				

A	B	AE	V	Points
0	0	0		1
2	2	1		2
2	0	3		3
2	4	3	4	3
4	1	3	3	6

Total Technique 6

Mounting -	neither A nor B found errors	candidate passes
Cone Cut -	A and B found 2 identical errors	candidate fails
Film Placement -	A found 2 errors, B found none	candidate passes
Vertical Angulation -	A found 2 errors, B found 4 errors A validated errors on films 9 and 15 by placing an X on B's grid.	candidate fails
Horizontal Angulation -	A found 4 errors, B agreed with 1 of them B validated errors on films 16 and 17, but denied A's findings on film 7	candidate passes

E. FINALIZATION OF RESULTS

- Transfer the numerical grades from the master copy for Parts I, II, and III to the Totals column at the top of the evaluation form, and compute a final total for the written and clinical portions of the examination. Complete finalization of grades as required by the testing agency.

Total Possible Points: 100
Passing: 70

TOTALS	
PART I	<u>15</u>
PART II	<u>50</u>
PART III	<u> </u>
Technique	<u>6</u>
Recognition	<u>10</u>
Candidate's Score:	<u>81</u>

VI. CONCLUSION

This manual has outlined each critical step which you must complete during the administration of a dental hygiene clinical board examination. It has suggested procedures for your preparation, prior to the examination to bring about standardization within the evaluation process. The performance criteria, which must be thoroughly understood before attempting to conduct this clinical dental hygiene examination, have been presented. In addition, detailed instructions have been given for the examiner's procedures, use of the assistant, recording errors and computing grades.

It is hoped that you will now complete the necessary preparation for your forthcoming dental hygiene examination by practicing both the test and the evaluation procedures on several patients. Experience can be gained in the use of the evaluation form by completing the exercises attached to this manual.

Practice and study utilizing this manual, together with the Examiners' Orientation immediately prior to the examination itself should insure the administration of an objective, standardized examination. If you have any questions about the administration of this clinical board examination, please bring a list of such questions to the Examiner's Orientation.

PRACTICE EXERCISES TO BE UTILIZED
WITH EXAMINER'S EVALUATION FORM

Take a sample evaluation form and fill in your findings for each exercise. As you complete each Part, you may refer to the example showing the correctly completed form.

EXERCISE #1

Fill in the following information at the top of the page:

Candidate #84
Patient Condition: Calculus - Medium
Stain - Light
Tissue - Irritated (firm)
Assign: Periodontal Quadrant - LL
Prophylaxis - UL and LR

PART I

Examiner A is first examiner - Record Candidate number

Oral Inspection - Errors on B and E

Dental Charting - Record 29 Items charted - Errors on 10, 15 and 30

Periodontal Probing - Record Teeth ID #18, 19, 20, 21

Errors on #20-DF

Count and record number of errors A found in A's column of circles

Tear off the white sheet for Part I and transfer onto the green sheet the

Candidate's number, the number of the items on the dental chart, and the ID numbers for the Periodontal Teeth

Examiner B Findings

Oral Inspection - Errors on B and I

Dental Charting - Record 29 Items charted - Error on #10

Periodontal Probing - Error on #18 - ML

Count and record the number of errors B found in B's column of circles

Tear off the green sheet for Part I and assess the need for validation

Does Oral Inspection need validation? YES: 1 Allowable error

A validates B's error on I

Examiners found 1 identical error

B denies A's error on E

2 unconfirmed errors

Candidate FAILS with 2 confirmed errors

Does Dental Charting need validation? NO:

29 Items = 3 allowable errors

Candidate PASSES

Examiners found 1 identical error

2 unconfirmed errors

Does Periodontal Probing need validation: YES: Medium Patient = 1 Allowable error

A validates B's error on #18-ML

Examiners found 2 unconfirmed errors

B validates A's error on #20-DF

Candidate FAILS with 2 confirmed errors

Examiner B is first examiner - Record Candidate number
Examiner B records Tooth ID numbers for the prophylaxis sample. They are:
#15, 13, 11, 9, 26, 28, 30
Subgingival - Errors on #26 - M and D
Supragingival - Errors on #15 -F, #9 -L, #30 - Occlusal
Tissue - Error on #15-F

Count and record the number of errors B found in B's column of circles
Tear off the white sheet for Part II and transfer onto the green sheet the
Candidate's number and the ID number for the teeth in the prophylaxis sample

Subgingival - Errors on #15-M and D
Supragingival - Error on #30-Occlusal
Tissue - Errors on #15-F, #9-L

Count and record the number of errors A found in A's column of circles
Tear off the green sheet for Part II and assess the need for validation

Does Subgingival need validation? NO: Medium Patient = 4 Allowable errors
Examiners found 4 unconfirmed errors

Does Supragingival need validation? YES: 1 Allowable Error
A validates B's error on #9-L & #15-F Examiners found 1 identical error
Candidate FAILS with 3 confirmed errors 2 unconfirmed errors

Does Tissue need validation? NO: 0 Allowable Errors
CANDIDATE FAILS Examiners found 1 identical error
1 unconfirmed error

Examiner A rerolls Candidate #84
Mounting - Errors on films 3 and 5
Cone Cut - Errors on film 7
Film Placement - Errors on films 1, 6, 8, 15
Vertical Angulation - Errors on films 1, 2, 7
Horizontal Angulation - Errors on films 2, 9, 16, 17

Count and record the number of A's errors in A's column of circles
Tear off the white sheet and transfer the Candidate number onto the green sheet

Mounting - Errors on films 3 and 5
Cone Cut - No Findings
Film Placement - Errors on films 1, 6, 13, 15
Vertical Angulation - Errors on films 2, 7
Horizontal Angulation - Errors on films 9, 16, 17, 18

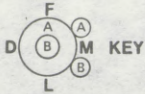
Count and record the number of B's errors in B's column of circles
Tear off the green sheet and assess the need for validation

EXERCISE #1 (Cont.) - Candidate #84 - Page 3

Does Mounting need validation? Candidate FAILS	NO: 0 Allowable Errors Examiners found 2 identical errors
Does Cone Cut need validation? Candidate PASSES	NO: 1 Allowable Error Examiners found 1 unconfirmed error
Does Film Placement need validation? A validates B's error on 13 B validates A's error on 8 Candidate FAILS with 5 confirmed errors	YES: 3 Allowable Errors Examiners found 3 Identical errors 2 unconfirmed error
Does Vertical Angulation need validation? Candidate PASSES	NO: 3 Allowable Errors Examiners found 2 Identical errors 1 unconfirmed error
Does Horizontal Angulation need validation? A denies B's error on 18 B denies A's error on 2 Candidate PASSES	YES: 3 Allowable Errors Examiners found 3 identical errors 2 unconfirmed error

CLINICAL TOTALS:

Record total scores at the top of the form and compare your Exercise Sheet with the Example for Exercise #1.



EXAMINER'S EVALUATION FORM

Exercise 1

Total Possible Points: 100

Passing: 70

Candidate's Number 84 Examiner A _____
Examiner B _____

Patient Condition (Circle):

CALCULUS (Medium) Med/Hvy Heavy
 Stain: (Light) Medium Heavy
 Gingiva: Normal Irritated (but firm) Irritated (spongy & hemorrhagic)

Candidate Assignments (circle)

Periodontal Measurements: UR UL (LL) LR
 Prophylaxis Quadrants: UR (UL) LL (LR)

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
 32 31 30 29 28 27 26 25 24 23 22 21 20 19 18 17

TOTALS

PART I _____

PART II 25

PART III _____

Technique _____

Recognition _____

Candidate's Score: _____

PART III RADIOGRAPHS (10 points)

Candidate Number 84, 84

If validated errors exceed circled amount, deduct all points for that category.

A				
1	3	5		
2	7			
3	1	6	8	15
4	1	2	7	
5	2	9	16	17

- 1 Improper mounting
 2 Cone cut
 3 Improper film placement
 4 Elongation or foreshortening
 5 Interproximal overlapping

B				
1	3	5		
2				
3	1	6	8	15
4	2	7		
5	9	16	17	18

A	B	AE	V	Points
(2)	(2)	(0)	(0)	X
(1)	(0)	(1)	(0)	2
(4)	(4)	(3)	(5)	X
(3)	(2)	(3)	(0)	2
(4)	(4)	(3)	(3)	3
Total Technique				7

PART II ORAL PROPHYLAXIS (50 points)

Candidate Number 84, 84

Record errors by placing a dot on the appropriate tooth surface. Record validated errors with an X.

13, 15 # 13, 13 # 11, 11 # 9, 9 # 26, 26 # 28, 28 # 30, 30

A	B	AE	V	Points
(2)	(2)	(0)	(0)	25
M = 4 MH = 5 H = 6				

SUPRAGINGIVAL



(1)	(3)	(1)	(3)	X
-----	-----	-----	-----	---

TISSUE



(2)	(1)	(0)	(0)	X
-----	-----	-----	-----	---

Total Part II 25

PART I CHARTING (25 points)

Candidate Number 84, 84

Record errors by circling item letter or tooth number. Record validated errors with an X.

ORAL INSPECTION

A A (B) C D (E) F G H X J
 B A (B) C D E F G H (I) J

A	B	AE	V	Points
(2)	(2)	(1)	(2)	X

DENTAL CHARTING

Items Charted 29, 29

A														
1	2	3	4	5	6	7	8	9	(10)	11	12	13	14	(15)
32	31	(30)	29	28	27	26	25	24	23	22	21	20	19	18
B														
1	2	3	4	5	6	7	8	9	(10)	11	12	13	14	15
32	31	30	29	28	27	26	25	24	23	22	21	20	19	18

(3)	(1)	(3)	(0)	10
-----	-----	-----	-----	----

0 - 10 = 1 21 - 30 = 3
 11 - 20 = 2 31 - 40 = 4

PERIODONTAL MEASUREMENTS:

Record errors by checking tooth sextant on which error is located.
 Record validated errors with an X.



(1)	(1)	(1)	(2)	X
-----	-----	-----	-----	---

M = 1 MH = 2 H = 3

Total Part I 10

EXERCISE #2

Fill in the following information at the top of the page:

Candidate #16

Patient Condition: Calculus - Heavy
Stain - Medium
Tissue - Irritated and Hemorrhagic

Assign: Periodontal Quadrant - LR
Prophylaxis - LL

PART I

Examiner B is first examiner - Record Candidate number

Oral Inspection - Error on H

Dental Charting - Record 14 Items Charted - Errors on # 13, 15, 26

Periodontal Probing - Record Teeth ID #31, 30, 29, 28. Error on #30-MF

Count and record the number of errors B found in B's column of circles

Tear off the white sheet for Part I and transfer onto the green sheet the

Candidate's number, the number of items on the dental chart and the tooth
ID numbers to be checked on Periodontal Measurements

Examiner A's Findings

Oral Inspection - Error on H

Dental Charting - Errors on 2, 13 and 26

Periodontal Probing - Errors on #31-F, #28-DL

Count and record the number of errors A found in A's column of circles

Tear off the green sheet for Part I and assess the need for validation

Does Oral Inspection need validation? NO: 1 Allowable Errors
Candidate PASSES Examiners found 1 identical error

Does Dental Charting need validation? YES: 14 items = 2 allowable errors
B validates A's error on #2 Examiners found 2 identical errors
A denies B's error on #15 2 unconfirmed errors
Candidate FAILS with 3 confirmed errors

Does Periodontal Probing need validation? NO: Heavy Patient = 3 Allowable errors
Candidate PASSES Examiners found 3 unconfirmed errors

PART II

Examiner A is first examiner - Record Candidate number

Examiner A records Tooth ID number for prophylaxis sample: #18,19,20,21,22,23,24

Subgingival - Errors on #18-D, #19-M, #21-D, #22-F, #24-M and D

Supragingival - Error on #23-L

Tissue - No Findings

Count and record the number of errors A found in A's column of circles

Tear off the white sheet for Part II and transfer onto the green sheet the

Candidate number and the ID number for the teeth in the prophylaxis sample

Examiner B's Findings

Subgingival - Errors on #18-D and L, #19-M, #22-F, #24-D

Supragingival - Errors on #23-L, #24-F

Tissue - No Findings

Count and record the number of errors B found in B's column of circles

Tear off the green sheet for Part II and assess the need for validation

EXERCISE #2 (Cont.) - Candidate #16 - Page 2

Does Subgingival need Validation? YES: Heavy Patient = 6 Allowable Errors
 Examiner B validates A's error #24-M Examiners found 4 Identical Errors
 Examiner B denies A's error #21-D 3 Unconfirmed Errors
 VALIDATION CAN STOP BECAUSE TOTAL WILL NOT EXCEED 6
 Candidate PASSES

Does Supragingival need validation? YES: 1 Allowable Error
 A validates B's error on #24-F Examiners found 1 Identical Error
 Candidate FAILS 1 Unconfirmed Error

Does Tissue need validation? NO: 0 Allowable Errors
 Candidate PASSES Examiners found no errors

PART III

Examiner A records Candidate #16
 Mounting - No findings
 Cone Cut - Errors on films 1, 2, 15
 Film Placement - Errors on films 6, 9, 18
 Vertical Angulation - Error on film 5
 Horizontal Angulation - Errors on films 15, 16, 17, 18
 Count and record the number of A's errors in A's column of circles
 Tear off the white sheet and transfer the Candidate number onto the green sheet

Examiner B Findings

Mounting - No findings
 Cone Cut - Errors on films 1, 2, 15, 17
 Film Placement - Error on film 16, 17, 18
 Vertical Angulation - Error on film 7
 Horizontal Angulation - Errors on films 3, 5, 17
 Count and record the number of B's error in B's column of circles
 Tear off the green sheet and assess the need for validation.

Does Mounting need validation? NO: 0 Allowable errors
 Candidate PASSES Examiners found no errors

Does Cone Cut need validation? NO: 1 Allowable Error
 Candidate FAILS Examiners found 3 Identical Errors
 1 Unconfirmed Error

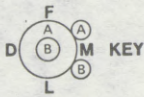
Does Film Placement need validation? YES: 3 Allowable Errors
 B validates A's errors on 6 and 9 Examiners found 1 Identical Error
 A denies B's error on 17 and 16 4 Unconfirmed Errors
 Candidate PASSES

Does Vertical Angulation need validation? NO: 3 Allowable Errors
 Candidate PASSES Examiners found 2 Unconfirmed errors

Does Horizontal Angulation need validation? YES: 3 Allowable Errors
 A validates B's errors on 3 and 5 Examiners found 1 Identical Error
 B validates A's error on 15 and 18 5 Unconfirmed Errors

Candidate FAILS with 5 confirmed errors

RECORD TOTAL SCORES AND COMPARE YOUR EXERCISE SHEET WITH THE EXAMPLE.



EXAMINER'S EVALUATION FORM

Exercise 2

 Total Possible Points: 100
 Passing: 70
Candidate's Number 16
 Examiner A _____
 Examiner B _____

Patient Condition (Circle):

 CALCULUS: Medium Med/Hvy Heavy
 Stain: Light Medium Heavy
 Gingiva: Normal Irritated (but firm) Irritated spongy & hemorrhagic

Candidate Assignments (circle)

 Periodontal Measurements: UR UL LL LR
 Prophylaxis Quadrants: UR UL LL LR
 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
 32 31 30 29 28 27 26 25 24 23 22 21 20 19 18 17

TOTALS

PART I 15PART II 30

PART III _____

Technique 5

Recognition _____

Candidate's Score: _____

PART III RADIOGRAPHS (10 points)

Candidate Number 16 / 16

If validated errors exceed circled amount, deduct all points for that category.

TECHNIQUE Record in the appropriate grid the identification number of unacceptable radiographs for each category. Record validated errors with an X.

A				
1				
2	1	2	15	
3	X	X	17	
4	5			
5	X	16	17	X

- Improper mounting
- Cone cut
- Improper film placement
- Elongation or foreshortening
- Interproximal overlapping

B				
1				
2	1	2	15	17
3	16	17	18	
4	7			
5	X	X	17	

A	B	AE	V	Points
0	0	0	0	1
3	4	1	0	2
3	3	3	3	2
1	1	3	0	2
4	3	3	5	6
Total Technique				6

PART II ORAL PROPHYLAXIS (50 points)

Candidate Number 16 / 16

Record errors by placing a dot on the appropriate tooth surface. Record validated errors with an X.

SUBGINGIVAL

18, 18 # 19, 19 # 20, 20 # 21, 21 # 22, 22 # 23, 23 # 24, 24

A	B	AE	V	Points
6	5	6	6	25
M = 4 MH = 5 H = 6				

SUPRAGINGIVAL



1	2	1	2	X
---	---	---	---	---

TISSUE



0	0	0	0	5
---	---	---	---	---

Total Part II 30

PART I CHARTING (25 points)

Candidate Number 16 / 16

Record errors by circling item letter or tooth number. Record validated errors with an X.

ORAL INSPECTION

A	A	B	C	D	E	F	G	H	I	J
B	A	B	C	D	E	F	G	H	I	J

A	B	AE	V	Points
1	1	1	0	5

DENTAL CHARTING

Items Charted 14, 14

A	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
32	31	30	29	28	27	26	25	24	23	22	21	20	19	18	17	
B	1	X	3	4	5	6	7	8	9	10	11	12	13	14	15	16
32	31	30	29	28	27	26	25	24	23	22	21	20	19	18	17	

3	3	2	3	X
---	---	---	---	---

 0 - 10 = 1 21 - 30 = 3
 11 - 20 = 2 31 - 40 = 4

PERIODONTAL MEASUREMENTS:

 Record errors by checking tooth sextant on which error is located.
 Record validated errors with an X.


2	1	3	0	10
---	---	---	---	----

M = 1 MH = 2 H = 3

Total Part I 15

*EXAMINER ASSISTANT GUIDEBOOK
TO THE
DENTAL HYGIENE
CLINICAL BOARD EXAMINATION*



*American Dental Hygienists' Association
Clinical Testing Evaluation Service
211 East Chicago Avenue, Suite 1616
Chicago, Illinois 60611*

January, 1978

EXAMINER ASSISTANT GUIDEBOOK

As an examiner assistant, your role is critical to the efficient administration of a fair, thorough dental hygiene clinical examination. This Guidebook has been developed to help you prepare for your role so that you can fulfill your responsibilities within the examination process. The examination consists of three parts: Part I - Data Gathering and Charting; Part II - Oral Prophylaxis; and Part III - Radiography. You will be assisting only with Parts I and II. The examination is based on specific criteria for acceptable performance in each clinical function.

The examiners will be paired in teams of two, and each examiner will be assigned an assistant. Examiners may be dentists or dental hygienists. Whenever clinical facilities permit, the examiners will set aside two or three operatories where they will remain to conduct all their evaluations. Patients will be brought to the examiners at these examiner stations. Your primary responsibility is to manage the activities at the examiner stations, with the exception of the actual patient evaluation. Your responsibilities include:

1. Managing the flow of patients to and from examiner stations.

A sheet should be posted close to the examiner stations for the candidates to sign when they are ready for evaluation. (A sample sign-up sheet is attached.) The candidates may sign up for evaluation, return to their operatories and continue working until you notify them that the examiners are ready to evaluate their patient. Following the order listed on the sign-up sheet, you will go to the candidate's operatory, take the candidate's Progress Folder along with their mirror, #2 explorer and probe in an autoclave bag or napkin, and escort the patient to the examiner station. When the evaluation is completed, you will accompany the patient to the candidate's operatory and escort the next patient to the examiner station.

2. Supplying and sanitizing examiner stations between patients.

At the beginning of the examination, you should check to see that stools are available for the examiner and assistant and that each unit functions properly. Be sure to check air, water, suction, and chair operation. The stations should contain an adequate supply of the following items:

- a. headrest covers
- b. 2 x 2 gauze sponges
- c. instrument table covers
- d. alcohol swabs
- e. soap and hand towels
- f. extra sterile examining instruments
- g. disclosing agent and cotton tip applicators (if requested by examiners)

After each patient is dismissed, sanitize the chair and unit and replace the headrest and instrument table cover. If an instrument is dropped during the course of an evaluation, provide a sterile replacement. If examining instruments need to be sterilized at the end of the examination period, make arrangements with the testing site staff to ensure that these procedures can be carried out.

3. Providing chairside assistance to the examiners.

Since examiners will not be engaging in treatment procedures, there will be limited necessity for such traditional chairside assisting as rinsing and evacuation. The most important functions that you will provide are air-drying the teeth and reading charts to the examiners. The air syringe is an essential examining instrument and you can be of great assistance to the examiner by delivering air to the correct location during the examination process. In addition, you will read the candidate's charting to the examiner so that the findings can be corroborated in the mouth. This alone will facilitate the evaluation.

4. Recording the examiner's findings on the Examiner's Evaluation Form.

The Evaluation Form is a 3-page NCR form. The first two pages allow each examiner to independently evaluate the candidate's performance and immediately compare their findings on the third page. The third page is the master copy and provides a precise documentation of examination results. At an orientation prior to the examination, you will be given detailed instructions about using the Form. You will be responsible for recording the identification numbers of the teeth the examiners select for evaluation, and then recording the location of any errors that are identified.

5. Maintaining the Examiner's Evaluation Forms.

You and your assisting partner should maintain the Evaluation Forms in a secure, easily accessible location at the examiner stations. As each patient enters the station, you should select the Evaluation Form for the candidate who has completed the patient and attach it to a clipboard for the evaluation procedure. When the evaluation is completed, the Form should be removed and the forms for the next candidate's patient attached to the clipboard.

EXAMINATION PROCEDURES

The Dental Hygiene Examination Coordinator will provide an orientation to all examination participants prior to the examination and review your responsibilities in detail. At that time, you will be instructed in the use of the Examiner's Evaluation Form. It is imperative that you attend the orientation in order to serve as an examiner assistant. A step-by-step summary of your responsibilities as an assistant during the examination procedures is outlined below:

1. **Patient Check-In:** Rather than bring patients to examiner stations to check them in, the examiners will move as a team from operator to operator. The candidate will be excused from the area while the examiners assess the patient's condition and assign the procedures the candidate is to complete.
 - a. One assistant should accompany the examiners in order to insert needed information on the Evaluation Forms. As the examiners approach an operator, the assistant should provide the Evaluation Form for that candidate and record candidate assignments as directed. Once this procedure is complete, the assistant will then direct the examiners to the next patient available for check-in procedures.
 - b. While the examiners are completing the patient check-in procedure, the second assistant should supply and prepare the examiner stations for use, as previously described. The sign-up sheet should be posted and all candidates informed of its location.
2. **Part I Evaluations.** During this portion of the examination, examiner assistants are to escort the patients to the examiner stations in the order listed on the sign-up sheet.
 - a. **Oral Inspection** - While the examiner is conducting the oral inspection, the examiner assistant should hold the form so that it can be readily utilized since the examiner can review it visually more quickly than it can be read aloud. At this time, record those errors which are identified.
 - b. **Dental Charting** - Read the charting to the examiner as the teeth are inspected. Air drying is essential to this evaluation. Therefore, the assistant should help with the air syringe and be prepared to record any errors that are identified.
 - c. **Periodontal Measurements** - The first examiner to see the patient will select four teeth in a quadrant and ask the assistant to record the tooth identification numbers for the teeth to be examined. If you are assisting the second examiner to see the patient, the tooth identification numbers will already be recorded on the Evaluation Form. Therefore, you should simply call them off to the examiner so that the correct teeth will be examined.

You should establish a pattern of examination with the examiner. Once this is done, you can then read the candidate's recorded measurements to the examiner in the pattern that you have identified. Be prepared to air-dry the teeth as needed and record any errors that are identified.

Both examiners must independently evaluate Part I, then compare their findings to determine whether or not any significant differences exist. If such differences do occur, they must return to the patient and validate their findings. As soon as the examiners have released the patient, the patient is to be returned to the candidate's operator, the examiner station sanitized, and another patient escorted promptly to the station.

3. Part II Evaluation: As candidates sign up for Part II evaluations, you are to bring patients to the examiner stations in the same manner as that described for Part I. The first examiner will select seven teeth to examine for the oral prophylaxis. You are to record these tooth identification numbers on the Evaluation Form. If you are assisting the second examiner to see the patient, the seven teeth will already be identified and recorded.

These seven teeth will be evaluated for the presence of subgingival calculus, supragingival deposits and tissue treatment. You will be asked to record any errors that are identified in any one of these three categories. Since air-drying is critical to this evaluation, you should assist the examiner with the air syringe. When the examiners have completed their evaluations of the prophylaxis and validated their findings, the patient is to be returned to the candidate. The candidate may either dismiss the patient or continue to complete unassigned portions of the prophylaxis as time permits.

4. Candidate Check-Out: When candidates have completed all examination assignments and their performance of these procedures evaluated, they must complete a simple check-out procedure. This requires that they submit all their forms and radiographs to be retained by the examining agency. The examiner's signature is necessary to verify the fact that all forms have been completed and returned. You can assist with finalizing this procedure by checking the candidate's packet to ensure that it includes:
 - a. Identification badge
 - b. Candidate's Progress Folder with appropriate examiner signatures in all areas
 - c. Mounted radiographic series which is numbered and includes the patient's name and candidate's identification number
 - d. Any necessary institutional clearance forms

Packets should be collected and given to the examiners at the conclusion of the examination.

GENERAL DIRECTIVES FOR EXAMINER ASSISTANTS

1. You are responsible to ensure the security of the examination just as the participating examiners are. Results of the candidate's performance are reported only by the testing agency when all grades are finalized. Although you will have access to a portion of the evaluation of the candidate's performance, you should keep in mind that scores on written exams and radiographs are only a part of the final grade. Therefore, no assumptions should be made about whether a candidate has passed or failed, based upon such incomplete information. It is essential that under no circumstances is the assistant placed in a position of making comments about a candidate's performance.
2. Although your role as an assistant is vital to the examination, it is the examiner who is responsible for evaluation. You should conscientiously avoid becoming involved in judgments about the candidate's performance. Even though a gross error might be readily observable to you from the assistant's chair, no attempt should be made to direct the examiner's attention to it. The examiner is applying specific evaluation criteria to a standardized sample of the candidate's performance, and only the examiner should make judgments about whether the candidate has met the criteria.
3. In your role as manager of patient flow to the examiner stations, you will have the most direct interface with candidates. Any questions from candidates about examination procedures that you cannot answer, should be referred to the examiners and the information reported back to the candidate by you. This saves the examiners from being distracted from their primary task of evaluation, and avoids the examiners' being influenced in their evaluation by personal contact with the candidate.
4. You should assist only the examiner to whom you are assigned throughout the examination. Because of the precise manner in which errors are recorded on the Evaluation Form, you will be able to function most effectively if you work consistently with the same examiner.

SUMMARY

This pamphlet has described your general functions as an examiner assistant. More detailed instructions will be provided at your orientation, and any questions you have will be addressed at that time. Clinical evaluation is an exacting, time-consuming responsibility. Your assistance is greatly appreciated and will allow the examiners to conduct a more thorough and reliable examination. Yours is an invaluable contribution to the examination process.

Candidate Sign-Up Sheet

Examiner Teams

Part I			Part II		
	Candidate #	Operatory #		Candidate #	Operatory #
1			1		
2			2		
3			3		
4			4		
5			5		
6			6		
7			7		
8			8		
9			9		
10			10		

RADIOGRAPHIC RECOGNITION TEST

PRINT YOUR NAME _____ EXAMINER TEAM # _____
(LAST) (FIRST) (MIDDLE) CANDIDATE NUMBER _____
TEST SITE _____ DATE _____

RECOGNITION - Slides 1 - 16

Observe each slide projected. Select the one best for each arrow indicated on the radiograph. Pencil in the appropriate box; one box for each arrow. The answers are listed in alphabetical order. Use a straight edge as a guide to the columns.

TECHNIQUE - Slides 17 - 24

Observe each slide projected. Select the technique errors displayed on each radiograph. Pencil in as many boxes as are necessary.

[illegible]

DENTAL HYGIENE CLINICAL EXAMINATION CANDIDATE FOLDER

Date _____

Candidate Number _____

CANDIDATE'S PROGRESS RECORD

GENERAL INFORMATION: It is the responsibility of the candidate to ensure that examiners place their initials in appropriate squares. The candidate's grade is computed from grades given by examiners on these procedures. Two examiners are required to complete every check. Radiographs will be retained by the Board until examination results are finalized.

Patient Check-In

Both members of your examining team must evaluate your patient's acceptability to determine:

1. Oral and systemic conditions acceptable for treatment
 2. Proper number of teeth (14 or more)
 3. Adequate deposits (medium to heavy subgingival calculus)
 4. Assigned quadrant for Periodontal Measurements: UR UL LL LR
 5. Oral Prophylaxis assignment: UR UL LL LR
- | | | | | | | | | | | | | | | | |
|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| 32 | 31 | 30 | 29 | 28 | 27 | 26 | 25 | 24 | 23 | 22 | 21 | 20 | 19 | 18 | 17 |

Examiner's Initials

HEALTH HISTORY PATIENT ACCEPTABILITY CANDIDATE ASSIGNMENTS

--	--

Part I Evaluation: Data Gathering and Charting

Complete Oral Inspection, Dental Charting and Periodontal Measurements. Periodontal Measurement will include six sulcular measurements for every tooth in the assigned quadrant, recording only those measurements of 3 mm or more. Present patient to examiners with mirror, probe and #2 explorer.

ORAL INSPECTION

DENTAL CHARTING

PERIODONTAL MEASUREMENTS

--	--

Part II Evaluation: Oral Prophylaxis

Complete prophylactic assignment and present the patient to examiners for evaluation with mirror and #2 explorer. Do not dismiss patient until released by examiners. If a complete prophylaxis has not been rendered, candidate should utilize remaining time to finish the prophylaxis.

PROPHYLAXIS

Completed Examination Check-Out

Complete radiographic procedures as directed by the Board. Mount radiographs in the ADA accepted form and submit the survey and progress folder to examiners.

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--	--

Radiographic Recognition (Slide Examination)

I certify that this progress folder is a complete record of my examination activities.

Signature _____

Date _____

HEALTH HISTORY

PATIENT'S NAME _____ DATE _____

ADDRESS _____ PHONE _____

OCCUPATION _____ DATE OF BIRTH _____ M or F

Please answer YES or NO. All YES answers require a comment.

	YES	NO	
A. Presently under physician's care			
B. Hospitalization (last five years)			
C. Recent Illnesses			
D. Heart Disease			
E. High Blood Pressure			
F. Bleeding Problems			
G. Blood Disease			
H. Rheumatic Fever			
I. Diabetes			
J. Kidney Disorders			
K. Liver Disorders (Hepatitis)			
L. Respiratory Problems			
M. Healing Problems			
N. Allergies (food and drugs)			
O. Taking Medication			
P. Dietary Restrictions			
Q. Are you pregnant?			
R. Epilepsy			
S. Venereal Disease			
T. Radiation Exposure			
U. Are alterations in treatment indicated because of conditions encountered in medical history?			

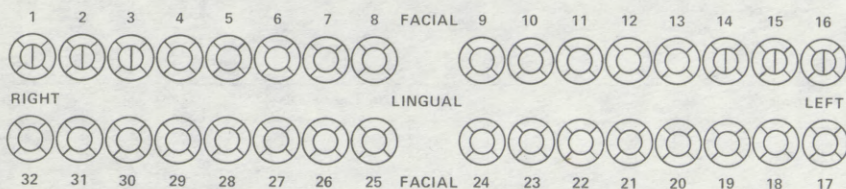
ORAL INSPECTION FORM

If the oral inspection test items listed below demonstrate no significant findings, place a check in the column marked "None."
If significant findings are noted, enter a one-line comment in the space provided describing the condition. Those findings that are considered significant are identified for each item.

Oral Inspection	None	Significant Finding
EXTRAORAL		
A. Face and Neck (lesions, moles, birthmarks)		
B. Lymph Nodes (hardness, nonmobility, enlargement)		
C. TMJ (pain, restricted opening, crepitation)		
INTRAORAL		
Soft Tissue - all soft tissue structures should be inspected for lesions, chemical or physical irritations or palpable nodules. Additionally, these areas should be examined for any other findings specifically noted below:		
D. Oral Mucosa		
E. Palate - tori		
F. Tongue (black hairy, geographic, glossitis, loss of papilla)		
G. Floor of mouth (ankyloglossia, tori, ranula)		
H. Gingiva (fibrosis, edema, hyperemia, hemorrhagic, severe recession)		
Dentition		
I. Teeth (abrasion, erosion, attrition)		
J. Occlusion (Angle's Class II or II, crossbite, openbite)		

DENTAL CHARTING

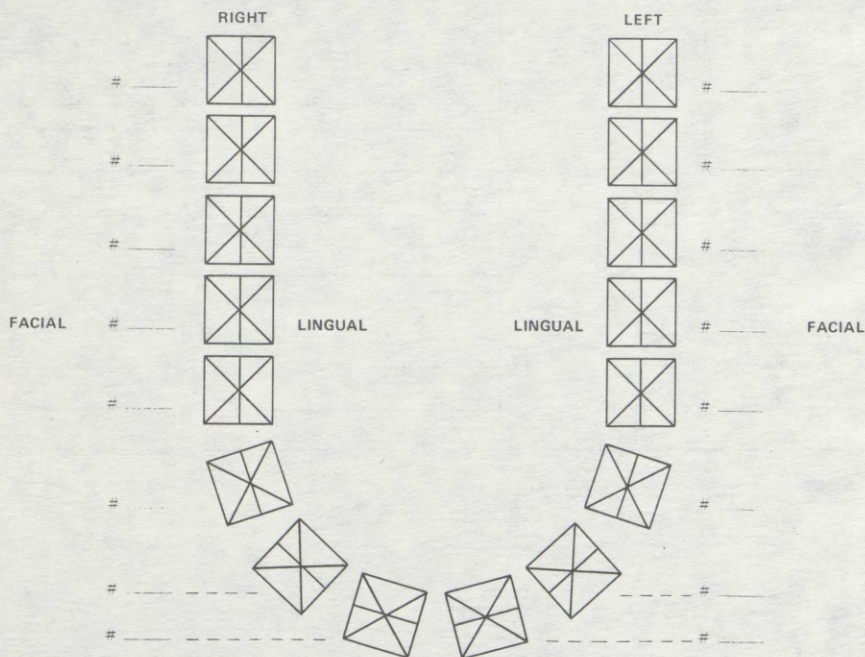
Record the location and extent of dental restorations, missing teeth and fixed prostheses in blue pencil. Fractured, missing, loose or temporary restorations should be shown in blue and outlined in red. Obvious caries should be charted in red. The presence of supernumerary, deciduous or partially erupted teeth should be noted in writing. NOTE: Chart findings visually without the use of radiographs and record the number of items charted in the space provided.

No. of items
charted

PERIODONTAL MEASUREMENTS

1. Circle quadrant assigned by examiner
- UR UL LL LR
2. Fill in tooth identification number for each tooth to be probed.
3. Probe six measurements for each tooth of sulcus and/or pocket depth, recording only those measurements of 3 mm or more.
- EXAMPLE 

EXAMPLE



Mr. ALTMAYER. As anyone who has read S. 500 can see, there is strong encouragement, if it becomes law, for HEW to work with the national accrediting institutions to set up minimum standards. It would be helpful, in that light, to see how much cooperation there has been to this point.

With respect to individuals that are certified through the ADAA accrediting arm, you have stated that those individuals are certified for competency and radiologic procedures. Therefore, were a patient to walk into a dental office and see a certification for the dental assistant on the wall, that individual could feel assured that that dental assistant, who might be taking X-rays, has the training and has demonstrated their competency?

Ms. BUTLER. Yes. We would be pleased if every dental assistant employed throughout the United States had this certification. But this is where our problem comes in. We see it every day.

Having an opportunity to work in an active office, I not only see it, I hear about it. Being of the older generation, there are many young dental assistants who are friends of mine and they chat with me quite a bit.

I had a dental assistant come to me recently. She was so happy because that very day her doctor told her that while he was out of the office for lunch, since she was so new on board as a dental assistant, that she and the other dental assistant could take turns taking X-rays of one another so that when he came back from lunch they could review them. She was real pleased because some were real good. He said, tomorrow or the next day you can repeat the process and we will get it right before it is all over with.

Mr. ALTMAYER. Dr. Brown, I realize that you would not condone that at all.

That concludes the questioning for this panel, unless there are some additional comments.

Mr. LEMOV. With respect to Mr. Villforth's testimony, to which I listened very carefully, there is one sentence that is perplexing us and that is his statement that the Department opposes S. 500 because it duplicates existing authority. We have reviewed S. 500. As attorneys, we have reviewed the House bills. We have reviewed the authority cited by Mr. Villforth, and it is simply not possible to conclude that the current authority duplicates S. 500 or any of the House bills. They include a sanction ultimately for failure to adopt a minimum standard, while the Department at present has no such sanction. That is my first point.

Second, Mr. Villforth referred repeatedly to either preliminary studies or at one point to a survey that the Bureau had done indicating 10 percent of the population dose would be administered by uncertified operators.

In view of the statistics that everyone seems to agree on, 40,000 to 70,000 uncertified operators in the country, it seems hard to accept that 10 percent figure. We have not seen that survey nor the preliminary figures referred to which seem to suggest that training and certification, which we all agree is essential, is not very important, or not as important as perhaps environment or rules of the work place. We certainly would like to see those surveys and have a chance to comment on them before that kind of statistic is placed in the record.

Mr. ALTMAYER. That is an excellent point, and we will request that survey and the verifying information from Mr. Villforth.

I thank you all very much.

Could Mr. Donohue, Mr. Alexander, and Mr. Stanton come back, please?

We appreciate your indulgence.

Senator Randolph asked me to note, Mr. Alexander, that the committee appreciates your testimony and your statement for the record. The area of nuclear medicine is a relatively new area in which many of us are not well versed.

Of those practicing nuclear medicine technology in the Nation, what percentage are certified by nuclear medicine technology certification boards?

Mr. ALEXANDER. About 75 percent.

Mr. ALTMAYER. Mr. Alexander, how many States require licensure and formal training for nuclear medicine technologists and how consistent are the standards in those States that do?

Mr. ALEXANDER. As far as I know, there are currently seven States that have or will have licensure. There is no consistency or uniformity. A specific case in point: If you had a passing score in the State of New Jersey of 70, and in Kentucky of 75, and you made a score of 74 in New Jersey, you would have to retake the certification in order to work in Kentucky.

Mr. ALTMAYER. Does your membership express concern with respect to the variance among the States that do have licensing requirements, inasmuch as it deters their ability to move from one State to another and find employment as a nuclear medicine technologist?

Mr. ALEXANDER. Yes, very much concern. I believe that the way to countermand that would be to accept our national certification as a standard.

Mr. ALTMAYER. Do the Federal agencies with jurisdiction over nuclear medicine require all technologists to be certified or only to have formal training and on-the-job experience?

Mr. ALEXANDER. I think in order to answer that question, you have to relate this to Federal agencies which already regulate us; namely, the big one is the Nuclear Regulatory Commission, which regulates us as far as regulating the use of pharmaceuticals.

I think you might say that this would be analogous to the situation faced by the radiologic technologists. If that is a proper assumption, then we have indeed already met the standards of what S. 500 is trying to do.

Mr. ALTMAYER. To be more direct, for instance, under Federal reimbursement programs where nuclear medicine technology may be involved, is it required that those technologists be certified by your Board?

Mr. ALEXANDER. Yes, sir.

Mr. ALTMAYER. Again, Mr. Alexander, is the practice of nuclear medicine limited to hospitals accredited by the Joint Commission on Accreditation of Hospitals, or is it also practiced in nonaccredited hospitals, clinics and physicians' offices?

Mr. ALEXANDER. That is a very hard question to answer and I do not really know the answer to it. If you check the JCAH nuclear medicine standards, they State that every hospital must have nu-

clear medicine services available for its patient population. So I would say that by this methodology, many of these patients may be referred to an accredited hospital for service.

To our best knowledge, in my immediate area, for example, all are credentialed for JCAH.

Mr. ALTMAYER. Within this situation where you may have a hospital that is not accredited by the JCAH, it is possible that they may have individuals operating in nuclear medicine who are not certified?

Mr. ALEXANDER. It is possible; that is right.

Mr. ALTMAYER. If I could turn now to Mr. Stanton.

Mr. Stanton, do you feel that the States have the necessary manpower and resultant expertise to develop standards for licensure and accreditation?

Mr. STANTON. I hardly think that it is up to any individual State, as has been evidenced by the somewhat—diversity in the programs that exist.

I hardly think that the individual States are the ones who should be stuck with, if you will, proposing standards; and that has been evidenced by the 10 jurisdictions that now have standards, and they do have conflicting points about them. That is precisely why the conference in general and the credentialing task force in particular support S. 500, simply because it brings a degree of uniformity to the credentialing program.

As far as the States having sufficient personnel, you did not mention funds, but I will mention funds. They kind of go hand in hand.

The blanket answer is, probably not. I realize there is a grant mechanism for State programs. However, the grant mechanism does not appear to go far enough as it stands. I cannot speak for every State, but a 50-percent grant to run a credentialing program probably means that the program will not be done at all.

Mr. ALTMAYER. Would you approximate for the committee the cost of putting a State licensing and accreditation program into place? I realize that is a difficult question, but based upon possibly your experience in States that you have programs, could you work up any estimate?

Mr. STANTON. I doubt that I could get you a seat-of-the-pants estimate. I would be pleased to go back to the Credentialing Task Force and see if they have any work. Probably, the best answer is a cost per licensee or certificate, or something such as that. I am sure it would vary greatly.

Mr. ALTMAYER. That would be helpful, if you could possibly check with your colleagues on that.

[The following was received for the record:]

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

a. Includes travel and salary. Does not include data processing, printing, overhead, or duplicating. Total estimated figure \$72,000

b. (Fiscal '79 figures given) Estimated program cost for 1980 is \$733,358. Recovery will be \$380,000 or 52%.

c. State law requires certifying boards to be self-supporting.

d. Does not include data processing, printing, overhead, or duplicating.

e. \$10,000 goes to Bureau of Licensing and Collection for receiving applications and fees and preparing and mailing out certificates.

f. Significant funds (\$200,000) have been collected from Jan. 1979 to April 1980. Majority of this fund is in reserve for production of a workbook. No testing has been done yet.

Mr. ALTMeyer. A followup question to that, and again we might have the same response, would it be safe to assume that once a program was put into operation, that the revenues from licensees would be sufficient to cover the continuing operating costs of that program in a State?

Mr. STANTON. I have heard a comment—I have forgotten from whom—that approximately a 50-percent realization of the total program costs is obtained from the fee schedule. We do run a fee schedule in our own State, not for that, but for licensing of radiologic material users and registration of X-ray machines, and our cost realization is somewhere in the range of 35 to 45 percent.

Mr. ALTMeyer. Mr. Donohue, I believe that you have addressed yourself to that point earlier. Could you possibly make a comment?

Mr. DONOHUE. The total cost of operation in the State of California for their entire program of radiation control is almost \$1,500,000. However, that includes not just the moneys associated with credentialing of the technologists and the programs relative to that, but also the inspections of machines, et cetera. The infusion of the certification added some \$800,000 to the already budgeted program of which the receipts coming in are over \$900,000 from the registration of operators, et cetera, in the State of California. It is not a cost figure in the State of California as the figure I have for 1977 in their report to the legislature—excuse me—the report on August 24, 1979, to the legislature.

Mr. ALTMeyer. Mr. Stanton, as an individual who has contact with all the States through the conference, please inform us why the States are reticent to enact licensure laws. What are the constraining parameters?

Mr. STANTON. I have been thinking about that, and I can come up with four reasons.

No. 1—not necessarily in this order, but, No. 1 is insufficient funds and/or personnel; No. 2 seems to be a question in individual States as to whether the certification program should be in: A, radiology; B, a State licensing program simply for radiologic technology; C, an umbrella licensing agency.

The third reason why I believe States are reticent to adopt those things is the question as to whether certification brings with it a concomitant radiation exposure reduction as evidenced by what Mr. Villforth said, the fact that there appears to be not a great deal of less exposure for any given radiographic procedure from credentialed versus noncredentialed operators.

Finally, a past history of pressure on state legislatures from voluntary credentialing groups which are already organized in States and feel that it would be a duplication of effort.

Mr. ALTMeyer. Would Mr. Alexander or Mr. Donohue care to comment on that question. Why have States been apparently reticent to enact licensure laws?

Mr. ALEXANDER. As relates to nuclear medicine technology, again we feel very, very strongly, as the States do, that we are already covered adequately by existing Federal regulatory agencies.

Mr. ALTMeyer. Mr. Stanton, earlier, Mr. Villforth, Director of the Bureau of Radiological Health, testified that HEW has existing authority to effectuate the purposes of S. 500. Mr. Lemov also directed a comment to that assertion by Mr. Villforth.

Generally, however, based upon your experience in the area of radiologic medicine, would you have any reason to believe that BRH or HEW will actively pursue the issue of radiologic health with the States in the foreseeable future?

Mr. STANTON. Of radiological health in general, or credentialing in particular?

Mr. ALTMAYER. Credentialing in particular.

Mr. STANTON. I see no reason why that will not be the case.

We, the States, who had generally a good working relationship with the Bureau of Radiological Health in the past—however long they have been in existence. We have cooperated in the BENT, DENT, and other quality assurance programs.

Prior to the moratorium on credentialing legislation, several States participated with the Bureau in the formation of the model regulation and, again, the Credentialing Task Force of the conference, which is composed of State members, has already drawn up model standards, so to speak, in conjunction with the Bureau.

Yes, I think the cooperation is ongoing and will continue.

Mr. ALTMAYER. Would you like to comment, Mr. Donohue?

Mr. DONOHUE. No.

Mr. ALTMAYER. Mr. Alexander?

Mr. ALEXANDER. No.

Mr. ALTMAYER. Mr. Donohue, an estimated 45,000 to 70,000 uncertified individuals are currently operating X-ray equipment in the Nation.

How would you advise the committee to provide an opportunity for those individuals to become certified?

Mr. DONOHUE. As was alluded to earlier, the 10 States currently having licensure have quite a diversity in their mechanisms for implementation of the law. However, all of them developed mechanisms relevant to either proficiency testing apparatus and/or education with a written testing tool. Others have identified grandfathering mechanisms and such.

I would assume that the other States therefore involved with enactment following S. 500 would also provide such activities and mechanisms for people currently in the profession to meet the criteria established under minimum standards.

Mr. ALTMAYER. Also, Mr. Donohue, what percentage of graduates from accredited programs seek certification from the American Registry of Radiologic Technologists, and what percentage of those obtain certification?

Mr. DONOHUE. The percentage of graduates in approved schools that seek certification fall in the range between 95 and 98 percent of graduates. Of that figure, some 90 percent of those taking the examination pass the examination the first time taken.

Mr. ALTMAYER. Mr. Donohue, it is estimated that there are approximately 850 accredited radiologic technology programs in the United States.

Do you have an estimate of the number of nonaccredited programs?

Mr. DONOHUE. I really don't have an estimate of the nonaccredited programs because there are no specific vehicles to investigate or to find that out. However, I know the State of California, in the State of California, following the implementation of their particu-

lar law, there were a total of some 47 schools of medical assisting, dental assisting, et cetera, who applied for approval of their programs and when a number of them, when they found out the criteria they would have to establish to have approval withdrew applications. But now there is a total of some 39 such programs that are not fully accredited as far as a 2-year AMA-approved program, but the State certified programs in the State of California.

Mr. ALTMAYER. Mr. Alexander, in the Society of Nuclear Medicine, of the institutions that are certified—we know that there are a number of institutions certified.

Are there also institutions giving instruction in nuclear medicine technology that are not certified?

Mr. ALEXANDER. A prerequisite to take the certification boards is that you come from a CAHEA-approved program. I believe that currently we have about 144 approved training programs, and I think there are somewhere in the neighborhood of 40 that are being reviewed now for final approval.

Mr. ALTMAYER. You had stated earlier that approximately 75 percent of the practicing nuclear technicians are certified. Of the remaining 25 percent, would it be safe to assume that a number of those have received their training at an institution that was not certified?

Mr. ALEXANDER. I think it would be safer to restate that there are individuals taking on-the-job training, which is an important vehicle, I believe.

Mr. ALTMAYER. Mr. Donohue, to your knowledge, have studies been conducted which compare the amount of exposure for specific radiologic procedures performed by certified and noncertified X-ray operators; and could you comment upon that?

Mr. DONOHUE. I believe Mr. Villforth earlier alluded to several studies, the NEXT, which makes a comparison between credentialed and noncredentialed, the scope of which seems to identify that, No. 1, credentialed operators were not working to their maximum capacity or safe relationship. However, also clearly pointed out was that the noncredentialed operators were doing poor activities. There is a similar report from the State of California, referred to as the California limited permit survey, or CALIPSUR, which identifies some conclusions. This compared their validation studies to those of NEXT, predicated on the view that NEXT is a valid method to determine safe operating practices. Then from these results, it is concluded that the California limited permittees demonstrated a proficiency in their category of work that is at least comparable with and, in some cases, better than, credentialed operators. Therefore the Department's regulation of the limited permit training program has achieved its goals set forth by the 1969 California Legislature.

That goal was to protect the public from unnecessary and excess use of ionizing radiation.

Mr. ALTMAYER. Mr. Donohue, in addition to being president of the American Society of Radiologic Technologists—you are also from California.

Would you make any observations on the cost impact of the California program which is the most extensive in the country since its inception?

More specifically, we are all aware that there is a cost impact in the administration of the program.

Is there also a cost saving from reduction in unnecessary or repeat X-rays as a result of their licensure program?

Mr. DONOHUE. Mr. Joseph Ward, who is the department chief of the Department of Health of the State of California, in testimony given in July—July 24, 1979, before the House Committee on Oversight Hearings on Excessive and Unnecessary Ionizing Radiation, identified cost savings to the public of some \$400,000 since the enactment of the legislation out in California and again, in their report to the legislature on August 24, 1979, I would quote from the study, and I will make a copy available to the committee.

The research and planning of the California Medical Association has studied the overall cost of medicine in California, and relative indices for various physician services, radiologic services, et cetera. Their study indicates that during the interval, December 1976 to June 1977, overall physician fees increased 92 percent, while those for radiologic services increased only 59.2 percent.

Further analysis of the early data indicates that this did not cause an abnormal increase in the cost of radiologic services.

Mr. ALTMAYER. I would like to thank all of the witnesses for their testimony and for your time.

For the other witnesses' information, the record will remain open until April 11 if you care to submit any additional statements or any additional points you would like to make with respect to any issues that were raised this morning that you are not prepared to address now.

[The following was received for the record:]

UP-DATE OF THE
RADIOLOGIC TECHNOLOGY REPORT
TO THE 1976 CALIFORNIA LEGISLATURE

8/24/79

I. Background

The Radiologic Technology Act of 1969 declared that the people of this state should be protected from excessive and improper exposure to ionizing radiation. It further defined the purpose of the Act as establishing standards of education, training, and experience for persons who use X-rays on human beings. The Act was to be operative only until January 1, 1976.

In 1974, legislation was introduced to, among other things, delete the expiration date of the Act. At the direction of the legislature, a report was submitted outlining the progress of the Certification Unit of the Radiologic Health Section, Department of Health, in carrying out the mandate of the Act. As a result of the 1974 legislation, the expiration date was not deleted but extended until January 1, 1980.

Legislation has again been introduced to extend the Act and contained herein is a summary of the 1976 Legislative Report on Radiologic Technology, up-dated to reflect recent program accomplishments.

II. Program Progress

A. Licentiates of the Healing Arts

The Act makes it unlawful for any licentiate of the healing arts to administer or supervise the use of X-rays on humans unless such person has been certified by the Department. To be eligible for a certificate the individual must possess a valid California professional healing arts license and pass an examination on the fundamentals of radiation protection for the patient and operator.

Provision has been made to recognize persons certified by an examining board in radiology (American Board of Radiology and the American Osteopathic College of Radiology) and for the granting of a certificate to persons who previously operated or supervised the operation of X-ray equipment ("grandfather" provision). Also, licensed dentists were exempt from the Act, as they are covered by the Dental Practice Act.

Accomplishments to date, are as follows:

1. Some 13,282 licentiates have been certified, including 9,682 MD's and osteopaths, 2,776 Chiropractors, and 824 podiatrists.
11,549 MD's - 2,500 - 8,253; DC - 2,535; DPM - 754
2. The California qualifying radiation protection test has been incorporated in the national board test administered by the National Board of Podiatry Examiners and the state board exam given by the State Board of Chiropractic Examiners.

3. A comprehensive syllabus on "Diagnostic X-Ray Radiation Protection" has been developed and is distributed to all licentiate candidates taking the certifying examination.
4. A curriculum for training in radiological sciences has been developed for guidance of California chiropractic schools.

B. Certified Radiologic Technologists

A certified radiologic technologist may engage in the full range of diagnostic or therapeutic X-ray practice, providing they have been issued an appropriate certificate by the Department. To be eligible for a certificate, an individual must complete a two-year course of instruction which includes as a minimum, 450 hours of classroom training (including 54 hours of radiation protection) and 2000 hours of clinical education. In addition, they must pass an examination dealing with the practical and theoretical aspects of administering X-rays and on radiation protection procedures for patient and operator.

Again, provisions have been made for reciprocity and "grandfathering" of qualified technologists.

Accomplishments to date, are as follows:

1. Some 13,808 technologists have met all requirements and have been certified to administer or use X-rays on humans.
2. The certifying examination is now administered once each month instead of semi-annually and this procedure has eliminated the problem of unqualified persons being given temporary authorization to operate X-ray units while awaiting examination.
3. Over 95% of the California candidates passed the 1976 national certification exam administered by the American Registry of Radiologic Technologists; whereas, the national average is only 81%.
4. During the period March 1977 to date, some 705 candidates have taken the California fully certified radiologic technology examination and 578 passed ($578/705 = 82\%$).

C. Limited Permit X-Ray Technicians

To accomodate the needs for X-ray operators in non-radiologist offices and departments, the limited permit X-ray technician program was established. The program represents a new concept in radiation control regulation and is unique to California. Whereas the certified radiologic technologist is authorized to perform the full range of X-ray procedures, the limited permit X-ray technician is only allowed to conduct diagnostic or therapeutic radiologic technology limited to the

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performance of specific radiographic procedures or the application of X-rays to specific areas of the human body, providing they have been issued a permit by the Department. To be eligible for a limited permit, an individual must complete as a minimum, 100 hours of classroom training and up to 12 months of supervised clinical training. They are also required to pass an appropriate examination.

Since this program is unique to California, no reciprocity requirement was considered. However, provision has been made for the "grandfathering" of qualified X-ray technicians.

Accomplishments to date include:

1971 - 3,600; 1972 - 5,011; 1973 - 7,794

1. Some 4,936 Technicians have met all applicable requirements and have been issued a limited permit to administer X-rays to a specific portion of the human body (1,843 have a single permit and 3,093 have a dual permit).
1,469 2,727
2. Minimum training standards and associated curriculum requirements have been established and adopted for schools teaching limited-permit X-ray technology.
3. All schools training candidates for the state limited permit examination have been inspected:
 - a. 43 schools have been approved (36 proprietary, 6 commerial medical assisting schools, 1 public school system, 8 community college programs, and 1 correspondence school course - University of California Independent Study Division).
 - b. 42 X-ray programs of substandard training have been disapproved.
4. Training manuals have been developed and published to make available to all X-ray operators instruction and illustrations designed to reduce patient and operator exposure to ionizing radiation.
5. Field experience conducted by a group of California limited permittees were compared with data compiled by the Federal Bureau of Radiological Health and shows that the limited permit X-ray technicians perform as safely in their category as does the average credentialed (certified) radiologic technologists in the nation.

D. On-the-Job Training Program

The Radiologic Technology Act was amended in 1973 and authorized the Department to approve a licentiate of the healing arts to give on-the-job training to a limited permit radiologic technology student. The on-the-job training (OJT) is limited to one year and there can be no more than one trainee per licentiate.

Diagnostic CR Schools: University Hospital - 4
Community College/Hospital - 21
Hospital - 21
Total: 46
Correctional Institutions - 3
Grand Total: 49

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An on-the-job trainee receives the clinical training from a licentiate of the healing arts on a one-to-one basis, but the didactic (i.e., classroom) training must be given by the licentiate (referred to as "OJT only") or taken in an approved school. An analysis of the didactic training for the 243 trainees currently enrolled in the OJT program and comparison with the didactic training distribution discussed in the 1976 report is displayed in the following table:

TABLE 1
OJT DIDACTIC TRAINING

Source of Training	1976 Report		Present	
	Participants	%	Participants	%
OJT Only	123	14.4	14	6
Commercial Schools	594	69.4	108	44
Podiatric College	76	9.0	21	9
Community Colleges	51	6.0	39	16
UC Extension Program	10	1.2	61	25

As indicated, the shift has been from "OJT only" and the commercial schools to the UC extension home-study program and the community colleges. The reasons are primarily monetary, since a student can enroll in a community college virtually tuition free or in the UC program for \$150.00, as opposed to the \$1,000 to \$1,800 tuition at a commercial school. With regard to the drop in "OJT only" enrollments, the ease and convenience of the UC home-study course convinces most doctors that they could better use their time without impairing the quality of the students didactic training.

As far as examination performance is concerned, during the period 4 March 1974 through June 1977 the following completed their OJT program and took the state examination:

	Number of Candidates	June 1977 Passed	Number Passed	Percent Passed
1979 Jan - not available OJT Only	63	67	37	59
Commercial Schools	857	276	518	60
Podiatric Colleges	46	—	27	59
Community Colleges	209	100	160	77
UC Extension Program	101	233	91	90
Total:	1,276	906	833	65%

As shown, the UC Extension home-study course has been the most effective program in preparing graduates for the state examination. The community colleges are also effective in preparing their students and there is basically no difference in the performance of those who complete the "OJT only" program or the commercial school graduates.

Jan. 1978 to present Total: 442; Number passed 244 - 55%

Further analysis of the 243 trainees enrolled in the OJT program reveals: (1) 90% are women, of which over half are married and one-third are 30 years of age or older, and (2) 15% of the students have Spanish surnames and 2.5% oriental surnames.

In other words, in addition to being economical and providing an income while learning, the limited permit/on-the-job training program is a way for minorities, married women, and persons over 30 years of age to enter a profession that can provide a meaningful livelihood.

E. Correctional Institution Programs

3. *Fortuna* *will*

Programs have been established in four correctional institutions in the state to train inmates as radiologic technologists and limited permit technicians. However, at the present time only three programs are operational. The programs are required to meet the same training standards as the commercial schools and colleges throughout the state.

The primary purpose of the program is to provide for qualified technologists and technicians inside the prison to administer and use X-rays on fellow inmates. In addition, this training provides the inmate with knowledge and experience which can be used upon their release.

The program has been successful in that there is keen competition among the inmates to participate in the training and this is reflected in their performance in the state examination. Since May 1975, some 59 inmates have completed their training and 57 (57/59 = 97%) passed the state examination on their first try. Further, in reviewing the program at the California Mens Colony, San Luis Obispo, and the Correctional Institution at Corona, we find that of the 74 inmates who were trained and certified, and subsequently released, 49 (49/74 = 66%) are gainfully employed in the radiologic technology field, 2 (2/74 = 3%) are back in prison, and 23 (23/74 = 31%) whose whereabouts are unknown. Thus it appears the radiologic technology training enables the parolees to find gainful employment upon their release.

F. Compliance with the Radiologic Technology Act

Although the Radiologic Technology Act does not specifically authorize inspection for the purpose of verifying compliance with the certification laws, citations are issued by state inspections during the course of their radiation machine inspection program. Since 1973, some 555 individuals have been cited for operating or supervising the operation of an X-ray machine without being certified by the Department. Of these, all but 5 (a dermatologist and his two technicians, and a podiatrist and his technician) have acknowledged the requirements and applied for and received proper certification. The Department's Office of Legal Affairs and the State Attorney General are in the process of bringing injunctive action against the two licentiates who have refused to comply with the

G. Medical/Radiology Costs and the Certification Program

The Bureau of Research and Planning of the California Medical Association, has studied the overall cost of medicine in California and relative indices for various specific types of physicians services: medical procedures (visits, consultations, electrocardiograms, etc.), surgical procedures, radiologic services, and pathology services. Their study indicates that during the interval December 1966 to June 1977, overall physicians fees increased 92.7%, while those for radiology services increased only 59.2%. Further, an analysis of the yearly data indicates that enactment of the Radiologic Technology Act did not cause an abnormal increase in the cost of radiologic services.

III. Conclusions

- A. Administration of the Act has been successful in protecting the health of the public by educating and training X-ray supervisors and operators in proper techniques to reduce the exposure to medical X-rays. Some 32,026 persons have been certified since the effective date of the Act.
- B. Standards have been established for schools teaching X-ray operators and those schools unable to meet these standards have been dropped from the program.
- C. The monthly examining of candidates in lieu of semi-annual testing has eliminated the problem of unqualified persons being given temporary authorization to operate X-ray units while awaiting examination.
- D. California certified radiologic technologists perform well above the national average on the national certification examination.
- E. California's limited permit X-ray technicians perform as safely in their category as does the average credentialed radiologic technologists in the nation.
- F. The on-the-job training program is an economical method for minorities, married women, and persons over 30 years of age to enter the X-ray technology profession. In addition, it provides income while they are learning.
- G. The University of California Extension Program home-study course has been an effective means of preparing limited permit candidates for the state examination.
- H. The limited permit candidates who receive their didactic training from the licentiate supervising their OJT clinical training ("OJT only"), perform equally as well on the state examination as graduates from the commercial schools.

- I. The radiologic technology training program at the Corona, Vacaville, and San Luis Obispo correctional institutions provide a resource of qualified inmates to use X-rays inside the prisons and develops an employable skill which they can use when released.
- J. Virtually all persons cited for non-compliance with the Act take necessary action to correct the violation. However, the compliance program would be more effective if provision was made in the law to inspect to ensure supervisors and operators were complying with certification requirements.
- K. Enactment of the Radiologic Technology Act of 1969 has not caused an abnormal increase in the cost of radiology services.

IV. Program Goals

As indicated, considerable progress has been made toward establishing standards of education, training and experience for persons who use X-rays on humans in California. Nevertheless, we are not only working to continue the effective program that has been established, but we are working toward initiation of the following:

- A. Although the "Minimum Standards for Diagnostic Radiologic Technology Programs" have been developed and adopted, California schools must still adhere to the essentials established by the Joint Review Committee (JRC) of the American Medical Association, Council on Medical Education. JRC approval is necessary so the California school graduates can sit for the American Registry of Radiologic Technologists (ARRT) examination. To avoid this duplication of certification, we are working with JRC to establish their recognition of our standards and acceptance of our inspection team report and school approval.
- B. At the present we recognize certification by the ARRT as being reasonably equivalent to the standards established by the Department. Accordingly we will issue a California certificate to a holder of an ARRT certificate, if they meet the reciprocity standards we have established. Presently, a holder of a California certificate cannot obtain an ARRT certificate by reciprocity; however, we are working with the ARRT Board of Directors to initiate a policy of true reciprocity.
- C. In our continuing effort to reduce patient and operator exposure, we are developing standards of training and experience regarding the use of a fluoroscope by a certified radiologic technologist. Previously this procedure was considered as patient diagnosis and as such was precluded by law. However, with the advent of electronic advances, the new cine recording devices makes it possible for the technologist to view the dynamic image and make appropriate video and/or X-ray recordings which can be subsequently reviewed and diagnosed by the physician/radiologist. Strict training and operational requirements are necessary to ensure adequate radiation safety for patient and operator.

- D. We are continually reviewing and revising all of our examinations to ensure they are compatible with new methods and procedures. In this regard, we are not only reviewing the questions, but in order to accomodate the large Spanish speaking population, we are translating the exam into Spanish. These technologists fluent in Spanish, but with limited command of the English language, could be tested for their knowledge of radiologic technology in their native tongue. These certified technologists are employed in facilities catering to a Spanish speaking clientele.

V. Recommendations

The Radiologic Technology Act should be extended so the people of California will continue to be protected from excessive and improper exposure to medical X-rays. To accomplish this, legislation should be enacted to, among other things, (1) delete the January 1, 1980 expiration date of the Act, (2) delete the expiration date of the on-the-job training of limited permit technicians, and (3) provide for inspection of operator and employee to determine certification violations. Hesitancy on the part of the legislature in enacting this legislation could seriously damage the established program continuity and overall program effectiveness.

ATTACHMENT C

REPORT ON
CALIFORNIA LIMITED PERMITTEE SURVEY
(CALIPERS)

4800 Limited Permits
13,000 CRT

Radiologic Health Section
California Department of Health

I. Objective

The goal of the California Limited Permittee Survey (CALIPERS) was to determine if the limited permittee performs routine X-ray examinations, authorized by his permit, to the same degree of proficiency in radiation protection procedures as does the credentialed operator (a certified radiologic technologist) for such examinations.

II. Experimental Plan

The survey was conducted on a random sample of persons holding limited permits who performed a series of simulated X-ray examinations in their place of employment. The protocol for the examinations and the processing of the resultant X-radiation data had been developed by the Task Force for the Nationwide Evaluation of X-Ray Trends (NEXT) under the joint sponsorship of the U.S. Department of Health, Education, and Welfare's Bureau of Radiological Health and the Conference of Radiation Control Program Directors. NEXT data accumulated over two years of sampling around the nation were available for comparison purposes. The experimental results from our CALIPERS group were furnished to the U.S. HEW Bureau of Radiological Health. Since the California version of NEXT involved a random sampling of operators, rather than facilities, the resulting data were identified by the Bureau of Radiological Health as "Modified NEXT" and stored in the computer separately. Subsequently, these data were compared with similar performances by selected groups from all of the states.

Selection of X-Ray Examinations

Of the 12 X-ray examinations conducted under the National Evaluation of X-Ray Trends (NEXT) program, only 4 were selected for comparison, i.e., chest, cervical spine, thoracic spine, and lumbosacral spine. The reason for such selection was (1) the X-ray examinations had to be within the California limited-permit categories and (2) within such constraints, national data in sufficient numbers to make reliable comparisons only existed for the examinations selected.

Sampling Process

The population to be sampled for testing and verification was chosen from the X-ray technicians who passed the 1974 California limited-permit examinations in the chest and musculoskeletal categories. Most of these technicians had been exposed to student training which was regulated by the Department. All had passed our examinations which were designed to verify their knowledge in designated limited X-ray procedures. It was assumed that if such persons performed as well as did the credentialed radiologic technologists in the nation, then California's limited-permit program had met its primary goal.

A questionnaire (following page) asking information about present X-ray employment was sent out to 345 limited-permit technicians who had passed the recent 1974 state examinations. The original mailing was done in February 1975. We were fortunate that 246, or 71 percent, had returned the questionnaire by April 1975 and were presently working as X-ray operators.

DEPARTMENT OF HEALTH

P STREET
SACRAMENTO, CALIFORNIA 95814

February 1975



SURVEY

We are uncertain about the employment opportunities and status of newly qualified persons in the field of radiologic technology. The candidates who passed the 1974 state examinations in radiologic technology have been chosen for this survey. Would you kindly complete this form and return it in the enclosed self-addressed envelope.

1. Indicate corrections to:

Your Name _____

Address _____

Telephone No. () _____

2. Are you working in the field of medical X-ray? ____ Yes ____ No

Employer's Name _____

Address _____

Telephone No. () _____

3. If you answered No to Item 2, in your experience are there X-ray employment opportunities available in your geographical area?

☐ Yes☐ No

Comments: _____

4. What are your normal work days?

- ☐ 5 days/wk starting on _____
- ☐ 6 days/wk starting on _____
- ☐ Part-time, _____ days/wk
- ☐ Other explain _____

5. Indicate your normal working hours:

- ☐ 8 AM to 5 PM
- ☐ _____ A/PM to _____ P/AM
- ☐ Other _____

6. Percent of workday using X-rays (circle approximate value)

100 75 50 25 10

7. Check the procedures which you normally perform:

- | | |
|--|---|
| ☐ Chest (heart and lungs) | ☐ Flat abdomen |
| ☐ Extremities | ☐ Upper gastrointestinal tract |
| ☐ Leg (podiatry) | ☐ Lower gastrointestinal tract |
| ☐ Cervical spine | ☐ Skull |
| ☐ Thoracic spine | ☐ Gallbladder |
| ☐ Lumbar spine | ☐ Intravenous pyelogram |
| ☐ Pelvis | ☐ Other (list below) |

Thank you for your cooperation.

Sincerely yours,

K. B. Fess, Chief
 Certification Unit
 Radiologic Health Section

Fifty limited-permit technicians who are authorized to perform chest radiography and 50 who are authorized to perform musculoskeletal radiography were selected by simple random sampling.

(Most limited-permit technicians who are authorized for musculoskeletal radiography are also authorized to perform chest radiography.) Of those selected in the random sample, 34 technicians had not responded to the questionnaire. Only nine of these technicians could be located by phone to obtain information for the survey.

Unexpectedly by June 10, 1975 (starting date of the survey), many of the permittees were no longer employed at the facility indicated on the questionnaire and could not be immediately located. Some were not performing either chest or musculoskeletal radiography; some could not get permission for a surveyor to enter the facility to make the survey.

In fact, only 45 of the original 100 permittees chosen in the random sample were actually surveyed. Substitutes were chosen at random from a back-up list of permittees who answered the original questionnaire. County distribution of technicians and type of X-ray examination performed were maintained.

Since the original random sample was changed by the entrance of 55 new names, there was concern that the group finally selected did not represent the population of the experimental group. Accordingly, an analysis of age, X-ray schooling, X-ray experience, and percent of work time devoted to X-ray was made of two groups -- (1) the initial 100 permittees chosen at random and (2) the 99 permittees of which 55 were chosen by the alternative scheme.

Comparisons of the four characteristics showed that the two samples were similar with respect to X-ray schooling, experience, and work time; however, average age was two years older in the original random sample. Since schooling, experience, and work time were almost the same, it was judged that the two-year difference in average age would not be a biasing factor.

Special Features

Generally, the conduct of the X-ray examinations was made in accordance with the routine procedures developed for NEXT. There were two basic modifications made, however.

First, the simulated X-ray examination was performed only by the selected individual. If such person was absent or sick, then a second appointment was made; however, one candidate failed to meet the commitment so there were only 99 persons in CALIPERS. No substitutions of candidates were made at the facility.

Second, upon completion of all the procedures the operator was asked to respond to three questions. These questions were designed to ascertain whether the technique used by the operator was based upon procedures learned in training or whether it was directed by the supervisor. Also it was of importance to discover if the operator knew what factors could be changed to reduce radiation exposure without affecting the quality of the radiograph.

DEPARTMENT OF HEALTH

714 P STREET
SACRAMENTO, CALIFORNIA 95814



Modified NEXT Survey - Certification Unit

A. Where did you learn how to manipulate technical factors?

- | | |
|---|----|
| ☐ formal X-ray course | 63 |
| ☐ on-the-job training (doctor) | 55 |
| ☐ detail men | 3 |
| ☐ trial and error | |
| ☐ other Explain: _____ | |

B. How do you determine the technical factors for each exam?

- | | |
|--|----|
| ☐ technique chart | 92 |
| ☐ doctor gives technique for each patient | 4 |
| ☐ guess (trial and error) | 5 |
| ☐ other Explain: _____ | 2 |

C. If the technique is specified, what changes would you recommend?

- | | |
|---|----|
| ☐ higher kilovoltage | 40 |
| ☐ higher mR | 1 |
| ☐ shorter time | 7 |
| ☐ no changes | 47 |
| ☐ other Explain: _____ | 7 |

The tabulated results of this questioning (previous page) are listed opposite each possible answer. In some cases two answers were given and since some examiners failed to ask for the most significant factor, both answers were recorded.

Although about 85 percent of the sample had received clinical training in a doctor's office, only half had learned manipulative techniques from the practitioner, which is evidence that formal training is effective in providing instruction of a practical nature.

~~From the answers in question "A",~~ it would seem that the bulk of the operators use a technique chart for guidance; however, by subsequent questioning over the telephone, it became evident that the technique charts used could be simply a list of technical factors locally produced by the chief technologist or the licentiate and these may differ considerably from the charts utilized in classroom or laboratory work.

It was heartening to note ~~from question "C"~~ that the new technicians were aware of the safety benefits of using higher kilovoltage and shorter times. Three of the miscellaneous comments recognized that the patient's conformation or condition could be important.

On the other hand, two persons felt that changing development conditions (of the film processing) could be beneficial. It was not clear if this comment referred to sight development (which is an improper adjustment) or if it meant that proper film development procedures would in turn cause a desirable change in the machine settings. One technician said

that the licentiate had required her to use certain technical factors but that if allowed to use her own judgment, she would have used machine settings recommended in training. The settings actually used were much too high, yielding a calculated 3,792 mR exposure at skin entrance for a lumbosacral examination!

Comparison Results

Initially, we planned to make a comparison of the relative performance of the CALIPERS group versus "All States" (certified operators in the United States). Later we felt that despite sparse data, the California credentialed operators would provide an interesting comparison. Finally, realizing that one of our criteria used for comparison was not available on the "All States" credentialed group, we selected a third group, the "All States" noncredentialed operators employed in offices of general practice. This latter group is representative of the employment situation of our limited-permittee group.

The possible health hazards inherent in X-rays give us reason for concern; therefore, the evaluation of operator performance focuses on radiation protection criteria. Criteria selected were (a) Exposure at Skin Entrance (ESE) and (b) Beam Area to Film Area ratio (BA/FA). The ESE measures the amount of radiation (milliRoentgens, mR) received at the skin, and so is a measure of whether an excessive radiation exposure is used to obtain a proper radiograph. The BA/FA is a factor which indicates the total area of the skin exposed compared with the size

of the film. A large factor means that more of the patient's body is needlessly exposed.

In each of the following tables, the column "CALIPERS" refers to the selected sample group of limited permittees; "Credentialed" means a fully qualified radiologic technologist certified by a state or a national credentialing agency; "General Practitioner's Office" means a noncredentialed operator working in the private office of a general practitioner. "Representative" data are derived from performances of all types of operators including practitioners. Data identified as "California" do not include the CALIPERS results; "All States" information is all selected data in the files including California operators, excluding CALIPERS.

Also, please refer to the footnotes where double stars (**) indicate that no assessment was made for statistical significance because of a small sample or because the standard error was too large with respect to the mean value.

In Tables I, II, and III, our limited permittee group had lower mean ESE values than any of the listed comparison groups and in most cases were significantly better as indicated by the single star (*). The mean ESE values on the exposures derived from the lumbosacral examinations (Table IV) are not statistically different between CALIPERS and any of the comparison groups.

Entrance Skin Exposure

Beam Area / Field Area

Using the criteria of beam area to film area ratio, the comparisons were somewhat disappointing. As shown in Table V, our group had mean BA/FA values comparable with the "California Representative" operators but less proficient than the California credentialed group, although not significantly so. Table V also shows that the CALIPERS group had a substantial advantage over all states noncredentialed operators who work in general practitioners' offices.

A further comparison was made on the effect of using an adjustable beam collimator. This device allows the operator to adjust the area of beam more precisely. As expected, the BA/FA ratio was reduced for chest examinations by about 15 percent. Since the majority of the credentialed operators work in a hospital facility (only one of the CALIPERS group was so employed), it was believed that differing work environments could distort the comparative data. Therefore, a selection of data was assembled from the computer on the California credentialed operators not in hospitals. The 14 cases (for chest radiography) so identified resulted in a mean BA/FA ratio of 1.77 which is virtually the same as the 1.81 value of our survey group.

For a final comparison data was obtained on the length of time the X-ray operators had been employed in radiologic technology. The reason for this review was twofold: (a) to verify our assumption that the CALIPERS group were relatively inexperienced and (b) to determine if the persons from "All States" had greater experience.

It seemed logical to assume that more experience should lead to better practices. The results in Table VI verify this on both expectations of experience level. However, it seems that from the previous tables on ESE, more experience is no guarantee of safer performance.

Conclusions

Predicated on the view that the use of the NEXT experiments is a valid method to determine safe operating practices of X-ray operators, then from these results it is concluded that the California limited permittees demonstrated a protection proficiency in their category of work that is at least comparable with, and in some cases better than, credentialed operators. Therefore, the Department's regulation of the limited-permit training program has achieved the goal set for it by the 1969 California Legislature.

It is also evident that more attention must be placed on enforcing the requirement to limit the X-ray beam to the area of clinical interest. This matter needs to be addressed through joint action under the X-ray machine compliance program and the X-ray training schools inspection program.

Table I

Estimated Mean Exposure at Skin Entrance for P/A Chest Films for California
CALIPERS and Selected Comparison Groups of NEXT Data

	Mean (mR)	STD Error	Number
CALIPERS, All	16.5	1.1	91
<u>COMPARISON GROUPS</u>			
All California			
Representative Data	26.9*	3.0	99
Credentialed Operators	31.1* ^v	4.2	68
All States			
Representative Data	24.3*	0.5	2,791
Credentialed Operators	24.6	4.0	1,674
Noncredentialed	28.0**	8.7	1,072
Credentialed Nonhospital	25.4	5.9	379
Noncredentialed Nonhospital	20.0	1.0	764
General Practitioners' Offices	23.4*	0.9	610

* Mean is significantly different from CALIPERS value at 95 percent confidence level.

** Tests of significance were not performed because the computed mean index was not considered reliable. For the mean index to be reliable, there must be at least 5 surveys and the standard error cannot exceed 25 percent of the mean index value.

ALARA

Table II

Estimated Mean Exposure at Skin Entrance for A/P Cervical Spine for California
CALIPERS and Selected Comparison Groups of NEXT Data

	Mean (mR)	STD Error	Number
CALIPERS, All	142.7	11.2	43
<u>COMPARISON GROUPS</u>			
All California			
Representative Data	327.2**	131.8	19
Credentialed Operators	291.9*	58.2	8
All States			
Credentialed Operators	<u>282.7</u>	44.3	133
Noncredentialed	<u>195.5*</u>	16.5	47
Credentialed Nonhospital	289.5*	51.7	66
Noncredentialed Nonhospital	191.4	28.5	37
General Practitioners' Offices	450.1**	246.8	10

* Mean is significantly different from CALIPERS value at 95 percent confidence level.

** Tests of significance were not performed because the computed mean index was not considered reliable. For the mean index to be reliable, there must be at least 5 surveys and the standard error cannot exceed 25 percent of the mean index value.

Table III

Estimated Mean Exposure at Skin Entrance for A/P Thoracic Spine for
California CALIPERS and Selected Comparison Groups of NEXT Data

	Mean (mR)	STD Error	Number
CALIPERS, All	574.7	73.1	40
<u>COMPARISON GROUPS</u>			
All California			
Representative Data	936.2**	285.0	5
Credentialed Operators	1,365.3**	201.2	3
All States			
Credentialed Operators	960.7*	13.9	72
Noncredentialed	646.5	129.5	19
Credentialed Nonhospital	976.9*	12.4	23
Noncredentialed Nonhospital	668.7	134.5	15
General Practitioners' Offices	964.6	221.0	5

* Mean is significantly different from CALIPERS value at 95 percent confidence level.

** Tests of significance were not performed because the computed mean index was not considered reliable. For the mean index to be reliable, there must be at least 5 surveys and the standard error cannot exceed 25 percent of the mean index value.

Table IV

Estimated Mean Exposure at Skin Entrance for A/P Lumbosacral Spine for
California CALIPERS and Selected Comparison Groups of NEXT Data

	Mean (mR)	STD Error	Number
CALIPERS, All	780.8	91.3	44
<u>COMPARISON GROUPS</u>			
All California			
Representative Data	759.0	55.7	75
Credentialed Operators	712.9	65.6	49
All States			
Credentialed Operators	829.1	71.6	734
Noncredentialed	613.0	74.0	232
Credentialed Nonhospital	840.3	83.3	306
Noncredentialed Nonhospital	641.2	84.9	164
General Practitioners' Offices	952.1	61.7	101

Table V

Estimated Mean Ratio of Beam Area to Film Area for California CALIPERS
and for Selected Comparison Groups of NEXT Data

	Mean Ratio Beam Area / Film Area (BA/FA)											
	CALIPERS			California Representative Data			California Credentialed Operators			All States Operators, GP Office		
	Mean	S.E.	N	Mean	S.E.	N	Mean	S.E.	N	Mean	S.E.	N
Chest (P/A)	2.06	0.15	91	2.08	0.18	99	1.71	0.18	68	3.18*	0.13	610
Cervical Spine (A/P)	1.40	0.13	43	1.58	0.19	19	1.07	0.16	8	1.76**	0.44	10
Thoracic Spine (A/P)	0.99	0.07	40	0.91	0.16	5	0.74**	0.21	3	1.34	0.33	5
Lumbosacral Spine (A/P)	1.09	0.07	44	1.03	0.07	75	0.93	0.06	49	1.09	0.05	101

* Mean is significantly different from CALIPERS value at 95 percent confidence level.

** Tests of significance were not performed because the computed mean index was not considered reliable. For the mean index to be reliable, there must be at least 5 surveys and the standard error cannot exceed 25 percent of the mean index value.

Table VI

Mean Years of Experience of Operators by Type of X-Ray Projection for the California CALIPERS and All States NEXT Data

Type of Exam	"All States" Credentialed Operators			"All States" Noncredentialed Operators			California "CALIPERS"		
	Mean	S.E.	No. of Cases	Mean	S.E.	No. of Cases	Mean	S.E.	No. of Cases
Chest (P/A)	10.48	0.21	1,610	9.58	0.26	1,047	3.80	0.43	91
Cervical Spine (A/P)	9.17	0.64	122	8.23	1.36	44	2.77	0.30	43
Thoracic Spine (A/P)	10.80	1.15	64	9.00	2.11	18	2.73	0.32	40
Lumbosacral Spine (A/P)	10.03	0.31	696	9.75	0.95	220	2.73	0.30	44



AMERICAN COLLEGE OF RADIOLOGY: 20 NORTH WACKER DRIVE CHICAGO, ILLINOIS 60606 (312) 236-4963
WASHINGTON OFFICE: 6900 WISCONSIN AVENUE CHEVY CHASE, MARYLAND 20015 (301) 654-6900

April 3, 1980

The Honorable Jennings Randolph
3203 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Randolph:

On behalf of the 14,000 physician, physicist, and resident members of the American College of Radiology, I appreciate this opportunity to provide the Subcommittee on Health and Scientific Research of the Senator Labor and Human Resources Committee with our views on S. 500, the Consumer-Patient Radiation Health and Safety Act. We respectfully request that this letter be included in the official record of the hearings which you will conduct on S. 500.

Briefly stated, the College opposes the enactment of S. 500 as drafted. We do not support mandatory licensure of radiologic technologists. On the basis of providing radiological services to the public, we question most of the suggested benefits of technologist licensure and feel that the disadvantages to the public health would outweigh any advantages which might accrue. Beyond the mandatory licensure issue, we oppose S. 500 because it contains extraneous provisions regarding physicians and performance standards which we think inappropriate.

Radiologists are physicians who specialize in the uses of x-rays and other forms of radiation for the diagnosis and treatment of disease. We use visual evidence produced on x-ray films, fluoroscopic images on videotapes or movies, various kinds of computed tomography scanners, radioactive materials and ultrasound sources to make diagnoses. Our responsibilities involve both the production of images and their interpretation as well as the treatment of many diseases, primarily cancer. Radiologists are assisted in the production of images and the delivery of radiation treatments by people who work as radiologic technologists. The technologist functions under the specific direction and supervision of the physician.

Most radiologic technologists have been recruited from among high school graduates. They have been educated in a basic 2 year hospital based certificate program. A small percentage earn an associate degree through a community college and some have achieved a baccalaureate degree. The existence of programs currently approved by the joint review committees and accredited by the American Medical Association can be attributed largely to the efforts of radiologists and technologists within the ACR and American Society of Radiologic Technologists (ASRT), respectively.

In the 1960's, the American Medical Association joined us in sponsoring the Joint Review Committee on Education in Radiologic Technology and the Joint Review Committee for Nuclear Medicine Technology to provide essentials and

guidelines for educational programs in schools for radiologic technology. The joint review committees arrange onsite inspections of each program and make recommendations for accreditation to the AMA. Requirements for physical facilities, instructors, training essentials and curricula are reviewed by the joint review committees. Some 1100 schools of radiologic technology now meet professional standards.

For some 55 years, the American Registry of Radiologic Technologists, sponsored by the ACR and ASRT, has offered voluntary examinations to the graduates of these schools who wish to attain professional credentials. For the past 15 years, the registry has made graduation from an approved school of radiologic technology a prerequisite for its examinations.

The medical practice acts of states allow physicians and certain other limited licensed health practitioners to use x-rays in the diagnosis and treatment of disease. There are no current federal or state prohibitions upon the purchase and ownership of medical x-ray machines by anyone. Thus, it is most difficult to provide accurate figures for the numbers of medical x-ray machines and the numbers of persons who operate them. Based upon state registration requirements and upon data gathered in national surveys, the Bureau of Radiological Health estimates that between 130,000 and 170,000 persons are employed as x-ray operators in medical facilities. The registry currently lists more than 124,000 active registrants and estimates that 80 percent or more are employed. The active state programs estimate that as many as 10,000 persons hold state licenses but not the voluntary registry certification.

From the Bureau of Radiological Health study entitled, Nationwide Evaluation of X-ray Trends (NEXT), we note that about 82 percent of x-ray exams are performed by credentialed technologists. The study also estimated that approximately 90 percent of the medical radiation dose to the U.S. population is delivered by credentialed operators. Another BRH study, the 1970 national x-ray exposure study, showed that about two thirds of all medical x-ray examinations are performed under the supervision of radiologists. Most radiologists will employ only registered technologists. Thus, we may conclude that there are a relatively small number of x-ray examinations performed by uncredentialed technologists and the majority of uncredentialed operators are employed by physicians and other health practitioners who perform a limited range and quantity of procedures.

The American College of Radiology represents about 90 percent of the nation's radiologists and several hundred radiological physicists. The Council, with representatives of all state chapters, is the College's policy making body. In 1973, the council voted to oppose mandatory licensure of radiological technologists. At the basis of the College position is the belief that the current voluntary credentialing mechanism which has been in operation for some 55 years, has been effective in the development of a corps of competent and well motivated radiologic technologists. It does not follow that compulsory standards are more effective by virtue of their mandatory nature.

In 1975, the College and the American Society of Radiologic Technologists conducted a study of the impact of mandatory licensure on the practice of radiologic technology. The study reviewed the programs of New York, New Jersey and California; three states where licensure laws had been in effect for several years. The investigation was unable to demonstrate any significant difference in the levels of radiation exposure to patients between the states where credentialing or licensure was mandatory and thus, presumably universal,

and comparable states where credentialing was voluntary and less than universal.

A copy of the study is attached. We believe credentialed people are certain to be superior, but we could not demonstrate that compulsory licensure programs made any difference.

The results of the 1975 study, coupled with the fact that 82 percent of all x-ray exams are performed by credentialed technologists, leads us to question whether or not the public interest will be served by a federal requirement for mandatory state licensure programs.

The disadvantages of licensure appear to outweigh its advantages. With federal minimum licensure standards, voluntary credentials attained by the majority can be made universal and compulsory. However, physicians in underserved areas, rural clinics and hospitals may be unable to recruit licensed technologists. Should mandatory licensure deprive some communities of vital radiological services?

Mandatory federal licensure standards impose great rigidity upon any group. The size of the group from whom potential technologists can be drawn is circumscribed. Exceptions to the basic qualifications are difficult to grant. Alternative routes to competence, other than formal instruction in an approved school, are seldom allowed. A federal proficiency test requirement as a basis for private employment in itself poses an inherent contradiction.

Similarly, licensure on the basis of a single standard approximating the current mechanism would have little effect upon radiation safety practices in the absence of strong and continuing supervisory interest by radiologists. Furthermore, the imposition of licensure as a basis for entering the radiologic technology field would not relieve the medical profession of its current obligations for recruitment and training.

Thus looking at the matter broadly, the College must conclude that the advantages which mandatory federal licensure standards embody is more than offset by the disadvantages inherent in federal controls.

While opposing enactment of federal mandatory licensure for radiologic technologists, the College, nevertheless, cooperated with the Bureau of Radiological Health of the Food and Drug Administration to develop a model radiologic technologists licensure law for states. A copy of this model state law is attached. The College also seeks to assist its members and state chapters, who wish to take part in state or local level discussions of this matter.

Our previous comments have concentrated on the establishment of federal standards for radiologic technologists. We now offer comments on other provisions of the bill, which are of concern to the College. They are as follows:

1. Section 103(a) provides for the licensure of "all personnel administering radiation." We object strenuously to the inclusion of physicians under this section.
2. Section 104(3) provides the definition of a medical practitioner. The inclusion of chiropractic in this definition is not only erroneous but also contrary to accepted medical terminology.

3. Section 104(4) provides the definition of radiation. This definition is technically deficient. Who administers natural radiation?
4. The College strongly urges the deletion of Part II from the legislation. Part II is badly drawn and confused. The federal medical and dental radiation guidelines proposed by Section 121(a) are an intrusion into the practice of medicine and outside the purview of any legislation. In any regard, the Environmental Protection Agency lacks the expertise to undertake such a task. Section 121(b) (2) and (3) are redundant. The therapeutic application of radiation and the application of radiation in the treatment of disease are one and the same. Nuclear medicine procedures have diagnostic as well as therapeutic applications.
5. Section 131(a) requires minimum standards for the accreditation of "educational institutions conducting education programs in radiological services." There is no need to apply such standards to medical schools as suggested by this provision.
6. Section 132(a) would allow for the establishment of various levels of specialization. Such an effort would be unnecessary and result in considerable confusion.

In conclusion, we believe that there is not demonstrated a public health problem which would be remedied by the imposition of federal minimum standards for state licensure of radiologic technologists. The advantages of universality which would result from federal minimum standards would be outweighed by the disadvantages therein. Should the committee determine otherwise, we strongly urge that S. 500, with its provisions relating to physicians and performance standards, not be the vehicle for such an action.

Sincerely,

Helmut A. Mueller

Helmut A. Mueller, M. D.
Chairman,
Commission on Human Resources

HAM/alr

cc: ACR Board of Chancellors
Mr. William C. Stronach
Mr. J.T. Rutherford

Enclosures

Mr. ALTMAYER. These hearings are hereby adjourned, subject to the call of the Chair.

[Whereupon, at 12:45 p.m., the hearing adjourned, to reconvene subject to the call of the Chair.]

○