

SENATE BILL No. 525

May 28, 2003, Introduced by Senators GARCIA, BARCIA and HAMMERSTROM and referred to the Committee on Health Policy.

A bill to amend 1978 PA 368, entitled "Public health code," by amending sections 13501, 13505, 13506, 13515, 13517, 13521, 13522, 13525, 13535, and 13536 (MCL 333.13501, 333.13505, 333.13506, 333.13515, 333.13517, 333.13521, 333.13522, 333.13525, 333.13535, and 333.13536), sections 13501 and 13522 as amended by 1994 PA 100 and section 13521 as amended by 1989 PA 56, and by adding part 135A; and to repeal acts and parts of acts.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

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

2 (a) "Department" means the department of environmental
3 quality.

4 (b) ~~—(a)—~~ "General license" means a license, effective
5 pursuant to rules promulgated by the department without the
6 filing of an application, to transfer, acquire, own, possess, or

1 use quantities of, or devices or equipment utilizing, radioactive
2 material.

3 **(c)** ~~—(b)—~~ "Ionizing radiation" means gamma rays and x-rays,
4 alpha particles, beta particles, high speed electrons, neutrons,
5 protons, high speed ions, and other high speed nuclear
6 particles.

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

11 ~~—(d) "Mammography authorization" means authorization under~~
12 ~~section 13523 to use a radiation machine for mammography.~~

13 ~~—(e) "Mammography interpreter" means an individual who meets~~
14 ~~the requirements set forth in section 13523(2)(g) and is~~
15 ~~responsible for evaluating and interpreting mammographic images.~~

16 **(d)** ~~—(f)—~~ "Person" means a person as defined in section 1106
17 or a governmental entity.

18 **(e)** ~~—(g)—~~ "Radioactive material" means a solid, liquid, or
19 gas material ~~which~~ **that** emits ionizing radiation
20 spontaneously.

21 **(f)** ~~—(h)—~~ "Radiography" means the making of a film or other
22 record of an internal structure of the body by passing x-rays or
23 gamma rays through the body to act on film or other image
24 receptor.

25 **(g)** ~~—(i)—~~ "Registration" means registration of a source of
26 ionizing radiation in writing with the department.

27 **(h)** ~~—(j)—~~ "Source of ionizing radiation" means a device or

1 material that emits ionizing radiation.

2 **(i) ~~(k)~~** "Specific license" means a license issued **by the**
3 **department** to use, manufacture, produce, transfer, receive,
4 acquire, own, or possess quantities of, or devices or equipment
5 utilizing, radioactive material.

6 (2) In addition, article 1 contains general definitions and
7 principles of construction applicable to all articles in this
8 code.

9 Sec. 13505. A person shall not manufacture, produce,
10 transport, transfer, dispose of, acquire, own, possess, or use a
11 radioactive material or other source of ionizing radiation unless
12 **the person is** licensed ~~—, registered,—~~ or exempted **under this**
13 **part or is licensed or exempted** by the department in accordance
14 with rules promulgated ~~pursuant to~~ **by the department under** this
15 part. ~~—or unless exempted by this part.—~~

16 Sec. 13506. Sections 13505 and 13515 to 13536 do not apply
17 to the following sources or conditions, except as noted:

18 ~~(a) Electrical or other equipment or material not intended~~
19 ~~primarily to produce radiation which, by nature of design, does~~
20 ~~not produce radiation at the point of nearest approach at a~~
21 ~~weekly rate higher than 1/10 the appropriate limit generally~~
22 ~~accepted by the medical profession for any critical organ~~
23 ~~exposed.—The production testing or production servicing of the~~
24 ~~equipment is not exempt.—~~

25 ~~——(b) A radiation machine during process of manufacture or in~~
26 ~~storage or transit.—The production testing or production~~
27 ~~servicing of the machine is not exempt.—~~

1 **(a)** ~~-(e)-~~ A radioactive material while being transported
2 under the jurisdiction of and in conformity with regulations
3 adopted by the nuclear regulatory commission or the United States
4 department of transportation, or their successors, specifically
5 applicable to the transportation of ~~such~~ **the** radioactive
6 material.

7 **(b)** ~~-(d)-~~ Sound waves, radio waves, and visible, infrared, or
8 ultraviolet light.

9 **(c)** ~~-(e)-~~ A production or utilization facility, as defined in
10 the ~~federal~~ atomic energy act of 1954, ~~42 U.S.C. 2011 to 2281~~
11 **chapter 1073, 68 Stat. 919**, or a source of ionizing radiation
12 used in or in connection with the operation of a production or
13 utilization facility pursuant to a license from the federal
14 nuclear regulatory commission or **its** successor ~~thereto~~ **agency**.
15 However, the department may collect radiation data and perform
16 environmental monitoring in connection with the operation of the
17 facility in accordance with this part.

18 **(d)** ~~-(f)-~~ A source material, by-product material, or special
19 nuclear material over which the federal nuclear regulatory
20 commission or ~~a~~ **its** successor ~~thereto~~ **agency** has exclusive
21 regulatory jurisdiction under the ~~federal~~ atomic energy act of
22 1954, **chapter 1073, 68 Stat. 919**, which jurisdiction has not been
23 transferred to this state pursuant to an agreement under ~~Act~~
24 ~~No. 54 of the Public Acts of 1965, being sections 3.801 and 3.802~~
25 ~~of the Michigan Compiled Laws~~ **1965 PA 54, MCL 3.801 to 3.802**.

26 Sec. 13515. (1) The department is designated as the
27 radiation control agency of this state and shall coordinate

1 radiation control programs of state departments acting within
2 their statutory authorities.

3 (2) Pursuant to rules promulgated under this part, the
4 department shall require licensing ~~and registration~~ of
5 radioactive materials and other sources of ionizing radiation.

6 (3) The department shall develop and conduct programs for
7 evaluation and control of hazards associated with the use of
8 radioactive materials and other sources of ionizing radiation.

9 Sec. 13517. (1) The department may enter at all reasonable
10 times upon private or public property upon which sources of
11 ionizing radiation are reasonably believed to be located, with
12 the permission of the owner or custodian ~~thereof~~ **of the**
13 **property**, to determine if there is compliance with or violation
14 of this part or a rule **promulgated under this part** or **compliance**
15 **with or a violation of a license issued under this part.**

16 (2) If the department has reasonable **cause** or probable cause
17 to believe that a violation of this part or a rule **promulgated**
18 **under this part** or **a violation of a license issued under this**
19 **part** is being committed on private or public property or that
20 there exists on the property evidence of a violation, and
21 permission to enter ~~thereon~~ **on the property** is denied by the
22 owner or custodian ~~thereof~~ **of the property**, the department may
23 apply to the proper judicial officer under ~~Act No. 189 of the~~
24 ~~Public Acts of 1966, being sections 780.651 to 780.659 of the~~
25 ~~Michigan Compiled Laws~~ **1966 PA 189, MCL 780.651 to 780.659**, for
26 a warrant commanding the sheriff or a law enforcement officer,
27 with the aid of the department, to search the property and seize

1 any source of ionizing radiation that is possessed, controlled,
2 or used wholly or partially in violation of this part or a rule
3 **promulgated under this part or in violation of a license issued**
4 **under this part**, or any evidence of a violation of this part or a
5 rule or license.

6 Sec. 13521. (1) The department shall promulgate rules
7 providing for general or specific licenses ~~or registration,~~ or
8 exemption from licensing ~~or registration,~~ for radioactive
9 materials and other sources of ionizing radiation. The rules
10 shall provide for amendment, suspension, or revocation of
11 licenses. In ~~connection with these~~ **promulgating rules under**
12 **this subsection**, the department may ~~promulgate rules to~~
13 establish requirements for record keeping, permissible levels of
14 exposure, notification and reports of accidents, protective
15 measures, technical qualifications of personnel, handling,
16 transportation, storage, waste disposal, posting and labeling of
17 hazardous sources and areas, surveys, and monitoring.

18 (2) The rules **promulgated under subsection (1)** shall not
19 limit the intentional exposure of patients to radiation for the
20 purpose of lawful therapy or research conducted by licensed
21 health professionals.

22 ~~(3) The department shall promulgate rules specifying the~~
23 ~~minimum training and performance standards for an individual~~
24 ~~using a radiation machine for mammography as set forth in~~
25 ~~section 13523.~~

26 Sec. 13522. (1) In promulgating rules pursuant to this
27 part, the department shall avoid requiring dual licensing,

1 insofar as practical. Rules promulgated by the department may
2 provide for recognition of other state or federal licenses as the
3 department considers desirable. ~~—, subject to registration~~
4 ~~requirements prescribed by the department.~~ A person who, on the
5 effective date of an agreement under ~~Act No. 54 of the Public~~
6 ~~Acts of 1965, being sections 3.801 to 3.802 of the Michigan~~
7 ~~Compiled Laws~~ **1965 PA 54, MCL 3.801 to 3.802**, possesses a
8 license issued by the federal government for a source of ionizing
9 radiation of the type for which the state assumes regulatory
10 responsibility under the agreement, is considered to possess an
11 identical license issued pursuant to this part, which license
12 expires either 90 days after receipt of a written notice of
13 termination from the department or on the date of expiration
14 stated in the federal license, whichever occurs first.

15 (2) The department may promulgate rules to establish a
16 schedule of fees to be paid by applicants for licenses for
17 radioactive materials and devices and equipment utilizing the
18 radioactive materials.

19 (3) Except as otherwise provided in this subsection, the
20 department may promulgate rules to establish a schedule of fees
21 to be paid by an applicant for a license for other sources of
22 ionizing radiation and the renewal of the license. ~~—, and by a~~
23 ~~person possessing sources of ionizing radiation that are subject~~
24 ~~to registration. The registration or registration renewal fee~~
25 ~~for a radiation machine registered under this part is \$45.00 for~~
26 ~~the first veterinary or dental x ray or electron tube and \$25.00~~
27 ~~for each additional veterinary or dental x ray or electron tube~~

1 ~~annually, or \$75.00 annually per nonveterinary or nondental x-ray~~
2 ~~or electron tube. The department shall not assess a fee for the~~
3 ~~amendment of a radiation machine registration certificate. In~~
4 ~~addition, the department shall assess a fee of \$100.00 for each~~
5 ~~follow-up inspection due to noncompliance during the same year.~~
6 The department may accept a written certification from the
7 licensee ~~or registrant~~ that the items of noncompliance have
8 been corrected instead of performing a follow-up inspection. If
9 the department does not inspect a source of ionizing radiation
10 for a period of 5 consecutive years, the licensee ~~or registrant~~
11 of the source of ionizing radiation does not have to pay further
12 license ~~or registration~~ fees as to that source of ionizing
13 radiation until the first license ~~or registration~~ renewal date
14 following the time an inspection of the source of ionizing
15 radiation is made.

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

18 ~~(5) Except as otherwise provided in subsection (6), the~~
19 ~~department shall assess the following nonrefundable fees in~~
20 ~~connection with mammography authorization:~~

- 21 ~~—— (a) Inspection, per radiation machine..... \$ 100.00~~
- 22 ~~—— (b) Reinspection for reinstatement of~~
23 ~~mammography authorization, per radiation machine..... \$ 100.00~~
- 24 ~~—— (c) Department evaluation of compliance with~~
25 ~~section 13523(2)(a), per radiation machine..... \$ 700.00~~
- 26 ~~————— Each reevaluation of a radiation machine due~~
27 ~~to failure during the previous evaluation, relocation~~

1 of the radiation machine, or similar changes that
2 could affect earlier evaluation results..... \$ 300.00.

3 ~~(6) If an applicant for mammography authorization submits an~~
4 ~~evaluation report issued by the American college of radiology~~
5 ~~that evidences compliance with section 13523(2)(a), the~~
6 ~~department shall waive the fee under subsection (5) for~~
7 ~~department evaluation of compliance with that provision.~~

8 (5) ~~(7)~~ Except as otherwise provided in ~~subsections~~
9 **subsection (3), and (6),** the department shall not waive a fee
10 required under this section.

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

19 Sec. 13525. A municipality or a department, agency, or
20 official of a municipality ~~may~~ **shall** not license ~~— or~~
21 regulate ~~—, or require the registration of~~ a radioactive
22 material or other source of ionizing radiation.

23 Sec. 13535. A person who violates this part or a rule
24 promulgated under this part or who fails to obtain or comply with
25 conditions of licensure ~~— or registration~~ under this part is
26 guilty of a misdemeanor, punishable by imprisonment for not more
27 than 180 days, or a fine of not more than \$10,000.00, or both. A

1 court may fine a person not more than \$2,000.00 for each
2 violation of this part. Each day a violation continues ~~shall~~
3 ~~be~~ **is** a separate violation.

4 Sec. 13536. If, after thorough investigation by the
5 department, it is the judgment of the department that a person
6 has engaged in or is about to engage in an act or practice
7 ~~which~~ **that** constitutes a violation of this part or **of** a rule or
8 order **promulgated or issued under this part**, the attorney
9 general, at the request of the department, shall ~~make~~
10 ~~application~~ **apply** to the appropriate circuit court for an order
11 enjoining the act or practice or for an order directing
12 compliance with this part or a rule or order **promulgated or**
13 issued ~~pursuant to~~ **under** this part.

14 **PART 135A. Radiation machine control**

15 Sec. 13551. (1) As used in this part:

16 (a) "Ionizing radiation" means gamma rays and x-rays, alpha
17 particles, beta particles, high speed electrons, neutrons,
18 protons, high speed ions, and other high speed nuclear
19 particles.

20 (b) "Mammography" means radiography of the breast for the
21 purpose of enabling a physician to determine the presence, size,
22 location, and extent of cancerous or potentially cancerous tissue
23 in the breast.

24 (c) "Mammography authorization" means authorization under
25 section 13573 to use a radiation machine for mammography.

26 (d) "Mammography interpreting physician" means a physician
27 who meets the requirements set forth in section 13573(2)(g) and

1 is responsible for evaluating and interpreting mammographic
2 images.

3 (e) "Mammography system" means the radiation machine used for
4 mammography; automatic exposure control devices; imaging systems;
5 image processor; darkroom; and viewboxes.

6 (f) "Non-ionizing radiation" means sound waves, radar waves,
7 microwaves, radio frequency fields, magnetic fields, and visible,
8 infrared, or ultraviolet light.

9 (g) "Non-ionizing radiation device" means a machine or device
10 that produces non-ionizing radiation in intensities or
11 frequencies subject to regulation by department rule.

12 (h) "Person" means a person as defined in section 1106 or a
13 governmental entity.

14 (i) "Radiation machine" means a machine or device that
15 produces ionizing radiation in energies or intensities subject to
16 regulation by department rule.

17 (j) "Radiography" means the making of a film or other record
18 of an internal structure of the body by passing x-rays through
19 the body to act on film or other image receptor.

20 (k) "Registration" means registration of a radiation machine
21 in writing with the department.

22 (2) In addition, article 1 contains general definitions and
23 principles of construction applicable to all articles in this
24 code.

25 Sec. 13555. A person shall not manufacture, produce,
26 transport, transfer, dispose of, acquire, own, possess, or use a
27 radiation machine unless the radiation machine is registered or

1 exempted by this part or by the department in accordance with
2 rules promulgated by the department under this part.

3 Sec. 13556. Sections 13555 and 13565 to 13586 do not apply
4 to the following sources or conditions, except as noted:

5 (a) Electrical or other equipment or material not intended
6 primarily to produce radiation which, by nature of design, does
7 not produce radiation at the point of nearest approach at a
8 weekly rate higher than 1/10 the appropriate limit generally
9 accepted by the medical profession for any critical organ
10 exposed. The production testing or production servicing of the
11 equipment is not exempt.

12 (b) A radiation machine during process of manufacture or in
13 storage or transit. The production testing or production
14 servicing of the radiation machine is not exempt.

15 (c) Non-ionizing radiation sources or devices, unless
16 specifically addressed by rule promulgated by the department
17 under this part.

18 Sec. 13561. (1) The governor may enter into agreements with
19 the federal government, other states, or interstate agencies,
20 whereby the department shall perform for or on a cooperative
21 basis with the federal government, other states, or interstate
22 agencies inspections or other functions relating to control of
23 radiation machines.

24 (2) An agreement entered into under subsection (1) does not
25 transfer, delegate, or impose upon the department any power,
26 authority, or responsibility that is not fully consistent with
27 this part.

1 Sec. 13565. (1) The department is designated as the
2 radiation machine control agency of this state.

3 (2) Pursuant to rules promulgated under this part, the
4 department shall require registration of radiation machines.

5 (3) The department shall develop and conduct programs for
6 evaluation and control of hazards associated with the use of
7 radiation machines.

8 (4) The department may develop and conduct programs for
9 evaluation and control of hazards associated with the use of
10 non-ionizing radiation devices.

11 Sec. 13566. If the department finds that an emergency
12 exists requiring immediate action to protect occupational or
13 public health and safety, the department shall issue an order,
14 with or without notice or hearing, reciting the existence of the
15 emergency and providing for the protection of the public health
16 and safety. Notwithstanding this act or the administrative
17 procedures act of 1969, the order is effective immediately. A
18 person to whom the order is directed shall comply with the order
19 immediately. However, upon request, the department shall grant
20 the person a hearing on the order or on an issue concerning the
21 order within 15 days after receipt of the request. On the basis
22 of the findings of fact and conclusions of law made at the
23 hearing, the department shall continue, modify, or revoke the
24 order within 30 days after the hearing.

25 Sec. 13567. (1) The department may enter at all reasonable
26 times upon private or public property upon which radiation
27 machines are reasonably believed to be located, with the

1 permission of the owner or custodian of the property, to
2 determine if the radiation machine is in compliance with this
3 part and the rules promulgated under this part.

4 (2) If the department has probable cause to believe that a
5 violation of this part or a rule promulgated under this part is
6 being committed on private or public property or that there
7 exists on the property evidence of such a violation, and
8 permission to enter on the property is denied by the owner or
9 custodian of the property, the department may make an affidavit
10 for a search warrant under 1966 PA 189, MCL 780.651 to 780.659.
11 The search warrant issued to the department under 1966 PA 189,
12 MCL 780.651 to 780.659, will command the sheriff or a law
13 enforcement officer, with the aid of the department, to search
14 the property and seize the radiation machine that is possessed,
15 controlled, or used wholly or partially in violation of this part
16 or a rule promulgated under this part, or evidence of a violation
17 of this part or a rule promulgated under this part.

18 Sec. 13571. (1) The department shall promulgate rules
19 providing for the registration of radiation machines. The
20 department may promulgate rules for the registration of
21 non-ionizing radiation devices. In promulgating rules under this
22 subsection, the department may establish requirements for
23 exemption from registration, record keeping, permissible levels
24 of exposure, notification and reports of accidents, protective
25 measures, technical qualifications of personnel, handling,
26 posting and labeling of hazardous machines, devices, and areas,
27 surveys, and monitoring.

1 (2) In promulgating rules under subsection (1), the
2 department shall not limit the intentional exposure of a patient
3 to radiation for the purpose of lawful therapy or research
4 conducted by a licensed health professional.

5 (3) The department shall promulgate rules specifying the
6 minimum training and performance standards for an individual
7 using a radiation machine for mammography as set forth in section
8 13573.

9 (4) The department shall promulgate rules specifying the
10 minimum training and performance standards for an individual
11 using a radiation machine for human screening or for diagnostic
12 or therapeutic purposes.

13 Sec. 13572. (1) Except as otherwise provided in this
14 subsection, the department may promulgate rules to establish a
15 schedule of fees to be paid by an applicant for the registration
16 of a radiation machine or a non-ionizing radiation device. The
17 registration or registration renewal fee for a radiation machine
18 registered under this part is \$45.00 for the first veterinary or
19 dental x-ray or electron tube and \$25.00 for each additional
20 veterinary or dental x-ray or electron tube annually, or \$75.00
21 annually per nonveterinary or nondental x-ray or electron tube.
22 The department shall not assess a fee for the amendment of a
23 radiation machine registration certificate. In addition, the
24 department shall assess a fee of \$100.00 for each follow-up
25 inspection due to noncompliance during the same year. The
26 department may accept a written certification from the registrant
27 that the items of noncompliance have been corrected instead of

1 performing a follow-up inspection. If the department does not
2 inspect a radiation machine or non-ionizing radiation device for
3 a period of 5 consecutive years, the registrant of the radiation
4 machine or non-ionizing radiation device does not have to pay
5 further registration fees as to that radiation machine or
6 non-ionizing radiation device until the first registration
7 renewal date following the time an inspection of the radiation
8 machine or non-ionizing radiation device is made.

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

11 (3) Except as otherwise provided in subsection (4), the
12 department shall assess the following nonrefundable fees in
13 connection with mammography authorization:

14 (a) Inspection, per radiation machine..... \$ 100.00

15 (b) Reinspection for reinstatement of
16 mammography authorization, per radiation machine..... \$ 100.00

17 (c) Department evaluation of compliance with
18 section 13573(2)(a), per radiation machine..... \$ 700.00

19 (d) Each reevaluation of a radiation machine due
20 to failure during the previous evaluation, relocation
21 of the radiation machine, or similar changes that
22 could affect earlier evaluation results..... \$ 300.00.

23 (4) If an applicant for mammography authorization submits an
24 evaluation report issued by the American college of radiology
25 that evidences compliance with section 13573(2)(a), the
26 department shall waive the fee under subsection (3) for
27 department evaluation of compliance with that provision.

1 (5) Except as otherwise provided in subsections (1) and (4),
2 the department shall not waive a fee required under this
3 section.

4 (6) The department shall adjust on an annual basis the fees
5 prescribed by subsections (1) and (3) 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. 13573. (1) A person shall not use a radiation machine
13 to perform mammography unless the radiation machine is registered
14 with the department under department rules for registration of
15 radiation machines and is specifically authorized under this
16 section for use for mammography.

17 (2) The department shall authorize a radiation machine for
18 use for mammography if the radiation machine, the personnel
19 operating the radiation machine, and the facility in which the
20 radiation machine is used meet all of the following standards:

21 (a) The radiation machine and the facility in which the
22 radiation machine is used meet the criteria for the American
23 college of radiology mammography accreditation program dated
24 August, 1993 and amended 1995 (Res. 24, 53) and published by the
25 American college of radiology in the documents entitled "ACR
26 standards for the performance of screening mammography", which
27 documents and criteria are incorporated by reference, excluding

1 the physician interpreter and the accreditation fee schedule.
2 The department shall make copies of those criteria available to
3 the public and may by rule adopt modified criteria. The
4 department may accept an evaluation report issued by the American
5 college of radiology as evidence that a radiation machine, the
6 personnel operating the radiation machine, and the facility in
7 which the radiation machine is used meet those criteria. If at
8 any time the department determines that it will not accept any
9 evaluation reports issued by the American college of radiology as
10 evidence that a radiation machine, the personnel operating the
11 radiation machine, and the facility in which the radiation
12 machine is used meet those criteria, the department shall
13 promptly notify each person who has registered a radiation
14 machine used exclusively to perform mammography under this part
15 and the rules promulgated under this part.

16 (b) The radiation machine, the film or other image receptor
17 used in the radiation machine, and the facility in which the
18 radiation machine is used meet the requirements set forth in
19 department rules for radiation machines.

20 (c) The radiation machine is specifically designed to perform
21 mammography.

22 (d) The facility in which the radiation machine is used does
23 all of the following:

24 (i) At least annually has a qualified radiation physicist
25 provide on-site consultation to the facility, including, but not
26 limited to, a complete evaluation of the entire mammography
27 system to ensure compliance with this part and the rules

1 promulgated under this part.

2 (ii) Maintains for at least 7 years records of the
3 consultation required in subparagraph (i) and the findings of the
4 consultation.

5 (iii) Designates an allopathic physician or an osteopathic
6 physician licensed under article 15 as the lead interpreting
7 physician. The designated physician is responsible for the
8 clinical aspects of the x-ray examinations and other procedures
9 related to mammography. The physician designated under this
10 subparagraph is also responsible for conducting an on-site visit
11 to each mammography station within the facility at least monthly
12 for the purpose of providing professional feedback regarding
13 clinical image quality and quality assurance procedures, for
14 review of quality control documentation, and for ensuring that
15 safe operating procedures are used in the delivery of
16 mammographic services. If the physician designated under this
17 subparagraph practices primarily outside of the facility, the
18 physician shall keep a log of each on-site visit signed by the
19 physician. The chief administrative officer of the facility or
20 his or her designee may request to view the log at any time. The
21 physician designated under this subparagraph shall meet the
22 requirements of subdivision (g)(i) and (v).

23 (iv) Submits, as part of the application for authorization
24 and subsequent renewals, evidence of a surety bond, secured trust
25 fund, or other suitable secured instrument or mechanism that is
26 approved by the department and that insures proper patient
27 mammography record and film handling and transfer in the event of

1 facility closure. The facility shall attest that the method of
2 coverage chosen will completely cover all costs involved and will
3 be adjusted, as needed, accordingly.

4 (e) The radiation machine is used according to department
5 rules on patient radiation exposure and radiation dose levels.

6 (f) Each individual who operates the radiation machine can
7 demonstrate to the department that he or she is specifically
8 trained in mammography and meets the standards required by the
9 rules promulgated under section 13571(3) or is an allopathic
10 physician or an osteopathic physician.

11 (g) The x-ray images of each mammographic examination
12 performed with the radiation machine are interpreted by a
13 mammography interpreting physician who is an allopathic physician
14 or an osteopathic physician licensed under article 15 and who
15 meets all of the following requirements:

16 (i) Except as otherwise provided in this subparagraph, is
17 certified in radiology or diagnostic radiology by the American
18 board of radiology or the American osteopathic board of
19 radiology, has been eligible for certification in radiology or
20 diagnostic radiology for not more than 3 years, or is certified
21 or determined to be qualified in radiology or diagnostic
22 radiology by another professional organization approved by the
23 department.

24 (ii) Shall have successfully completed not less than 3 months
25 of formal training in reading mammograms with instruction in
26 medical radiation physics, radiation effects, and radiation
27 protection and has documentation of successful completion of the

1 training that is satisfactory to the department. For purposes of
2 this subparagraph, the department may accept time spent in a
3 residency program that includes specific training in mammography
4 if the individual has documentation of the residency program that
5 is satisfactory to the department.

6 (iii) Shall have initial training that includes documented
7 interpretation of not less than 240 mammographic examinations in
8 the 6 months immediately preceding the performance of independent
9 interpretation.

10 (iv) Shall have interpreted or multi-read not less than 960
11 mammographic examinations during the 24 months immediately
12 preceding the date of the mammography facility's annual
13 inspection or the last day of the calendar quarter preceding that
14 inspection, or any day in between those 2 days. The mammography
15 facility shall choose 1 of the 3 dates to determine the 24-month
16 period of this subparagraph.

17 (v) Shall successfully complete or teach not less than 15
18 hours of continuing medical education every 3 years after the
19 effective date of the amendatory act that added this part in the
20 technical aspects or clinical aspects, or both, of mammography in
21 courses or programs approved by the individual's respective
22 specialty organization and licensing board and has documentation
23 of successful completion or teaching that is satisfactory to the
24 department.

25 (vi) Maintains annual records concerning outcome data for
26 correlation of positive mammograms to biopsies done, and the
27 number of cancers detected.

1 (3) The department may issue a nonrenewable temporary
2 authorization for a radiation machine for use for mammography if
3 additional time is needed to allow submission of evidence
4 satisfactory to the department that the radiation machine, the
5 personnel operating the radiation machine, and the facility in
6 which the radiation machine is used meet the standards set forth
7 in subsection (2) for approval for mammography. A temporary
8 authorization granted under this subsection is effective for no
9 more than 12 months. The department may withdraw a temporary
10 authorization before its expiration if the radiation machine, the
11 personnel operating the radiation machine, or the facility in
12 which the radiation machine is used does not meet 1 or more of
13 the standards set forth in subsection (2).

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

1 mammography authorization is effective for 3 years contingent
2 upon the radiation machine for which the mammography
3 authorization is issued, the personnel operating the radiation
4 machine, and the facility in which the radiation machine is
5 operated meeting 1 of the following requirements:

6 (a) Maintaining continued accreditation by the American
7 college of radiology.

8 (b) Having an active accreditation application in process
9 with the American college of radiology.

10 (c) Maintaining approval or being in the process of obtaining
11 approval under a department evaluation process equivalent to that
12 described in subdivisions (a) and (b).

13 (5) No later than 90 days after initial mammography
14 authorization of a radiation machine under this section, the
15 department shall inspect the radiation machine. After that
16 initial inspection, the department shall annually inspect the
17 radiation machine and may inspect the radiation machine more
18 frequently. The department shall make reasonable efforts to
19 coordinate the inspections under this section with the
20 department's other inspections of the facility in which the
21 radiation machine is located.

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

1 machine.

2 (7) The department may withdraw the mammography authorization
3 for a radiation machine if it does not meet 1 or more of the
4 standards set forth in subsection (2).

5 (8) The department shall provide an opportunity for a hearing
6 in connection with a denial or withdrawal of mammography
7 authorization.

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

18 (10) If the department withdraws the mammography
19 authorization for a radiation machine, the radiation machine
20 shall not be used for mammography. An application for
21 reinstatement of a mammography authorization shall be filed and
22 processed in the same manner as an application for mammography
23 authorization under subsection (4), except that the department
24 shall not issue a reinstated certificate of mammography
25 registration until the department receives the reinspection fee
26 required under section 13572(3), inspects the radiation machine,
27 and determines that it meets the standards set forth in

1 subsection (2). The department shall conduct an inspection
2 required under this subsection no later than 60 days after
3 receiving a proper application for reinstatement of a mammography
4 authorization.

5 (11) In addition to the penalties provided in section 13585
6 and the reinspection fee required under section 13572, if a
7 person violates subsection (1), the department may impose an
8 administrative fine against the owner of the radiation machine
9 or, if a lessee of the radiation machine has effective control of
10 the radiation machine, the lessee, of not more than \$500.00 for
11 each calendar week in which a mammography is performed in
12 violation of subsection (1). If a person continues to violate
13 subsection (1) for a period of 2 weeks after a fine is imposed
14 under this subsection, the department shall post a conspicuous
15 notice on the unauthorized radiation machine and at the entry to
16 the facility where the radiation machine is located warning the
17 public that the facility is performing mammography using a
18 radiation machine that is a substantial hazard to the public
19 health.

20 (12) The department may promulgate rules necessary to
21 implement this section after consultation with the ionizing
22 radiation advisory committee established under section 13581.

23 Sec. 13574. (1) A facility in which a radiation machine is
24 located shall ensure that all individuals, except licensed
25 members of the healing arts, using the radiation machine for
26 human screening or for diagnostic or therapeutic purposes are
27 adequately instructed in the safe operating procedures of the

1 radiation machine, pursuant to this section. The facility shall
2 ensure that these individuals meet the specific requirements of
3 this section. The department may use interview, observation, or
4 both, to determine compliance with this section. A facility
5 described in this subsection shall maintain records in order to
6 demonstrate compliance with this section.

7 (2) Limited scope operators are limited in scope of practice
8 to only those procedures listed in subsection (6). Limited scope
9 operators shall meet the prerequisite qualifications, receive
10 training, and demonstrate competence as follows:

11 (a) Shall complete at least 48 hours of didactic instruction
12 in a formal program, approved by the department, as prescribed in
13 subsection (7).

14 (b) Achieve a passing score of 70% on the certification
15 examination for the limited scope of practice in radiography
16 developed by the American registry of radiologic technologists
17 and approved by the department in at least 1 but no more than 3
18 of the limited scope categories of chest, extremities,
19 skull/sinus, spine, or podiatric. A facility needing to perform
20 examinations in addition to any 3 of these categories shall
21 employ a comprehensive scope operator according to subsection
22 (3). A passing score on the basic chiropractic x-ray technology
23 examination given through the American chiropractic registry of
24 radiologic technologists and approved by the department is
25 considered to meet the requirements of this subdivision for
26 limited scope spinal radiography.

27 (c) Shall compete the clinical experience requirements in

1 subsection (8).

2 (d) Individuals who have been actively working as a medical
3 x-ray operator for at least 6 months before the effective date of
4 this part are exempt from the requirements of subdivision (c).
5 These individuals shall document completion of the didactic
6 training requirements in subdivision (a) and the examination
7 requirements in subdivision (b) within 3 years of the effective
8 date of this part.

9 (e) Shall obtain not less than 15 hours, in any 3-year
10 period, of continuing education in the technical or clinical, or
11 both, aspects and related subjects of x-ray examinations in their
12 scope of practice.

13 (3) Comprehensive scope operators are not limited in scope of
14 practice for performing medical x-ray procedures. Comprehensive
15 scope operators must meet the prerequisite qualifications,
16 receive training, and demonstrate competence as follows:

17 (a) Shall meet the standards for issuance of a registration
18 certificate as a registered technologist from the American
19 registry of radiologic technologists or other nationally
20 recognized accreditation body. These standards, entitled "Rules
21 and Regulations", as revised in February, 1990, and "By-Laws", as
22 revised in September, 1989, published by the American registry of
23 radiologic technologists, are incorporated by reference. These
24 standards are available from the radiation safety section,
25 Michigan department of consumer and industry services, 525 west
26 Ottawa street, p.o. box 30664, Lansing, Michigan, 48909, at no
27 charge. The standards are also available from the American

1 registry of radiologic technologists, 1255 Northland drive,
2 Mendota Heights, Minnesota, 55120, at no charge. A determination
3 by the American registry of radiologic technologists that an
4 individual meets its respective standards for issuance of a
5 registration certificate is prima facie evidence to the
6 department that the individual complies with the standards.

7 (b) Shall, if the scope of practice includes specialties such
8 as computed tomography or radiation therapy, meet the standards
9 for issuance of advanced certification in that speciality from
10 the American registry of radiologic technologists, as approved by
11 the department.

12 (4) Dental x-ray operators, except dentists licensed under
13 article 15, shall meet the prerequisite qualifications, receive
14 training, and demonstrate competence as follows:

15 (a) Shall complete at least 36 hours of didactic instruction
16 in a formal program, approved by the department, as prescribed in
17 subsection (9).

18 (b) Graduates of a dental hygiene or dental assisting program
19 certified by the commission on dental accreditation and approved
20 by the department are considered to have met the requirements of
21 subdivision (a).

22 (c) Individuals who have been actively working as a dental
23 x-ray operator for at least 6 months before the effective date of
24 this part shall document completion of the didactic training
25 requirements of subdivision (a) or (b) within 3 years after the
26 effective date of this part.

27 (5) Veterinary x-ray operators, unless under the direct

1 supervision of a veterinarian licensed under article 15, shall
2 meet the prerequisite qualifications, receive training, and
3 demonstrate competence as follows:

4 (a) Shall complete at least 36 hours of didactic instruction
5 in a formal program approved by the department as prescribed in
6 subsection (10).

7 (b) Individuals who have been actively working as a
8 veterinary x-ray operator for at least 6 months before the
9 effective date of this part shall document completion of the
10 didactic training requirements in subdivision (a) within 3 years
11 after the effective date of this part.

12 (6) Limited scope x-ray operators, as described in subsection
13 (2), shall perform only the following specific x-ray
14 examinations:

15 (a) The following x-ray examinations of the extremities:

- 16 (i) Hand and fingers..... PA, lateral, oblique.
- 17 (ii) Wrists..... PA, lateral, oblique.
- 18 (iii) Forearm..... AP, lateral.
- 19 (iv) Elbow..... AP, lateral.
- 20 (v) Humerus..... AP, lateral.
- 21 (vi) Foot and toes..... AP, lateral, oblique.
- 22 (vii) Ankle..... AP, lateral, oblique.
- 23 (viii) Tibia-fibula..... AP, lateral.
- 24 (ix) Knee..... AP, lateral.
- 25 (x) Femur..... AP, lateral.

26 (b) The following x-ray examinations of the spine:

- 27 (i) Cervical spine.....AP, lateral, odontoid,

1 non-trauma, swimmer's non-trauma.

2 (ii) Thoracic spine..... AP, lateral, swimmer's non-trauma.

3 (iii) Lumbar spine..... AP, lateral, L5-S1 lateral.

4 (c) PA, AP, lateral, oblique, decubitus, and apical lordotic
5 x-ray examinations of the chest.

6 (d) DP and lateral x-ray examinations of the ankle.

7 (e) The following x-ray examinations of the skull and sinus:

8 (i) Entire skull.

9 (ii) Paranasal sinuses.

10 (iii) Facial bones.

11 (iv) Mandible and temporomandibular joint.

12 (7) An individual described in subsections (2) and (3) shall
13 complete a minimum of 48 hours of didactic training in a formal
14 training course. After successful completion of the course, the
15 individual shall pass an examination appropriate to his or her
16 scope of practice and complete the clinical experience
17 requirements prescribed in subsection (8). The formal training
18 course is subject to department approval and shall provide
19 instruction in all of the following subjects:

20 (a) Radiation protection including all of the following:

21 (i) Patient protection.

22 (ii) Personnel protection.

23 (iii) Radiation exposure and monitoring.

24 (b) Equipment operation and maintenance including all of the
25 following:

26 (i) Radiographic unit components.

27 (ii) Principles of x-ray production.

1 (iii) Recognition of malfunctions.

2 (c) Image production and evaluation including all of the
3 following:

4 (i) Selection of technique factors.

5 (ii) Film processing and quality assurance.

6 (iii) Evaluation of radiographs.

7 (d) Patient care including all of the following:

8 (i) Legal and professional responsibilities.

9 (ii) Patient education, safety, and comfort.

10 (iii) Prevention and control of infection.

11 (iv) Patient monitoring.

12 (e) Radiographic procedure positioning.

13 (8) An individual who completes the requirements of
14 subsection (7) shall complete 1 month of clinical training during
15 which time he or she may perform the x-ray examinations allowed
16 under subsection (6) only under the direct supervision of the
17 physician in charge, a comprehensive scope operator, or a limited
18 scope operator with no less than 3 years of experience. An
19 individual described in this subsection shall be trained in
20 proper imaging procedures as listed below:

21 (a) Selection of appropriate film size.

22 (b) Selection of appropriate technique factors.

23 (c) Use of correct source-to-image distance.

24 (d) Establishment of proper direction of central ray.

25 (e) Execution of proper patient position.

26 (f) Collimation of the x-ray beam as appropriate.

27 (g) Providing gonadal shielding if appropriate.

- 1 (h) Using correct film markers.
- 2 (i) Giving proper patient instruction.
- 3 (j) Placing patient information correctly on the film.
- 4 (k) Completing examination in a timely manner.
- 5 (l) Obtaining desired anatomy and positioning results on the
- 6 film.

7 (m) Obtaining appropriate contrast and density on the film.

8 (n) Identifying visible motion or film artifacts and

9 repeating exam if needed.

10 (9) An individual described in subsection (4) shall complete

11 a minimum of 36 hours of didactic radiology training in a formal

12 training course. The course is subject to department approval

13 and shall provide instruction in all of the following subjects:

14 (a) Radiation protection, including all of the following:

15 (i) Patient protection.

16 (ii) Personnel protection.

17 (iii) Radiation exposure and monitoring.

18 (b) Equipment operation and maintenance, including all of the

19 following:

20 (i) Radiographic unit components.

21 (ii) Principles of x-ray production.

22 (iii) Recognition of malfunctions.

23 (c) Image production and evaluation, including all of the

24 following:

25 (i) Selection of technique factors.

26 (ii) Film processing and quality assurance.

27 (iii) Evaluation, mounting, and labeling of radiographs.

1 (d) Patient care, including all of the following:

2 (i) Legal and professional responsibilities.

3 (ii) Patient education, safety, and comfort.

4 (iii) Prevention and control of infection.

5 (iv) Patient monitoring.

6 (e) Radiographic procedure positioning and film selection,
7 including all of the following:

8 (i) Periapical.

9 (ii) Bitewing.

10 (iii) Occlusal.

11 (iv) Panoramic.

12 (v) Cephalometric, orthodontic only.

13 (vi) Transcranial and TMJ, oral/maxillofacial only.

14 (10) An individual described in subsection (5) shall complete
15 a minimum of 36 hours of didactic training in a formal training
16 course. The course is subject to department approval and shall
17 provide instruction in all of the following subjects:

18 (a) Radiation protection, including all of the following:

19 (i) Personnel protection.

20 (ii) radiation exposure and monitoring.

21 (b) Equipment operation and maintenance, including all of the
22 following:

23 (i) Radiographic unit components.

24 (ii) Principles of x-ray production.

25 (iii) Recognition of malfunctions.

26 (c) Image production and evaluation, including all of the
27 following:

- 1 (i) Selection of technique factors.
2 (ii) Film processing and quality assurance.
3 (iii) Evaluation and labeling of radiographs.
4 (iv) Infection control.
5 (d) Radiographic procedure positioning.

6 Sec. 13575. A municipality or a department, agency, or
7 official of a municipality shall not license, regulate, or
8 require the registration of a radiation machine or a non-ionizing
9 radiation device.

10 Sec. 13581. The director shall appoint an ionizing
11 radiation advisory committee. Members of the committee serve at
12 the pleasure of the director. The committee shall furnish to the
13 department technical advice the committee considers desirable or
14 the department may reasonably request on matters relating to the
15 radiation machine control program.

16 Sec. 13585. A person who violates this part or a rule
17 promulgated under this part or who fails to obtain or comply with
18 a condition of registration under this part is guilty of a
19 misdemeanor punishable by imprisonment for not more than 180
20 days, or a fine of not more than \$10,000.00, or both. A court
21 may fine a person not more than \$2,000.00 for each violation of
22 this part. Each day a violation continues is a separate
23 violation.

24 Sec. 13586. If, after thorough investigation by the
25 department, it is the judgment of the department that a person
26 has engaged in or is about to engage in an act or practice that
27 constitutes a violation of this part or a rule or order

1 promulgated or issued under this part, the attorney general, at
2 the request of the department, shall apply to the appropriate
3 circuit court for an order enjoining the act or practice or for
4 an order directing compliance with this part or a rule or order
5 promulgated or issued under this part.

6 Enacting section 1. Sections 13523 and 13531 of the public
7 health code, 1978 PA 368, MCL 333.13523 and 333.13531, are
8 repealed.