

SUBSTITUTE FOR
HOUSE BILL NO. 4898

A bill to amend 1978 PA 368, entitled "Public health code," by amending sections 13501, 13505, 13506, 13511, 13515, 13517, 13521, 13522, 13525, 13535, and 13536 (MCL 333.13501, 333.13505, 333.13506, 333.13511, 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

1 filing of an application, to transfer, acquire, own, possess, or
2 use quantities of, or devices or equipment utilizing, radioactive
3 material.

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

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

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

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

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

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

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

25 (f) ~~(i)~~ "Registration" means registration of a ~~source of~~
26 ~~ionizing radiation~~ **radioactive material or devices or equipment**
27 **utilizing radioactive material** in writing with the department.

1 ~~(j) "Source of ionizing radiation" means a device or~~
2 ~~material that emits ionizing radiation.~~

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

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

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

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

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

26 ~~—(b) A radiation machine during process of manufacture or in~~
27 ~~storage or transit. The production testing or production~~

1 ~~servicing of the machine is not exempt.~~

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

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

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

19 **(d)** ~~-(f)-~~ A source material, by-product material, or special
20 nuclear material over which the federal nuclear regulatory
21 commission or ~~a~~ **its** successor ~~thereto~~ **agency** has exclusive
22 regulatory jurisdiction under the ~~federal~~ atomic energy act of
23 1954, **chapter 1073, 68 Stat. 919**, which jurisdiction has not been
24 transferred to this state pursuant to an agreement under ~~Act~~
25 ~~No. 54 of the Public Acts of 1965, being sections 3.801 and~~
26 ~~3.802 of the Michigan Compiled Laws 1965 PA 54, MCL 3.801 to~~
27 **3.802.**

1 Sec. 13511. (1) The governor may enter into agreements with
2 the federal government, other states, or interstate agencies,
3 whereby the department shall perform for or on a cooperative
4 basis with the federal government, other states, or interstate
5 agencies inspections, environmental monitoring, or other
6 functions relating to control of ~~sources of ionizing radiation~~
7 **radioactive material**.

8 (2) An agreement entered into pursuant to subsection (1) does
9 not transfer, delegate, or impose upon the department any power,
10 authority, or responsibility that is not fully consistent with
11 this part.

12 Sec. 13515. (1) The department is designated as the
13 **radioactive material** radiation control agency of this state and
14 shall coordinate **radioactive material** radiation control programs
15 of state departments acting within their statutory authorities.

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

19 (3) The department shall develop and conduct programs for
20 evaluation and control of hazards associated with the use of
21 radioactive materials. ~~and other sources of ionizing radiation.~~

22 Sec. 13517. (1) The department may enter at all reasonable
23 times upon private or public property upon which ~~sources of~~
24 ~~ionizing radiation~~ **radioactive materials** are reasonably believed
25 to be located, with the permission of the owner or custodian
26 ~~thereof~~ **of the property**, to determine if there is compliance
27 with or violation of this part or a rule **promulgated under this**

1 **part or compliance with or a violation of a license or**
2 **registration issued under this part.**

3 (2) If the department has reasonable **cause** or probable cause
4 to believe that a violation of this part or a rule **promulgated**
5 **under this part or a violation of a license or registration**
6 **issued under this part** is being committed on private or public
7 property or that there exists on the property evidence of a
8 violation, and permission to enter ~~thereon~~ **on the property** is
9 denied by the owner or custodian ~~thereof~~ **of the property**, the
10 department may apply to the proper judicial officer under ~~Act~~
11 ~~No. 189 of the Public Acts of 1966, being sections 780.651 to~~
12 ~~780.659 of the Michigan Compiled Laws~~ **1966 PA 189, MCL 780.651**
13 **to 780.659**, for a warrant commanding the sheriff or a law
14 enforcement officer, with the aid of the department, to search
15 the property and seize any ~~source of ionizing radiation~~
16 **radioactive material** that is possessed, controlled, or used
17 wholly or partially in violation of this part or a rule
18 **promulgated under this part or in violation of a license or**
19 **registration issued under this part**, or any evidence of a
20 violation of this part, ~~or~~ a rule, ~~or~~ license, **or**
21 **registration.**

22 Sec. 13521. (1) The department shall promulgate rules
23 providing for general or specific licenses or registration, or
24 exemption from licensing or registration, for radioactive
25 materials. ~~and other sources of ionizing radiation.~~ The rules
26 shall provide for amendment, suspension, or revocation of
27 licenses **or registrations**. In ~~connection with those~~

1 **promulgating** rules under this subsection, the department may
2 ~~promulgate rules to~~ establish requirements for record keeping,
3 permissible levels of exposure, notification and reports of
4 accidents, protective measures, technical qualifications of
5 personnel, handling, transportation, storage, waste disposal,
6 posting and labeling of hazardous sources and areas, surveys, and
7 monitoring.

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

12 ~~(3) The department shall promulgate rules specifying the~~
13 ~~minimum training and performance standards for an individual~~
14 ~~using a radiation machine for mammography as set forth in~~
15 ~~section 13523.~~

16 Sec. 13522. (1) In promulgating rules pursuant to this
17 part, the department shall avoid requiring dual licensing,
18 insofar as practical. Rules promulgated by the department may
19 provide for recognition of other state or federal licenses as the
20 department considers desirable, subject to registration
21 requirements prescribed by the department. A person who, on the
22 effective date of an agreement under ~~Act No. 54 of the Public~~
23 ~~Acts of 1965, being sections 3.801 to 3.802 of the Michigan~~
24 ~~Compiled Laws 1965 PA 54, MCL 3.801 to 3.802~~, possesses a
25 license issued by the federal government for a ~~source of~~
26 ~~ionizing radiation~~ **radioactive material** of the type for which
27 the state assumes regulatory responsibility under the agreement,

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

6 (2) The department may promulgate rules to establish a
7 schedule of fees to be paid by applicants for licenses **or**
8 **registration** for radioactive materials and devices and equipment
9 utilizing the radioactive materials.

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

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

7 (3) ~~-(4)-~~ A fee collected under this part shall be deposited
8 in the state treasury and credited to the general fund of this
9 state.

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

13 ~~—— (a) Inspection, per radiation machine..... \$ 100.00~~

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

16 ~~—— (c) Department evaluation of compliance with
17 section 13523(2)(a), per radiation machine..... \$ 700.00~~

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

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
25 department shall waive the fee under subsection (5) for
26 department evaluation of compliance with that provision.~~

27 ~~—— (7) Except as otherwise provided in subsections (3) and (6),~~

1 ~~the department shall not waive a fee required under this~~
2 ~~section.~~

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

11 Sec. 13525. A municipality or a department, agency, or
12 official of a municipality ~~may~~ **shall** not license, regulate, or
13 require the registration of a radioactive material. ~~or other~~
14 ~~source of ionizing radiation.~~

15 Sec. 13535. A person who violates this part or a rule
16 promulgated under this part or who fails to obtain or comply with
17 conditions of licensure or registration under this part is guilty
18 of a misdemeanor, punishable by imprisonment for not more than
19 180 days, or a fine of not more than \$10,000.00, or both. A
20 court may fine a person not more than \$2,000.00 for each
21 violation of this part. Each day a violation continues ~~shall~~
22 ~~be~~ **is** a separate violation.

23 Sec. 13536. If, after thorough investigation by the
24 department, it is the judgment of the department that a person
25 has engaged in or is about to engage in an act or practice
26 ~~which~~ **that** constitutes a violation of this part or **of** a rule or
27 order **promulgated or issued under this part**, the attorney

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

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

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

8 (a) "Department" means the department of consumer and
9 industry services.

[(b) "Direct supervision" means that a physician, dentist, or
veterinarian, or a comprehensive scope operator or limited scope operator
as provided under section 13574(8), complies with all of the following:

(i) Designates a patient of record upon whom the procedures are to be
performed and describes the procedures to be performed.

(ii) Examines the patient before prescribing the procedures to be
performed and upon completion of the procedures.

(iii) Is physically present in the office suite or facility in which
the radiation machine is located at the time the procedures are being
performed.

10 [(c)] "Ionizing radiation" means gamma rays and x-rays, alpha
11 particles, beta particles, high speed electrons, neutrons,
12 protons, high speed ions, and other high speed nuclear
13 particles.

14 [(d)] "Mammography" means radiography of the breast for the
15 purpose of enabling a physician to determine the presence, size,
16 location, and extent of cancerous or potentially cancerous tissue
17 in the breast.

18 [(e)] "Mammography authorization" means authorization under
19 section 13573 to use a radiation machine for mammography.

20 [(f)] "Mammography interpreting physician" means a physician
21 who meets the requirements set forth in section 13573(2)(g) and
22 is responsible for evaluating and interpreting mammographic
23 images.

24 [(g)] "Mammography system" means the radiation machine used for

25 mammography; automatic exposure control devices; imaging systems;
26 image processor; darkroom; and viewboxes.

27 [(h)] "Non-ionizing radiation" means sound waves, radar waves,

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1 microwaves, radio frequency fields, magnetic fields, and visible,
2 infrared, or ultraviolet light.

3 [(i)] "Non-ionizing radiation device" means a machine or device
4 that produces non-ionizing radiation in intensities or
5 frequencies subject to regulation by department rule.

6 [(j)] "Person" means a person as defined in section 1106 or a
7 governmental entity.

8 [(k)] "Radiation machine" means a machine or device that
9 produces ionizing radiation in energies or intensities subject to
10 regulation by department rule.

11 [(l)] "Radiography" means the making of a film or other record
12 of an internal structure of the body by passing x-rays through
13 the body to act on film or other image receptor.

14 [(m)] "Registration" means registration of a radiation machine
15 in writing with the department.

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

19 Sec. 13555. A person shall not manufacture, produce,
20 transport, transfer, dispose of, acquire, own, possess, or use a
21 radiation machine unless the radiation machine is registered or
22 exempted by this part or by the department in accordance with
23 rules promulgated by the department under this part.

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

26 (a) Electrical or other equipment or material not intended
27 primarily to produce radiation which, by nature of design, does

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1 not produce radiation at the point of nearest approach at a
2 weekly rate higher than 1/10 the appropriate limit generally
3 accepted by the medical profession for any critical organ
4 exposed. The production testing or production servicing of the
5 equipment is not exempt.

6 (b) A radiation machine during process of manufacture or in
7 storage or transit. The production testing or production
8 servicing of the radiation machine is not exempt.

9 (c) Non-ionizing radiation sources or devices [.
10
11]

12 Sec. 13561. (1) The governor may enter into agreements with
13 the federal government, other states, or interstate agencies,
14 whereby the department shall perform for or on a cooperative
15 basis with the federal government, other states, or interstate
16 agencies inspections or other functions relating to control of
17 radiation machines.

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

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

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

26 (3) The department shall develop and conduct programs for
27 evaluation and control of hazards associated with the use of

1 radiation machines.

2 [

3

4]

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

19 Sec. 13567. (1) The department may enter at all reasonable
20 times upon private or public property upon which radiation
21 machines are reasonably believed to be located, with the
22 permission of the owner or custodian of the property, to
23 determine if the radiation machine is in compliance with this
24 part and the rules promulgated under this part.

25 (2) If the department has probable cause to believe that a
26 violation of this part or a rule promulgated under this part is
27 being committed on private or public property or that there

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1 using a radiation machine for mammography as set forth in section
2 13573.

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

7 Sec. 13572. (1) Except as otherwise provided in this
8 subsection, the department may promulgate rules to establish a
9 schedule of fees to be paid by an applicant for the registration
10 of a radiation machine []. The
11 registration or registration renewal fee for a radiation machine
12 registered under this part is \$61.51 for the first veterinary or
13 dental x-ray or electron tube and \$34.14 for each additional
14 veterinary or dental x-ray or electron tube annually, or \$102.54
15 annually per nonveterinary or nondental x-ray or electron tube.
16 The department shall not assess a fee for the amendment of a
17 radiation machine registration certificate. In addition, the
18 department shall assess a fee of \$136.75 for each follow-up
19 inspection due to noncompliance during the same year. The
20 department may accept a written certification from the registrant
21 that the items of noncompliance have been corrected instead of
22 performing a follow-up inspection. If the department does not
23 inspect a radiation machine []for
24 a period of 5 consecutive years, the registrant of the radiation
25 machine [] does not have to pay
26 further registration fees as to that radiation machine []
27 [] until the first registration

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1 renewal date following the time an inspection of the radiation
2 machine [] is made.

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

5 (3) Except as otherwise provided in subsection (4), the
6 department shall assess the following nonrefundable fees in
7 connection with mammography authorization:

8 (a) Inspection, per radiation machine..... \$ 136.75

9 (b) Reinspection for reinstatement of

10 mammography authorization, per radiation machine..... \$ 136.75

11 (c) Department evaluation of compliance with

12 section 13573(2)(a), per radiation machine..... \$ 700.00

13 (d) Each reevaluation of a radiation machine due

14 to failure during the previous evaluation, relocation
15 of the radiation machine, or similar changes that

16 could affect earlier evaluation results..... \$ 300.00.

17 (4) If an applicant for mammography authorization submits an
18 evaluation report issued by the American college of radiology
19 that evidences compliance with section 13573(2)(a), the
20 department shall waive the fee under subsection (3) for
21 department evaluation of compliance with that provision.

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

25 (6) The department shall adjust on an annual basis the fees
26 prescribed by subsections (1) and (3) by an amount determined by
27 the state treasurer to reflect the cumulative annual percentage

1 change in the Detroit consumer price index, not to exceed 5%. As
2 used in this subsection, "Detroit consumer price index" means the
3 most comprehensive index of consumer prices available for the
4 Detroit area from the bureau of labor statistics of the United
5 States department of labor.

6 Sec. 13573. (1) A person shall not use a radiation machine
7 to perform mammography unless the radiation machine is registered
8 with the department under department rules for registration of
9 radiation machines and is specifically authorized under this
10 section for use for mammography.

11 (2) The department shall authorize a radiation machine for
12 use for mammography if the radiation machine, the personnel
13 operating the radiation machine, and the facility in which the
14 radiation machine is used meet all of the following standards:

15 (a) The radiation machine and the facility in which the
16 radiation machine is used meet the criteria for the American
17 college of radiology mammography accreditation program dated
18 August, 1993 and amended 1995 (Res. 24, 53) and published by the
19 American college of radiology in the documents entitled "ACR
20 standards for the performance of screening mammography", which
21 documents and criteria are incorporated by reference, excluding
22 the physician interpreter and the accreditation fee schedule.
23 The department shall make copies of those criteria available to
24 the public and may by rule adopt modified criteria. The
25 department may accept an evaluation report issued by the American
26 college of radiology as evidence that a radiation machine, the
27 personnel operating the radiation machine, and the facility in

1 which the radiation machine is used meet those criteria. If at
2 any time the department determines that it will not accept any
3 evaluation reports issued by the American college of radiology as
4 evidence that a radiation machine, the personnel operating the
5 radiation machine, and the facility in which the radiation
6 machine is used meet those criteria, the department shall
7 promptly notify each person who has registered a radiation
8 machine used exclusively to perform mammography under this part
9 and the rules promulgated under this part.

10 (b) The radiation machine, the film or other image receptor
11 used in the radiation machine, and the facility in which the
12 radiation machine is used meet the requirements set forth in
13 department rules for radiation machines.

14 (c) The radiation machine is specifically designed to perform
15 mammography.

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

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

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

26 (iii) Designates an allopathic physician or an osteopathic
27 physician licensed under article 15 as the lead interpreting

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

17 (iv) Submits, as part of the application for authorization
18 and subsequent renewals, evidence of a surety bond, secured trust
19 fund, or other suitable secured instrument or mechanism that is
20 approved by the department and that insures proper patient
21 mammography record and film handling and transfer in the event of
22 facility closure. The facility shall attest that the method of
23 coverage chosen will completely cover all costs involved and will
24 be adjusted, as needed, accordingly.

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

27 (f) Each individual who operates the radiation machine can

1 demonstrate to the department that he or she is specifically
2 trained in mammography and meets the standards required by the
3 rules promulgated under section 13571(3) or is an allopathic
4 physician or an osteopathic physician.

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

10 (i) Except as otherwise provided in this subparagraph, is
11 certified in radiology or diagnostic radiology by the American
12 board of radiology or the American osteopathic board of
13 radiology, has been eligible for certification in radiology or
14 diagnostic radiology for not more than 3 years, or is certified
15 or determined to be qualified in radiology or diagnostic
16 radiology by another professional organization approved by the
17 department.

18 (ii) Shall have successfully completed not less than 3 months
19 of formal training in reading mammograms with instruction in
20 medical radiation physics, radiation effects, and radiation
21 protection and has documentation of successful completion of the
22 training that is satisfactory to the department. For purposes of
23 this subparagraph, the department may accept time spent in a
24 residency program that includes specific training in mammography
25 if the individual has documentation of the residency program that
26 is satisfactory to the department.

27 (iii) Shall have initial training that includes documented

1 interpretation of not less than 240 mammographic examinations in
2 the 6 months immediately preceding the performance of independent
3 interpretation.

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

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

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

22 (3) The department may issue a nonrenewable temporary
23 authorization for a radiation machine for use for mammography if
24 additional time is needed to allow submission of evidence
25 satisfactory to the department that the radiation machine, the
26 personnel operating the radiation machine, and the facility in
27 which the radiation machine is used meet the standards set forth

1 in subsection (2) for approval for mammography. A temporary
2 authorization granted under this subsection is effective for no
3 more than 12 months. The department may withdraw a temporary
4 authorization before its expiration if the radiation machine, the
5 personnel operating the radiation machine, or the facility in
6 which the radiation machine is used does not meet 1 or more of
7 the standards set forth in subsection (2).

8 (4) To obtain authorization from the department to use a
9 radiation machine for mammography, the person who owns or leases
10 the radiation machine or an authorized agent of the person shall
11 apply to the department for mammography authorization on an
12 application form provided by the department and shall provide all
13 of the information required by the department as specified on the
14 application form. A person who owns or leases more than 1
15 radiation machine used for mammography shall obtain authorization
16 for each radiation machine. The department shall process and
17 respond to an application within 30 days after the date of
18 receipt of the application. Upon determining to grant
19 mammography authorization for a radiation machine, the department
20 shall issue a certificate of registration specifying mammography
21 authorization for each authorized radiation machine. A
22 mammography authorization is effective for 3 years contingent
23 upon the radiation machine for which the mammography
24 authorization is issued, the personnel operating the radiation
25 machine, and the facility in which the radiation machine is
26 operated meeting 1 of the following requirements:

27 (a) Maintaining continued accreditation by the American

1 college of radiology.

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

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

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

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

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

26 (8) The department shall provide an opportunity for a hearing
27 in connection with a denial or withdrawal of mammography

1 authorization.

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

12 (10) If the department withdraws the mammography
13 authorization for a radiation machine, the radiation machine
14 shall not be used for mammography. An application for
15 reinstatement of a mammography authorization shall be filed and
16 processed in the same manner as an application for mammography
17 authorization under subsection (4), except that the department
18 shall not issue a reinstated certificate of mammography
19 registration until the department receives the reinspection fee
20 required under section 13572(3), inspects the radiation machine,
21 and determines that it meets the standards set forth in
22 subsection (2). The department shall conduct an inspection
23 required under this subsection no later than 60 days after
24 receiving a proper application for reinstatement of a mammography
25 authorization.

26 (11) In addition to the penalties provided in section 13585
27 and the reinspection fee required under section 13572(3), if a

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

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

17 Sec. 13574. (1) A facility in which a radiation machine is
18 located shall ensure that all individuals, except licensed
19 members of the healing arts, using the radiation machine for
20 human screening or for diagnostic or therapeutic purposes are
21 adequately instructed in the safe operating procedures of the
22 radiation machine, pursuant to this section. The facility shall
23 ensure that these individuals meet the specific requirements of
24 this section. The department may use interview, observation, or
25 both, to determine compliance with this section. A facility
26 described in this subsection shall maintain records in order to
27 demonstrate compliance with this section.

1 (2) Except as otherwise provided in this subsection, limited
2 scope operators are limited in scope of practice to only those
3 procedures listed in subsection (6). In an emergency and under
4 the direct supervision of a physician, a limited scope operator
5 may perform procedures not listed in subsection (6) if determined
6 necessary by the supervising physician. Limited scope operators
7 shall meet the prerequisite qualifications, receive training, and
8 demonstrate competence as follows:

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

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

25 (c) Shall complete the clinical experience requirements in
26 subsection (8).

27 (d) Individuals who have been actively working as a medical

1 x-ray operator for at least 6 months before the effective date of
2 this part are exempt from the requirements of subdivision (c).
3 These individuals shall document completion of the didactic
4 training requirements in subdivision (a) and the examination
5 requirements in subdivision (b) within 3 years of the effective
6 date of this part.

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

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

15 (a) Shall meet the standards for issuance of a registration
16 certificate as a registered technologist from the American
17 registry of radiologic technologists or other nationally
18 recognized accreditation body. These standards, entitled "Rules
19 and Regulations", as revised in February, 1990, and "By-Laws", as
20 revised in September, 1989, published by the American registry of
21 radiologic technologists, are incorporated by reference. These
22 standards are available from the Michigan department of consumer
23 and industry services and the American registry of radiologic
24 technologists or any other nationally recognized credentialing
25 body. A determination by the American registry of radiologic
26 technologists that an individual meets its respective standards
27 for issuance of a registration certificate is prima facie

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1 evidence to the department that the individual complies with the
2 standards.

3 (b) Shall, except as otherwise provided in this subdivision,
4 if the scope of practice includes specialties such as computed
5 tomography or radiation therapy, meet the standards for issuance
6 of advanced certification in that specialty from the American
7 registry of radiologic technologists, as approved by the
8 department. A facility that, on a form as prescribed by the
9 department, can demonstrate, based on the number, complexity, and
10 variety of specialty procedures performed at that facility and
11 any other facility under the same ownership within the preceding
12 12-month period, that a comprehensive scope operator could not
13 possibly satisfy the comprehensive experience standards required
14 to obtain an advanced certification in that specialty may, if
15 approved by the department, be exempt from satisfying this
16 subdivision.

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

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

23 (b) Graduates of a dental hygiene or dental assisting program
24 certified by the commission on dental accreditation and approved
25 by the department [or individuals who have successfully completed the
Michigan dental association radiology training program] are considered to
have met the requirements of
26 subdivision (a).

27 (c) Individuals who have been actively working as a dental

1 x-ray operator for at least 6 months before the effective date of
2 this part shall document completion of the didactic training
3 requirements of subdivision (a) or (b) within 3 years after the
4 effective date of this part.

5 (5) Veterinary x-ray operators, unless under the direct
6 supervision of a veterinarian licensed under article 15, shall
7 meet the prerequisite qualifications, receive training, and
8 demonstrate competence as follows:

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

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

17 (6) Limited scope x-ray operators, as described in subsection
18 (2), shall perform only the following specific x-ray examinations
19 unless otherwise authorized under subsection (2):

- 20 (a) The following x-ray examinations of the extremities:
- 21 (i) Hand and fingers..... PA, lateral, oblique.
- 22 (ii) Wrists..... PA, lateral, oblique.
- 23 (iii) Forearm..... AP, lateral.
- 24 (iv) Elbow..... AP, lateral.
- 25 (v) Humerus..... AP, lateral.
- 26 (vi) Foot and toes..... AP, lateral, oblique.
- 27 (vii) Ankle..... AP, lateral, oblique.

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- 1 (viii) Tibia-fibula..... AP, lateral.
- 2 (ix) Knee..... AP, lateral.
- 3 (x) Femur..... AP, lateral.

4 [(b) X-ray examinations of the 5 regions of the spine as ordered by a physician.]

- 5 (i) Cervical spine.....AP, lateral, odontoid,
- 6 non-trauma, swimmer's non-trauma.
- 7 (ii) Thoracic spine..... AP, lateral, swimmer's non-trauma.
- 8 (iii) Lumbar spine..... AP, lateral, L5-S1 lateral.

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

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

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

- 13 (i) Entire skull.
- 14 (ii) Paranasal sinuses.
- 15 (iii) Facial bones.
- 16 (iv) Mandible and temporomandibular joint.

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

- 25 (a) Radiation protection including all of the following:
- 26 (i) Patient protection.
- 27 (ii) Personnel protection.

1 (iii) Radiation exposure and monitoring.

2 (b) Equipment operation and maintenance including all of the
3 following:

4 (i) Radiographic unit components.

5 (ii) Principles of x-ray production.

6 (iii) Recognition of malfunctions.

7 (c) Image production and evaluation including all of the
8 following:

9 (i) Selection of technique factors.

10 (ii) Film processing and quality assurance.

11 (iii) Evaluation of radiographs.

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

13 (i) Legal and professional responsibilities.

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

15 (iii) Prevention and control of infection.

16 (iv) Patient monitoring.

17 (e) Radiographic procedure positioning.

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

26 (a) Selection of appropriate film size.

27 (b) Selection of appropriate technique factors.

- 1 (c) Use of correct source-to-image distance.
- 2 (d) Establishment of proper direction of central ray.
- 3 (e) Execution of proper patient position.
- 4 (f) Collimation of the x-ray beam as appropriate.
- 5 (g) Providing gonadal shielding if appropriate.
- 6 (h) Using correct film markers.
- 7 (i) Giving proper patient instruction.
- 8 (j) Placing patient information correctly on the film.
- 9 (k) Completing examination in a timely manner.
- 10 (l) Obtaining desired anatomy and positioning results on the
- 11 film.
- 12 (m) Obtaining appropriate contrast and density on the film.
- 13 (n) Identifying visible motion or film artifacts and
- 14 repeating exam if needed.
- 15 (9) An individual described in subsection (4) shall complete
- 16 a minimum of 36 hours of didactic radiology training in a formal
- 17 training course. The course is subject to department approval
- 18 and shall provide instruction in all of the following subjects:
- 19 (a) Radiation protection, including all of the following:
- 20 (i) Patient protection.
- 21 (ii) Personnel protection.
- 22 (iii) Radiation exposure and monitoring.
- 23 (b) Equipment operation and maintenance, including all of the
- 24 following:
- 25 (i) Radiographic unit components.
- 26 (ii) Principles of x-ray production.
- 27 (iii) Recognition of malfunctions.

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

- 3 (i) Selection of technique factors.
- 4 (ii) Film processing and quality assurance.
- 5 (iii) Evaluation, mounting, and labeling of radiographs.

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

- 7 (i) Legal and professional responsibilities.
- 8 (ii) Patient education, safety, and comfort.
- 9 (iii) Prevention and control of infection.

10 (iv) Patient monitoring.

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

- 13 (i) Periapical.
- 14 (ii) Bitewing.
- 15 (iii) Occlusal.
- 16 (iv) Panoramic.
- 17 (v) Cephalometric, orthodontic only.
- 18 (vi) Transcranial and TMJ, oral/maxillofacial only.

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

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

- 24 (i) Personnel protection.
- 25 (ii) Radiation exposure and monitoring.

26 (b) Equipment operation and maintenance, including all of the
27 following:

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- 1 (i) Radiographic unit components.
- 2 (ii) Principles of x-ray production.
- 3 (iii) Recognition of malfunctions.
- 4 (c) Image production and evaluation, including all of the
- 5 following:
- 6 (i) Selection of technique factors.
- 7 (ii) Film processing and quality assurance.
- 8 (iii) Evaluation and labeling of radiographs.
- 9 (iv) Infection control.
- 10 (d) Radiographic procedure positioning.

11 Sec. 13575. A municipality or a department, agency, or

12 official of a municipality shall not license, regulate, or

13 require the registration of a radiation machine [.

14]

15 Sec. 13581. The director shall appoint an ionizing

16 radiation advisory committee. Members of the committee serve at

17 the pleasure of the director. The committee shall furnish to the

18 department technical advice the committee considers desirable or

19 the department may reasonably request on matters relating to the

20 radiation machine control program.

21 Sec. 13585. A person who violates this part or a rule

22 promulgated under this part or who fails to obtain or comply with

23 a condition of registration under this part is guilty of a

24 misdemeanor punishable by imprisonment for not more than 180

25 days, or a fine of not more than \$10,000.00, or both. A court

26 may fine a person not more than \$2,000.00 for each violation of

27 this part. Each day a violation continues is a separate

1 violation.

2 Sec. 13586. If, after thorough investigation by the
3 department, it is the judgment of the department that a person
4 has engaged in or is about to engage in an act or practice that
5 constitutes a violation of this part or a rule or order
6 promulgated or issued under this part, the attorney general, at
7 the request of the department, shall apply to the appropriate
8 circuit court for an order enjoining the act or practice or for
9 an order directing compliance with this part or a rule or order
10 promulgated or issued under this part.

11 Enacting section 1. Sections 13523 and 13531 of the public
12 health code, 1978 PA 368, MCL 333.13523 and 333.13531, are
13 repealed.