

HOUSE BILL No. 6103

September 22, 1992, Introduced by Reps. Berman, Gubow, Byrum, Brown, Dobronski, Barns, Ciaramitaro, Gire, Pitoniak, Kilpatrick, VanSingel and Dolan and referred to the Committee on Public Health.

A bill to amend sections 13501, 13522, and 13523 of Act No. 368 of the Public Acts of 1978, entitled as amended "Public health code," section 13501 as amended and section 13523 as added by Act No. 56 of the Public Acts of 1989 and section 13522 as amended by Act No. 88 of the Public Acts of 1992, being sections 333.13501, 333.13522, and 333.13523 of the Michigan Compiled Laws.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1 Section 1. Sections 13501, 13522, and 13523 of Act No. 368
2 of the Public Acts of 1978, section 13501 as amended and section
3 13523 as added by Act No. 56 of the Public Acts of 1989 and sec-
4 tion 13522 as amended by Act No. 88 of the Public Acts of 1992,
5 being sections 333.13501, 333.13522, and 333.13523 of the
6 Michigan Compiled Laws, are amended to read as follows:

1 Sec. 13501. (1) As used in this part:

2 (a) "General license" means a license, effective pursuant to
3 rules promulgated by the department without the filing of an
4 application, to transfer, acquire, own, possess, or use quanti-
5 ties of, or devices or equipment utilizing, radioactive
6 material.

7 (b) "Ionizing radiation" means gamma rays and x-rays, alpha
8 particles, beta particles, high speed electrons, neutrons, pro-
9 tons, high speed ions, and other high speed nuclear particles.

10 (c) "Mammography" means radiography of the breast for the
11 purpose of enabling a physician to determine the presence, size,
12 location, and extent of cancerous or potentially cancerous tissue
13 in the breast.

14 (d) "Mammography authorization" means authorization under
15 section 13523 to use a radiation machine for mammography.

16 (E) "MAMMOGRAPHY INTERPRETER" MEANS AN INDIVIDUAL WHO MEETS
17 THE REQUIREMENTS SET FORTH IN SECTION 13523(2)(I) AND IS RESPON-
18 SIBLE FOR EVALUATING AND INTERPRETING MAMMOGRAPHIC IMAGES.

19 (F) "MAMMOGRAPHY SUPERVISOR" MEANS AN INDIVIDUAL WHO MEETS
20 THE REQUIREMENTS SET FORTH IN SECTION 13523(2)(H) AND IS RESPON-
21 SIBLE FOR QUALITY CONTROL, RADIATION SAFETY, AND TECHNICAL
22 ASPECTS OF ALL X-RAY EXAMINATIONS AND PROCEDURES RELATED TO MAM-
23 MOGRAPHY INCLUDING, BUT NOT LIMITED TO, THE SUPERVISION OF INDI-
24 VIDUALS WHO OPERATE MAMMOGRAPHY MACHINES OR OTHERWISE PERFORM
25 MAMMOGRAPHIC SERVICES.

26 (G) ~~-(e)-~~ "Person" means a person as defined in section 1106
27 or a governmental entity.

1 (H) ~~(f)~~ "Radioactive material" means a solid, liquid, or
2 gas material which emits ionizing radiation spontaneously.

3 (I) ~~(g)~~ "Radiography" means the making of a film or other
4 record of an internal structure of the body by passing x-rays or
5 gamma rays through the body to act on film or other image
6 receptor.

7 (J) ~~(h)~~ "Registration" means registration of a source of
8 ionizing radiation in writing with the department.

9 (K) ~~(i)~~ "Source of ionizing radiation" means a device or
10 material that emits ionizing radiation.

11 (L) ~~(j)~~ "Specific license" means a license issued to use,
12 manufacture, produce, transfer, receive, acquire, own, or possess
13 quantities of, or devices or equipment utilizing, radioactive
14 material.

15 (2) In addition, article 1 contains general definitions and
16 principles of construction applicable to all articles in this
17 code.

18 Sec. 13522. (1) In promulgating rules pursuant to this
19 part, the department shall avoid requiring dual licensing, inso-
20 far as practical. Rules promulgated by the department may pro-
21 vide for recognition of other state or federal licenses as the
22 department considers desirable, subject to registration require-
23 ments prescribed by the department. A person who, on the effec-
24 tive date of an agreement under Act No. 54 of the Public Acts of
25 1965, being sections 3.801 to 3.802 of the Michigan Compiled
26 Laws, possesses a license issued by the federal government for a
27 source of ionizing radiation of the type for which the state

1 assumes regulatory responsibility under the agreement, is
2 considered to possess an identical license issued pursuant to
3 this part, which license expires either 90 days after receipt of
4 a written notice of termination from the department or on the
5 date of expiration stated in the federal license, whichever
6 occurs first.

7 (2) The department may promulgate rules to establish a
8 schedule of fees to be paid by applicants for licenses for radio-
9 active materials and devices and equipment utilizing the radioac-
10 tive materials.

11 (3) Except as otherwise provided in this subsection, the
12 department may promulgate rules to establish a schedule of fees
13 to be paid by an applicant for a license for other sources of
14 ionizing radiation and the renewal of the license, and by a
15 person possessing sources of ionizing radiation that are subject
16 to registration. The registration or registration renewal fee
17 for a radiation machine registered under this part is \$45.00 for
18 the first veterinary or dental x-ray or electron tube and \$25.00
19 for each additional veterinary or dental x-ray or electron tube
20 annually, or \$75.00 annually per nonveterinary or nondental x-ray
21 or electron tube. The department shall not assess a fee for the
22 amendment of a radiation machine registration certificate. In
23 addition, the department shall assess a fee of \$100.00 for each
24 followup inspection due to noncompliance during the same year.
25 The department may accept a written certification from the
26 licensee or registrant that the items of noncompliance have been
27 corrected instead of performing a followup inspection. If the

1 department does not inspect a source of ionizing radiation for a
 2 period of 5 consecutive years, the licensee or registrant of the
 3 source of ionizing radiation does not have to pay further license
 4 or registration fees as to that source of ionizing radiation
 5 until the first license or registration renewal date following
 6 the time an inspection of the source of ionizing radiation is
 7 made.

8 (4) A fee collected under this part shall be deposited in
 9 the state treasury and credited to the general fund of this
 10 state.

11 (5) Except as otherwise provided in subsection (6), the
 12 department shall assess the following nonrefundable fees in con-
 13 nection with mammography authorization:

14	(a) Inspection, per radiation machine.....	\$ 100.00
15	(b) Reinspection for reinstatement of mammo- 16 phy authorization, per radiation machine.....	\$ 100.00
17	(c) Department evaluation of compliance with 18 section 13523(2)(a), first radiation machine.....	\$ 500.00 700.00
19		
20	Each additional radiation machine.....	\$ 400.00 600.00.
21		

22 (6) If an applicant for mammography authorization submits an
 23 evaluation report issued by the American college of radiology
 24 that evidences compliance with section 13523(2)(a), the depart-
 25 ment shall waive the fee under subsection (5) for department
 26 evaluation of compliance with that provision.

1 (7) Except as otherwise provided in subsections (3) and (6),
2 the department shall not waive a fee required under this
3 section.

4 (8) The department shall adjust on an annual basis the fees
5 prescribed by subsections (3) and (5) by an amount determined by
6 the state treasurer to reflect the cumulative annual percentage
7 change in the Detroit consumer price index, not to exceed 5%. As
8 used in this subsection, "Detroit consumer price index" means the
9 most comprehensive index of consumer prices available for the
10 Detroit area from the bureau of labor statistics of the United
11 States department of labor.

12 Sec. 13523. (1) Beginning ~~60 days after the effective date~~
13 ~~of this section~~ AUGUST 16, 1989, a person shall not use a radi-
14 ation machine to perform mammography unless the radiation machine
15 is registered with the department under department rules for reg-
16 istration of radiation machines and is specifically authorized
17 under this section for use for mammography.

18 (2) The department shall authorize a radiation machine for
19 use for mammography if the radiation machine meets all of the
20 following standards:

21 (a) The radiation machine meets the criteria for the
22 American college of radiology mammography accreditation program
23 as adopted in June, 1987 and amended in September, 1988 and pub-
24 lished by the American college of radiology, which criteria are
25 incorporated by reference. The department shall make copies of
26 those criteria available to the public and may by rule adopt
27 modified criteria. The department may accept an evaluation

1 report issued by the American college of radiology as evidence
2 that a radiation machine meets those criteria. If at any time
3 the department determines that it will not accept any evaluation
4 reports issued by the American college of radiology as evidence
5 that a radiation machine meets those criteria, the department
6 shall promptly notify each person who has registered a radiation
7 machine under this part and the rules promulgated under this
8 part.

9 (b) The radiation machine, the film or other image receptor
10 used in the radiation machine, and the facility where the radi-
11 ation machine is used meet the requirements set forth in depart-
12 ment rules for radiation machines.

13 (c) The radiation machine is specifically designed to per-
14 form mammography.

15 (d) The radiation machine is used exclusively to perform
16 mammography.

17 (e) The radiation machine is used in a facility that does
18 all of the following:

19 (i) At least annually has a qualified radiation physicist
20 provide on-site consultation to the facility, including, but not
21 limited to, a complete evaluation of the entire mammography
22 system to ensure compliance with this part and the rules promul-
23 gated under this part.

24 (ii) Maintains for at least 7 years records of the consulta-
25 tion required in subparagraph (i) and the findings of the
26 consultation.

1 (f) The radiation machine is used according to department
2 rules on patient radiation exposure and radiation dose levels.

3 (g) The radiation machine is operated only by an individual
4 who can demonstrate to the department that he or she is specifi-
5 cally trained in mammography or an individual who is a physician
6 or an osteopathic physician, ~~Beginning~~ AND BEGINNING 60 days
7 after the rules required under section 13521(3) are promulgated,
8 the radiation machine is operated only by an individual who can
9 demonstrate to the department that he or she meets the standards
10 required by those rules or an individual who is a physician or an
11 osteopathic physician. If the department promulgates emergency
12 rules covering the subject matter described in section 13521(3),
13 then for a period beginning 60 days after those emergency rules
14 are promulgated and ending on the day that those emergency rules
15 cease to be in effect, the DEPARTMENT SHALL AUTHORIZE A RADIATION
16 MACHINE FOR USE FOR MAMMOGRAPHY IF THE radiation machine is oper-
17 ated only by an individual who can demonstrate to the department
18 that he or she meets the standards required by those emergency
19 rules or an individual who is a physician or an osteopathic
20 physician.

21 (H) THE RADIATION MACHINE IS OPERATED ONLY UNDER THE SUPER-
22 VISION OF A MAMMOGRAPHY SUPERVISOR WHO MEETS ALL OF THE FOLLOWING
23 REQUIREMENTS:

24 (i) IS A PHYSICIAN OR OSTEOPATHIC PHYSICIAN LICENSED UNDER
25 ARTICLE 15.

26 (ii) SPECIALIZES IN RADIOLOGY AND IS CERTIFIED BY THE
27 AMERICAN BOARD OF RADIOLOGY OR THE AMERICAN OSTEOPATHIC BOARD OF

1 RADIOLOGY OR ANOTHER PROFESSIONAL ORGANIZATION APPROVED BY THE
2 DEPARTMENT.

3 (iii) HAS DOCUMENTATION SATISFACTORY TO THE DEPARTMENT THAT
4 THE INDIVIDUAL HAS SUCCESSFULLY COMPLETED NOT LESS THAN 40 HOURS
5 OF CONTINUING MEDICAL EDUCATION APPROVED BY THE DEPARTMENT IN
6 MEDICAL RADIATION PHYSICS, MEDICAL RADIATION EFFECTS, MEDICAL
7 RADIATION PROTECTION, AND THE TECHNICAL ASPECTS OF MAMMOGRAPHY.

8 (iv) SUCCESSFULLY COMPLETES NOT LESS THAN 15 HOURS OF CON-
9 TINUING MEDICAL EDUCATION APPROVED BY THE DEPARTMENT EVERY 3
10 YEARS AFTER THE EFFECTIVE DATE OF THE AMENDATORY ACT THAT ADDED
11 THIS SUBDIVISION IN MAMMOGRAPHY INTERPRETATION, TECHNICAL ASPECTS
12 OF MAMMOGRAPHY, AND OTHER SUBJECTS RELATED TO MAMMOGRAPHY, AND
13 HAS DOCUMENTATION OF SUCCESSFUL COMPLETION THAT IS SATISFACTORY
14 TO THE DEPARTMENT.

15 (I) THE RESULTS OF EACH MAMMOGRAPHY PERFORMED WITH THE RADI-
16 ATION MACHINE ARE INTERPRETED BY A MAMMOGRAPHY INTERPRETER WHO
17 MEETS ALL OF THE FOLLOWING REQUIREMENTS:

18 (i) THE REQUIREMENTS OF SUBDIVISION (H)(i), (ii), AND (iv).

19 (ii) HAS HAD NOT LESS THAN 2 MONTHS OF FORMAL, DOCUMENTED
20 TRAINING APPROVED BY THE DEPARTMENT IN READING MAMMOGRAMS, WITH
21 SPECIFIC INSTRUCTION IN MEDICAL RADIATION PHYSICS, MEDICAL RADI-
22 ATION EFFECTS, AND MEDICAL RADIATION PROTECTION. THE DEPARTMENT
23 MAY ACCEPT TIME SPENT IN A RESIDENCY PROGRAM SPECIFICALLY LIMITED
24 TO MAMMOGRAPHY IF THE INDIVIDUAL HAS DOCUMENTATION OF THE RESI-
25 DENCY PROGRAM THAT IS SATISFACTORY TO THE DEPARTMENT.

26 (iii) INTERPRETS NOT LESS THAN 520 MAMMOGRAPHIC EXAMINATIONS
27 EACH YEAR.

1 (iv) MAINTAINS ANNUAL RECORDS SATISFACTORY TO THE DEPARTMENT
2 OF OUTCOME DATA THAT RELATES POSITIVE MAMMOGRAMS TO BIOPSIES DONE
3 AND THAT INDICATES THE NUMBER OF CANCERS DETECTED.

4 (3) The department may issue a nonrenewable temporary autho-
5 rization for a radiation machine for use for mammography if addi-
6 tional time is needed to allow submission of evidence satisfac-
7 tory to the department that the radiation machine meets the stan-
8 dards set forth in subsection (2) for approval for mammography.
9 A temporary authorization granted under this subsection during
10 the first 18 months after ~~the effective date of this section~~
11 ~~shall be~~ JUNE 16, 1989 ARE effective for no more than
12 12 months. A temporary authorization granted under this subsec-
13 tion after ~~18 months after the effective date of this section~~
14 ~~shall be~~ FEBRUARY 16, 1991 ARE effective for no more than
15 6 months. The department may withdraw a temporary authorization
16 ~~prior to~~ BEFORE its expiration if the radiation machine does
17 not meet 1 or more of the standards set forth in subsection (2).

18 (4) To obtain authorization from the department to use a
19 radiation machine for mammography, the person who owns or leases
20 the radiation machine or an authorized agent of the person shall
21 apply to the department for mammography authorization on an
22 application form provided by the department and shall provide all
23 of the information required by the department as specified on the
24 application form. A person who owns or leases more than 1 radi-
25 ation machine used for mammography shall obtain authorization for
26 each radiation machine. The department shall process and respond
27 to an application within 30 days after the date of receipt of the

1 application. Upon determining to grant mammography authorization
2 for a radiation machine, the department shall issue a certificate
3 of registration specifying mammography authorization for each
4 authorized radiation machine. A mammography authorization is
5 effective for 3 years.

6 (5) No later than 60 days after initial mammography authori-
7 zation of a radiation machine under this section, the department
8 shall inspect the radiation machine, except that ~~for a period~~
9 ~~not to exceed 1 year after the effective date of this section~~
10 UNTIL JUNE 16, 1990, the department may conduct that initial
11 inspection later than 60 days after initial mammography authori-
12 zation under this section. After that initial inspection, the
13 department shall annually inspect the radiation machine and may
14 inspect the radiation machine more frequently. The department
15 shall make reasonable efforts to coordinate the inspections under
16 this section with the department's other inspections of the
17 facility in which the radiation machine is located.

18 (6) After each satisfactory inspection by the department,
19 the department shall issue a certificate of radiation machine
20 inspection or a similar document identifying the facility and
21 radiation machine inspected and providing a record of the date
22 the radiation machine was inspected. The facility shall post the
23 certificate or other document near the inspected radiation
24 machine.

25 (7) The department may withdraw the mammography authoriza-
26 tion for a radiation machine if it does not meet 1 or more of the
27 standards set forth in subsection (2).

1 (8) The department shall provide an opportunity for a
2 hearing in connection with a denial or withdrawal of mammography
3 authorization.

4 (9) Upon a finding that a deficiency in a radiation machine
5 used for mammography or a violation of this part or the rules
6 promulgated under this part seriously affects the health, safety,
7 and welfare of individuals upon whom the radiation machine is
8 used for mammography, the department may issue an emergency order
9 summarily withdrawing the mammography authorization of the radi-
10 ation machine. The department shall incorporate its findings in
11 the order and shall provide an opportunity for a hearing within 5
12 working days after issuance of the order. The order ~~shall be~~
13 IS effective during the proceedings.

14 (10) If the department withdraws the mammography authoriza-
15 tion of a radiation machine, the radiation machine shall not be
16 used for mammography. An application for reinstatement of a mam-
17 mography authorization shall be filed and processed in the same
18 manner as an application for mammography authorization under sub-
19 section (4), except that the department shall not issue a rein-
20 stated certificate of mammography registration until the depart-
21 ment receives the reinspection fee required under section
22 13522(5), inspects the radiation machine, and determines that it
23 meets the standards set forth in subsection (2). The department
24 shall conduct an inspection required under this subsection no
25 later than 60 days after receiving a proper application for rein-
26 statement of a mammography authorization.

1 (11) In addition to the penalties provided in section 13535
2 and the reinspection fee required under section 13522(5), if a
3 person violates subsection (1), the department may impose an
4 administrative fine against the owner of the radiation machine
5 or, if a lessee of the radiation machine has effective control of
6 the radiation machine, the lessee, of not more than \$500.00 for
7 each calendar week in which a mammography is performed in viola-
8 tion of subsection (1). If a person continues to violate
9 subsection (1) for a period of 2 weeks after a fine is imposed
10 under this subsection, the department shall post a conspicuous
11 notice on the unauthorized radiation machine and at the entry to
12 the facility where the radiation machine is located warning the
13 public that the facility is performing mammography using a radi-
14 ation machine that is a substantial hazard to the public health.

15 (12) The department may promulgate rules necessary to imple-
16 ment this section after consultation with the radiation advisory
17 board established under section 13531.

18 (13) As used in this section:

19 (a) "Radiation machine" means a machine, other than those
20 exempted by department rule, that emits ionizing radiation.

21 (b) "Mammography system" means the radiation machine used
22 for mammography; automatic exposure control devices; films,
23 screens, and cassettes; image processor; darkroom; and
24 viewboxes.