

**REGULATION OF RADIATION
MACHINES AND PERSONNEL**

House Bill 4898
Sponsor: Rep. Larry Julian
Committee: Health Policy

Complete to 9-2-03

A SUMMARY OF HOUSE BILL 4898 AS INTRODUCED 6-26-03

The bill would amend the Public Health Code to revise the regulations pertaining to radiation machines and to establish educational and training standards for personnel, other than licensed members of the healing arts, who use a radiation machine for human screening or for diagnostic or therapeutic purposes.

Sections 13523 and 13531 of the code would be repealed, although most of Section 13523 would be incorporated into the newly created Part 135A, entitled "Radiation Machine Control". Several provisions relating to radiation machines and mammography currently contained in Part 135, Radiation Control, would be moved to the new part. In addition, the Radiation Advisory Board would be eliminated and replaced with the Ionizing Radiation Advisory Committee. Details of the significant changes follow.

Ionizing Radiation Advisory Committee. The bill would repeal the provision that created the Radiation Advisory Board and established its powers and duties. Instead, the director of the Department of Consumer and Industry Services (CIS) would have to appoint an Ionizing Radiation Committee. The committee would have to furnish the department with technical advice considered to be desirable or which the department may request on matters relating to the radiation machine control program.

Part 135, Radiation Control. Generally, the provisions relating to the regulation of radioactive materials or sources of ionizing radiation would be unchanged. However, the bill would make some editorial changes to update and clarify the provisions. Also, the bill would move provisions pertaining to radiation machines and mammography to Part 135A, Radiation Machine Control, which would be created by the bill.

Part 135A, Radiation Machine Control. Virtually all of Section 13523, which would be repealed by the bill, would be incorporated into this new part. Changes to provisions currently in Section 13523, but which would be moved into the new part, are as follows:

1) For a radiation machine to be authorized by the department, certain requirements must be met for both the facility and personnel operating the machine. The bill would:

-Clarify that a facility must designate a licensed allopathic physician (M.D.) or osteopathic physician (D.O.) as the lead interpreting physician.

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- Require a facility to submit, as part of the application for authorization and subsequent renewals, evidence of a department-approved surety bond, secured trust fund, or other suitable secured instrument or mechanism that would insure proper patient mammography record and film handling and transfer in the advent of a facility closure. The facility would have to attest that the method chosen would completely cover all costs involved and would be adjusted accordingly, as needed.

- Require an interpreting physician to be certified in radiology by either the allopathic or osteopathic board of radiology, to have been eligible for certification in radiology or diagnostic radiology for not more than three years (instead of the current two years), or be certified or determined to be qualified by another professional organization approved by the department (instead of the Radiation Advisory Board). Also, the interpreting physician would have to complete not less than three months (instead of two) of formal training in reading mammograms. Further, the bill would add that the physician would have to have initial training that included documented interpretation of not less than 240 mammographic examinations in the six months immediately preceding the performance of independent interpretation. The current requirement to interpret not less than 520 mammographic examinations each year would be eliminated and replaced with a requirement that the interpreting physician must interpret or multi-read not less than 960 mammographic examinations during the 24 months immediately preceding the date of the mammography facility's annual inspection or the last day of the calendar quarter preceding that inspection, or any day in between those dates. The facility would have to choose one of those three dates to determine the 24-month period. Other requirements currently required by the health code for interpreting physicians would remain the same.

2) The bill would require the department to inspect a radiation machine not later than 90 days (instead of 60) after the initial authorization and annually thereafter.

In addition, the bill would add the following changes to current provisions that would be moved to the new part:

- Currently, the code contains several exemptions from the prohibition on manufacturing, producing, transporting, transferring, disposing of, acquiring, owning, possessing, or using an unregistered radiation machine. The bill would keep the current exemptions (although the exemptions that apply to radiation machines would be moved into the new Part 135A), and would add an exemption for non-ionizing radiation sources or devices, unless specifically addressed by departmental rule.

- The department would have to develop rules specifying the minimum training and performance standards for an individual using a radiation machine for human screening or for diagnostic or therapeutic purposes.

- The department could develop and conduct programs for evaluation and control of hazards associated with the use of non-ionizing radiation devices.

- Definitions for "mammography", "mammography authorization", and "mammography interpreter" would be deleted from Part 135 and placed in Part 135A. Many other terms would

be defined in both Part 135 and Part 135A. The bill would add two new definitions to Part 135A. “Non-ionizing radiation” would mean sound waves; radar waves; microwaves; radio frequency fields; magnetic fields; and visible, infrared, or ultraviolet light. A “non-ionizing radiation device” would mean a machine or device that produced non-ionizing radiation in intensities or frequencies subject to regulation by departmental rule. The definition for “radiation machine” would be moved to Part 135A and amended to mean a machine or device that produced ionizing radiation in energies or intensities subject to regulation by departmental rule. The definition for “mammography system”, originally contained in one of the repealed sections, would be amended to mean the radiation machine used for mammography; automatic exposure control devices; imaging systems; image processor; darkroom; and viewboxes.

-A municipality or a department, agency, or official of a municipality could not license, regulate, or require the registration of a radiation machine or a non-ionizing radiation device.

Training standards for x-ray technicians. Facilities would be required to ensure that all individuals, except licensed members of the healing arts, who use radiation machines for human screening or for diagnostic or therapeutic purposes be adequately instructed in safe operating procedures. The bill would establish minimum standards for training and competency for limited scope x-ray operators, comprehensive scope x-ray operators, dental x-ray operators, and veterinary x-ray operators.

Limited scope operators. The scope of practice would be limited to only those procedures listed in the bill, e.g., certain x-ray examinations of the extremities, spine, and chest. Operators would have to complete 48 hours of didactic instruction in a formal program that included subjects specified in the bill, successfully complete a department-approved certification examination developed by the American Registry of Radiologic Technologies (ARRT) in at least one but no more than three of the limited scope categories, complete one month of clinical training in proper imaging procedures as listed in the bill, and obtain at least 15 hours of continuing education in any three-year period in the technical and/or clinical aspects of x-ray examinations in their scope of practice. A person who had been actively working as a medical x-ray operator for at least six months before the bill’s effective date would not have to complete the clinical training, but would have to document completion of the didactic training requirements and the examination requirements within three years of the bill’s effective date.

Comprehensive scope operators. Comprehensive scope operators, who are not limited in scope of practice for performing medical x-rays, would have to meet prerequisite qualifications, receive training, and demonstrate competence as specified in the bill. This would include meeting the standards for issuance of a registration certificate as a registered technologist from the American Registry of Radiologic Technologists (ARRT) or other recognized nationally accreditation body. Meeting those standards would be prima facie evidence that an individual met the bill’s requirements. Also, an individual whose scope of practice included specialties such as computed tomography or radiation therapy would have to meet the standards for issuance of advanced certification in that specialty from the ARRT. Operators would also have to complete 48 hours of didactic instruction in a formal program that included subjects specified in the bill and complete one month of clinical training in proper imaging procedures as listed in the bill.

Dental x-ray operators. With the exception of licensed dentists, dental x-ray operators would have to complete at least 36 hours of didactic instruction in a department-approved formal program in subjects required by the bill. Graduates of a department-approved dental hygiene or dental assisting program certified by the Commission on Dental Accreditation would be considered to have met the preceding requirements. Those operators who had been actively working as a dental x-ray operator for at least six months prior to the bill's effective date would have to document completion of the didactic training requirements within three years of the bill's effective date.

Veterinary x-ray operators. Unless under the direct supervision of a licensed veterinarian, a veterinary x-ray operator would have to complete at least 36 hours of didactic instruction in a department-approved formal program in the subjects required by the bill. Individuals who had been actively working as a veterinary x-ray operator for at least six months prior to the bill's effective date would have to document completion of the didactic training requirements within three years of the bill's effective date.

Penalties. Penalties for a violation of Part 135A or a rule promulgated under it, or failure to comply with a condition of registration, would be the same as the current penalties for a violation of Part 135. A violation would be a misdemeanor punishable by imprisonment for not more than 180 days, a fine of not more than \$10,000, or both. A court could fine a person not more than \$2,000 for each violation, and each day a violation continued would be considered a separate violation. Further, as with a violation or impending violation of Part 135, the attorney general, at the department's request, could apply to the appropriate circuit court for an order enjoining the act or practice or for an order directing compliance with Part 135A or any associated departmental rules or orders.

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