

HOUSE BILL NO. 5116

June 24, 2021, Introduced by Reps. Wakeman, Frederick, Allor and Anthony 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 2018 PA 544, 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 labor and economic**
3 **opportunity.**

4 **(b) ~~(a)~~**"General license" means a license, effective pursuant
5 ~~to~~**under** rules promulgated by the department without the filing of
6 an application, to transfer, acquire, own, possess, or use
7 quantities of, or devices or equipment utilizing, radioactive
8 material.

9 **(c) ~~(b)~~**"Ionizing radiation" means gamma rays and ~~x-rays, X-~~
10 **rays**, alpha particles, beta particles, high speed electrons,
11 neutrons, protons, high speed ions, and other high speed nuclear
12 particles.

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

17 ~~(d) "Mammography authorization" means authorization under~~
18 ~~section 13523 to use a radiation machine for mammography.~~

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

22 **(d) ~~(f)~~**"Person" means ~~a person~~**that term** as defined in
23 section 1106 or a governmental entity.

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

26 **(f) ~~(h)~~**"Radiography" means the making of a film or other
27 record of an internal structure of the body by passing ~~x-rays X-~~
28 **rays** or gamma rays through the body to act on film or other image
29 receptor.

1 ~~(i) "Registration" means registration of a source of ionizing~~
2 ~~radiation in writing with the department.~~

3 ~~(g) (j) "Source of ionizing radiation" means a device or~~
4 ~~material that emits ionizing radiation.~~

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

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

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

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

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

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

29 ~~(a) (e) A radioactive material while being transported under~~

1 the jurisdiction of and in conformity with regulations adopted by
 2 the ~~nuclear regulatory commission~~ **federal Nuclear Regulatory**
 3 **Commission** or the United States ~~department of transportation,~~
 4 **Department of Transportation**, or their successors, specifically
 5 applicable to the transportation of ~~such~~ **the** radioactive material.

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

8 (c) ~~(e)~~ A production **facility** or utilization facility, ~~as~~
 9 ~~defined in the federal atomic energy act of 1954, 42 U.S.C. 2011 to~~
 10 ~~2291,~~ or a source of ionizing radiation used in or in connection
 11 with the operation of a production **facility** or utilization facility
 12 pursuant to a license from the federal ~~nuclear regulatory~~
 13 ~~commission~~ **Nuclear Regulatory Commission** or **its** successor ~~thereto~~
 14 **agency**. However, the department may collect radiation data and
 15 perform environmental monitoring in connection with the operation
 16 of the facility in accordance with this part. **As used in this**
 17 **subdivision, "production facility" and "utilization facility" mean**
 18 **those terms as defined in 42 USC 2014.**

19 (d) ~~(f)~~ A source material, by-product material, or special
 20 nuclear material over which the federal ~~nuclear regulatory~~
 21 ~~commission~~ **Nuclear Regulatory Commission** or ~~a~~ **its** successor ~~thereto~~
 22 **agency** has exclusive regulatory jurisdiction under the ~~federal~~
 23 atomic energy act of 1954, **42 USC 2011 to 2297h-13**, which
 24 jurisdiction has not been transferred to this state pursuant to an
 25 agreement under ~~Act No. 54 of the Public Acts of 1965, being~~
 26 ~~sections 3.801 and 3.802 of the Michigan Compiled Laws 1965 PA 54,~~
 27 **MCL 3.801 to 3.802.**

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

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

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

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

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

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

1 partially in violation of this part or a rule **promulgated under**
 2 **this part** or **in violation of a license issued under this part**, or
 3 any evidence of a violation of this part or a rule **promulgated**
 4 **under this part** or **a license issued under this part**.

5 Sec. 13521. (1) The department shall promulgate rules
 6 providing for general or specific licenses ~~or registration, or~~
 7 exemption from licensing ~~or registration,~~ for radioactive materials
 8 and other sources of ionizing radiation. The rules must provide for
 9 amendment, suspension, or revocation of licenses. In ~~connection~~
 10 ~~with these promulgating rules, subject to section 13527,~~ **under**
 11 **this subsection**, the department may promulgate rules to establish
 12 requirements for record keeping, permissible levels of exposure,
 13 notification and reports of accidents, protective measures,
 14 technical qualifications of personnel, handling, transportation,
 15 storage, waste disposal, posting and labeling of hazardous sources
 16 and areas, surveys, and monitoring.

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

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

24 Sec. 13522. (1) In promulgating rules ~~pursuant to~~ **under** this
 25 part, the department shall avoid requiring dual licensing, insofar
 26 as practical. Rules promulgated by the department may provide for
 27 recognition of other state or federal licenses as the department
 28 considers desirable. ~~, subject to registration requirements~~
 29 ~~prescribed by the department. A person who,~~ **that**, on the effective

1 date of an agreement under ~~Act No. 54 of the Public Acts of 1965,~~
2 ~~being sections 3.801 to 3.802 of the Michigan Compiled Laws 1965 PA~~
3 **54, MCL 3.801 to 3.802**, possesses a license issued by the federal
4 government for a source of ionizing radiation of the type for which
5 ~~the~~**this** state assumes regulatory responsibility under the
6 agreement, is considered to possess an identical license issued
7 ~~pursuant to~~**under** this part, which license expires either 90 days
8 after receipt of a written notice of termination from the
9 department or on the date of expiration stated in the federal
10 license, whichever occurs first.

11 (2) The department may promulgate rules to establish a
12 schedule of fees to be paid by applicants for licenses for
13 radioactive materials and devices and equipment utilizing the
14 radioactive materials.

15 (3) Except as otherwise provided in this subsection, the
16 department may promulgate rules to establish a schedule of fees to
17 be paid by an applicant for a license for other sources of ionizing
18 radiation and the renewal of the license. ~~, and by a person~~
19 ~~possessing sources of ionizing radiation that are subject to~~
20 ~~registration. The registration or registration renewal fee for a~~
21 ~~radiation machine registered under this part is \$45.00 for the~~
22 ~~first veterinary or dental x-ray or electron tube and \$25.00 for~~
23 ~~each additional veterinary or dental x-ray or electron tube~~
24 ~~annually, or \$75.00 annually per nonveterinary or nondental x-ray~~
25 ~~or electron tube. The department shall not assess a fee for the~~
26 ~~amendment of a radiation machine registration certificate. In~~
27 ~~addition, the department shall assess a fee of \$100.00 for each~~
28 ~~follow-up inspection due to noncompliance during the same year. The~~
29 **If the department conducts an inspection and finds an item of**

1 **noncompliance, the** department may accept a written certification
 2 from the licensee ~~or registrant~~ that ~~the items~~ **the item** of
 3 noncompliance ~~have~~ **has** been corrected instead of performing a
 4 follow-up inspection. If the department does not inspect a source
 5 of ionizing radiation for a period of 5 consecutive years, the
 6 licensee ~~or registrant~~ of the source of ionizing radiation does not
 7 have to pay further license ~~or registration~~ fees as to that source
 8 of ionizing radiation until the first license ~~or registration~~
 9 renewal date following the time an inspection of the source of
 10 ionizing radiation is made.

11 (4) A fee collected under this part ~~shall~~ **must** be deposited in
 12 the state treasury and credited to the general fund of this state.

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

16	(a) Inspection, per radiation machine.....	\$	-100.00
17	(b) Reinspection for reinstatement of mammography	\$	
18	authorization, per radiation machine.....		-100.00
19	(c) Department evaluation of compliance with section	\$	
20	13523(2)(a), per radiation machine.....		-700.00
21	Each reevaluation of a radiation machine due to	\$	
22	failure during the previous evaluation, relocation of the		
23	radiation machine, or similar changes that could affect		
24	earlier evaluation results.....		-300.00.

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

1 (5) ~~(7)~~—Except as otherwise provided in ~~subsections~~**subsection**
2 (3), ~~and (6)~~, the department shall not waive a fee required under
3 this section.

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

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

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

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

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

5 **PART 135A**

6 **RADIATION MACHINE CONTROL**

7 **Sec. 13551. (1) As used in this part, the words and phrases**
 8 **defined in sections 13552 to 13554 have the meanings ascribed to**
 9 **them in those sections.**

10 **(2) In addition, article 1 contains general definitions and**
 11 **principles of construction applicable to all articles in this code.**

12 **Sec. 13552. (1) "Certification organization" means a national**
 13 **certification organization that specializes in the certification**
 14 **and registration of medical imaging or radiation therapy technical**
 15 **personnel and is accredited by the National Commission for**
 16 **Certifying Agencies, ANSI National Accreditation Board, the**
 17 **International Organization for Standardization, or another**
 18 **accreditation organization that accredits certification**
 19 **organizations recognized by the department.**

20 **(2) "Computed tomography" means the process of producing**
 21 **sectional and 3-dimensional images using external ionizing**
 22 **radiation for diagnostic, interventional, or therapeutic purposes.**

23 **(3) "Department" means the department of labor and economic**
 24 **opportunity.**

25 **(4) "Director" means the director of the department or his or**
 26 **her designee.**

27 **(5) "Fluoroscopy" means the exposure of a patient to X-rays in**
 28 **a fluoroscopy mode, including the positioning of the patient and**
 29 **fluoroscopy equipment and the selection of exposure factors.**

1 (6) "Ionizing radiation" means gamma rays and X-rays, alpha
2 particles, beta particles, high-speed electrons, neutrons, protons,
3 high-speed ions, and other high-speed nuclear particles.

4 Sec. 13553. (1) "Licensed health professional" means an
5 individual who is licensed under article 15 to engage in the
6 practice of medicine, osteopathic medicine and surgery,
7 chiropractic, podiatric medicine and podiatric surgery, or
8 dentistry.

9 (2) "Limited X-ray machine operator" means an individual
10 certified by the department under this part to operate a radiation
11 machine as described in section 13576.

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

16 (4) "Mammography authorization" means authorization under
17 section 13573 to use a radiation machine for mammography.

18 (5) "Mammography interpreting physician" means a physician who
19 meets the requirements set forth in section 13573(2)(g) and is
20 responsible for evaluating and interpreting mammographic images.

21 (6) "Mammography system" means the radiation machine used for
22 mammography, automatic exposure control devices, imaging systems,
23 image processor, darkroom, and viewboxes.

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

27 (8) "Non-ionizing radiation device" means a machine or device
28 that produces non-ionizing radiation in intensities or frequencies
29 subject to regulation by the department by rule.

1 (9) "Nuclear medicine technologist" means an individual
2 certified by the department under this part to operate a radiation
3 machine as described in section 13575(3) to perform nuclear
4 medicine technology procedures.

5 (10) "Nuclear medicine technology" means a medical imaging and
6 therapeutic modality that uses sealed and unsealed radioactive
7 materials for diagnostic, treatment, and research purposes and that
8 may be combined with computed tomography and other modalities to
9 produce 3-dimensional images, the preparation of
10 radiopharmaceuticals, the use of adjunctive medicines including
11 contrast media and pharmaceuticals associated with nuclear medicine
12 procedures, and therapeutic procedures using sealed and unsealed
13 radioactive sources.

14 (11) "Nuclear medicine technology procedures" means nuclear
15 medicine and molecular imaging procedures using sealed and unsealed
16 radiation sources, ionizing radiation, nondiagnostic computed
17 tomography, and the preparation of radiopharmaceuticals, and the
18 use of adjunctive medicines including contrast media and
19 pharmaceuticals associated with nuclear medicine procedures and
20 therapeutic procedures using unsealed radioactive sources.

21 Sec. 13554. (1) "Person" means that term as defined in section
22 1106 or a governmental entity.

23 (2) "Radiation machine" means a machine or device that
24 produces or detects ionizing radiation in energies or intensities
25 subject to regulation by the department by rule.

26 (3) "Radiation therapist" means an individual who is certified
27 by the department under this part to operate a radiation machine as
28 described in section 13575(2) for purposes of performing radiation
29 therapy procedures.

1 (4) "Radiation therapy" means applying ionizing radiation
2 emitted from particle accelerators, cobalt 60 units, and sealed
3 sources of radioactive material to human beings for therapeutic
4 purposes.

5 (5) "Radiographer" means an individual who is certified by the
6 department to operate a radiation machine as described in section
7 13575(1) to perform a comprehensive set of diagnostic or
8 interventional radiographic procedures using external ionizing
9 radiation to produce radiographic, fluoroscopic, or digital images.

10 (6) "Radiography" means the making of a film, digital image,
11 or other record of an internal structure of the body by passing X-
12 rays through the body to act on film or other image receptor.

13 (7) "Radiologist assistant" means an individual who is
14 certified by the department under this part to operate a radiation
15 machine as described in section 13575(4).

16 (8) "Registration" means registration of a radiation machine
17 in writing with the department.

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

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

25 (a) Electrical or other equipment or material not intended
26 primarily to produce radiation that, by nature of design, does not
27 produce radiation at the point of nearest approach at a weekly rate
28 higher than 1/10 the appropriate limit generally accepted by the
29 medical profession for any critical organ exposed. The production

1 testing or production servicing of the equipment is not exempt.

2 (b) A radiation machine during process of manufacture or in
3 storage or transit. The production testing or production servicing
4 of the radiation machine is not exempt.

5 (c) Non-ionizing radiation sources or devices, unless
6 specifically addressed by a rule promulgated by the department
7 under this part.

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

14 (2) An agreement entered into under subsection (1) does not
15 transfer, delegate, or impose on the department any power,
16 authority, or responsibility that is not fully consistent with this
17 part.

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

20 (2) In the manner required by rules promulgated under this
21 part, the department shall require registration of radiation
22 machines.

23 (3) The department shall develop and conduct programs for
24 evaluation and control of hazards associated with the use of
25 radiation machines.

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

29 (5) In the manner required by this part and rules promulgated

1 under this part, the department shall require certification of
2 individuals who operate radiation machines for diagnostic,
3 interventional, or therapeutic purposes and who are not otherwise
4 exempted from this part.

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

19 Sec. 13567. (1) The department may enter at all reasonable
20 times on private or public property on which radiation machines are
21 reasonably believed to be located, with the permission of the owner
22 or custodian of the property, to determine if the radiation machine
23 or an individual operating the radiation machine is in compliance
24 with this 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 exists
28 on the property evidence of such a violation, and permission to
29 enter on the property is denied by the owner or custodian of the

1 property, the department may make an affidavit for a search warrant
2 under 1966 PA 189, MCL 780.651 to 780.659. The search warrant
3 issued to the department under 1966 PA 189, MCL 780.651 to 780.659,
4 must command the sheriff or a law enforcement officer, with the aid
5 of the department, to search the property and seize the radiation
6 machine that is possessed, controlled, or used wholly or partially
7 in violation of this part or a rule promulgated under this part, or
8 evidence of a violation of this part or a rule promulgated under
9 this part.

10 Sec. 13571. (1) The department shall promulgate rules
11 providing for the registration of radiation machines. The
12 department may promulgate rules for the registration of non-
13 ionizing radiation devices. In promulgating rules under this
14 subsection, the department may establish requirements for exemption
15 from registration, record keeping, permissible levels of exposure,
16 notification and reports of accidents, protective measures,
17 technical qualifications of personnel, handling, posting and
18 labeling of hazardous machines, devices, and areas, surveys, and
19 monitoring.

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

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

27 (4) The department shall promulgate rules providing for the
28 recognition of certification organizations and the certification of
29 individuals operating radiation machines for human screening or for

1 diagnostic, interventional, or therapeutic purposes. The rules must
2 specify minimum training and performance standards to ensure that
3 an individual receiving a certification from the department under
4 this part is adequately instructed in the safe operating procedures
5 of a radiation machine. In promulgating rules under this
6 subsection, the department may establish requirements for exemption
7 from certification.

8 Sec. 13572. (1) Except as otherwise provided in subsection
9 (2), the department may promulgate rules to establish a schedule of
10 fees to be paid by an applicant for the registration of a radiation
11 machine or a non-ionizing radiation device. The department shall
12 promulgate rules to establish a schedule of fees to be paid by an
13 applicant for certification to operate a radiation machine.

14 (2) The registration or registration renewal fee for a
15 radiation machine registered under this part is \$75.00 annually per
16 X-ray or electron tube. The department shall not assess a fee for
17 the amendment of a radiation machine registration certificate. In
18 addition, the department shall assess a fee of \$100.00 for each
19 follow-up 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 or non-ionizing radiation device for a
24 period of 5 consecutive years, the registrant of the radiation
25 machine or non-ionizing radiation device does not have to pay
26 further registration fees as to that radiation machine or non-
27 ionizing radiation device until the first registration renewal date
28 following the time an inspection of the radiation machine or non-
29 ionizing radiation device is made.

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

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

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

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

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

11 (d) Each reevaluation of a radiation machine due
12 to failure during the previous evaluation, relocation
13 of the radiation machine, or similar changes that
14 could affect earlier evaluation results..... \$300.00.

15 (5) If an applicant for mammography authorization submits an
16 evaluation report issued by the American College of Radiology that
17 evidences compliance with section 13573(2)(a), the department shall
18 waive the fee under subsection (4) for department evaluation of
19 compliance with that provision.

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

22 (7) The department shall adjust on an annual basis the fees
23 prescribed in this section by an amount determined by the state
24 treasurer to reflect the cumulative annual percentage change in the
25 Detroit Consumer Price Index, not to exceed 5%. As used in this
26 subsection, "Detroit Consumer Price Index" means the most
27 comprehensive index of consumer prices available for the Detroit
28 area from the Bureau of Labor Statistics of the United States
29 Department of Labor.

1 Sec. 13573. (1) A person shall not use a radiation machine to
2 perform mammography unless the radiation machine is registered with
3 the department under department rules for registration of radiation
4 machines and is specifically authorized under this section for use
5 for mammography.

6 (2) The department shall authorize a radiation machine for use
7 for mammography if the radiation machine, the personnel operating
8 the radiation machine, and the facility in which the radiation
9 machine is used meet all of the following standards:

10 (a) The radiation machine and the facility in which the
11 radiation machine is used meet the criteria for the American
12 College of Radiology Mammography Accreditation Program dated August
13 1993 and amended 1995 (Res. 24, 53) and published by the American
14 College of Radiology in the documents entitled "ACR Standards for
15 the Performance of Screening Mammography", which documents and
16 criteria are incorporated by reference, excluding the physician
17 interpreter and the accreditation fee schedule. The department
18 shall make copies of those criteria available to the public and may
19 by rule adopt modified criteria. The department may accept an
20 evaluation report issued by the American College of Radiology as
21 evidence that a radiation machine, the personnel operating the
22 radiation machine, and the facility in which the radiation machine
23 is used meet those criteria. If at any time the department
24 determines that it will not accept any evaluation reports issued by
25 the American College of Radiology as evidence that a radiation
26 machine, the personnel operating the radiation machine, and the
27 facility in which the radiation machine is used meet those
28 criteria, the department shall promptly notify each person who has
29 registered a radiation machine used exclusively to perform

1 mammography under this part and the rules promulgated under this
2 part.

3 (b) The radiation machine, the film or other image receptor
4 used in the radiation machine, and the facility in which the
5 radiation machine is used meet the requirements set forth in
6 department rules for radiation machines.

7 (c) The radiation machine is specifically designed to perform
8 mammography.

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

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

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

18 (iii) Designates a physician licensed under part 170 or 175 as
19 the lead interpreting physician. The physician designated under
20 this subparagraph is responsible for the clinical aspects of the X-
21 ray examinations and other procedures related to mammography and is
22 also responsible for conducting an on-site visit to each
23 mammography station within the facility at least monthly for the
24 purpose of providing professional feedback regarding clinical image
25 quality and quality assurance procedures, for review of quality
26 control documentation, and for ensuring that safe operating
27 procedures are used in the delivery of mammographic services. If
28 the physician designated under this subparagraph practices
29 primarily outside of the facility, the physician shall keep a log

1 of each on-site visit signed by the physician. The chief
2 administrative officer of the facility or his or her designee may
3 request to view the log at any time. The physician designated under
4 this subparagraph shall meet the requirements of subdivision (g) (i)
5 and (v).

6 (iv) Submits, as part of the application for authorization and
7 subsequent renewals, evidence of a surety bond, secured trust fund,
8 or other suitable secured instrument or mechanism that is approved
9 by the department and that ensures proper patient mammography
10 record and film handling and transfer in the event of facility
11 closure. The facility shall attest that the method of coverage
12 chosen will completely cover all costs involved and will be
13 adjusted, as needed, accordingly.

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

16 (f) Each individual who operates the radiation machine can
17 demonstrate to the department that he or she is specifically
18 trained in mammography and meets the standards required by the
19 rules promulgated under section 13571(3) or is a physician licensed
20 under part 170 or 175.

21 (g) The X-ray images of each mammographic examination
22 performed with the radiation machine are interpreted by a
23 mammography interpreting physician who is a physician licensed
24 under part 170 or 175 and who meets all of the following
25 requirements:

26 (i) Is certified in radiology or diagnostic radiology by the
27 American Board of Radiology or the American Osteopathic Board of
28 Radiology, has been eligible for certification in radiology or
29 diagnostic radiology for not more than 3 years, or is certified or

1 determined to be qualified in radiology or diagnostic radiology by
2 another professional organization approved by the department.

3 (ii) Has successfully completed not less than 3 months of
4 formal training in reading mammograms with instruction in medical
5 radiation physics, radiation effects, and radiation protection and
6 has documentation of successful completion of the training that is
7 satisfactory to the department. For purposes of this subparagraph,
8 the department may accept time spent in a residency program that
9 includes specific training in mammography if the individual has
10 documentation of the residency program that is satisfactory to the
11 department.

12 (iii) Has initial training that includes documented
13 interpretation of not less than 240 mammographic examinations in
14 the 6 months immediately preceding the performance of independent
15 interpretation.

16 (iv) Has interpreted or multi-read not less than 960
17 mammographic examinations during the 24 months immediately
18 preceding the date of the mammography facility's annual inspection
19 or the last day of the calendar quarter preceding that inspection,
20 or any day in between those 2 days. The mammography facility shall
21 choose 1 of the 3 dates to determine the 24-month period of this
22 subparagraph.

23 (v) Has successfully completed or taught not less than 15
24 hours of continuing medical education every 3 years after the
25 effective date of the amendatory act that added this part in the
26 technical aspects or clinical aspects, or both, of mammography in
27 courses or programs approved by the individual's respective
28 specialty organization and licensing board and has documentation of
29 successful completion or teaching that is satisfactory to the

1 department.

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

5 (3) The department may issue a nonrenewable temporary
6 authorization for a radiation machine for use for mammography if
7 additional time is needed to allow submission of evidence
8 satisfactory to the department that the radiation machine, the
9 personnel operating the radiation machine, and the facility in
10 which the radiation machine is used meet the standards set forth in
11 subsection (2) for approval for mammography. A temporary
12 authorization granted under this subsection is effective for not
13 longer than 12 months. The department may withdraw a temporary
14 authorization before its expiration if the radiation machine, the
15 personnel operating the radiation machine, or the facility in which
16 the radiation machine is used does not meet 1 or more of the
17 standards set forth in subsection (2).

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

1 registration specifying mammography authorization for each
2 authorized radiation machine. A mammography authorization is
3 effective for 3 years contingent on the radiation machine for which
4 the mammography authorization is issued, the personnel operating
5 the radiation machine, and the facility in which the radiation
6 machine is operated meeting 1 of the following requirements:

7 (a) Maintaining continued accreditation by the American
8 College of Radiology.

9 (b) Having an active accreditation application in process with
10 the American College of Radiology.

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

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

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

29 (7) The department may withdraw the mammography authorization

1 for a radiation machine if it does not meet 1 or more of the
2 standards set forth in subsection (2).

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

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

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

29 (11) In addition to the penalties provided in section 13585

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

14 Sec. 13573a. (1) If a patient's mammogram demonstrates dense
15 breast tissue, a person who provides mammography services in this
16 state shall provide notification to the patient that includes, but
17 is not limited to, the following information, in the summary of the
18 written report of the results of a mammography examination that is
19 sent directly to a patient under 42 USC 263b:

20 "Your mammogram shows that your breast tissue is dense. Dense
21 breast tissue is very common and is not abnormal. However, dense
22 breast tissue can make it harder to find cancer through a
23 mammogram. Also, dense breast tissue may increase your risk for
24 breast cancer. This information about the result of your mammogram
25 is given to you to raise your awareness. Use this information to
26 discuss with your health care provider whether other supplemental
27 tests in addition to your mammogram may be appropriate for you,
28 based on your individual risk. A report of your results was sent to
29 your ordering physician. If you are self-referred, a report of your

1 results was sent to you in addition to this summary."

2 (2) As used in this section, "dense breast tissue" means
3 heterogeneously or extremely dense breast tissue as defined in
4 nationally recognized guidelines or systems for breast imaging
5 reporting of mammography screening including, but not limited to,
6 the breast imaging reporting and data system established by the
7 American College of Radiology. If, after the effective date of the
8 amendatory act that added this section, new terms are defined in
9 revised guidelines or systems for breast imaging reporting of
10 mammography screening, and the department determines that those new
11 terms are more appropriate for the purposes of the information
12 required to be provided under this section, the department, by
13 order, may update the definition of dense breast tissue under this
14 subsection to use those new terms. On issuance, the department
15 shall forward an order issued under this subsection to the
16 legislature.

17 Sec. 13574. (1) A facility in which a radiation machine is
18 located shall ensure that each individual, except for a licensed
19 health professional, operating the radiation machine for screening
20 or for diagnostic, interventional, or therapeutic purposes holds a
21 certification from the department to operate the radiation machine
22 pursuant to this part.

23 (2) The department may use interview, observation, or both, to
24 determine compliance with this section. A facility described in
25 subsection (1) shall maintain records in order to demonstrate
26 compliance with this section.

27 Sec. 13575. (1) To be granted a certification from the
28 department under this part to operate a radiation machine as a
29 radiographer, an individual shall demonstrate to the department

1 that he or she meets the requirements for certification and
2 registration in radiography from the American Registry of
3 Radiologic Technologists or equivalent standards, as determined by
4 the department, in addition to any other requirement established by
5 the department under section 13571(4). An individual who is granted
6 a certification from the department as a radiographer under this
7 subsection may operate radiography and fluoroscopy radiation
8 machines.

9 (2) To be granted a certification from the department under
10 this part to operate a radiation machine as a radiation therapist,
11 an individual shall demonstrate to the department that he or she
12 meets the requirements for certification and registration in
13 radiation therapy from the American Registry of Radiologic
14 Technologists or equivalent standards, as determined by the
15 department, in addition to any other requirement established by the
16 department under section 13571(4). An individual who is granted a
17 certification from the department as a radiation therapist under
18 this subsection may operate a therapeutic radiation machine and a
19 computed tomography radiation machine for treatment planning
20 purposes.

21 (3) To be granted a certification from the department under
22 this part to operate a radiation machine as a nuclear medicine
23 technologist, an individual shall demonstrate to the department
24 that he or she meets the requirements for certification and
25 registration in nuclear medicine technology from the American
26 Registry of Radiologic Technologists, the Nuclear Medicine
27 Technology Certification Board, or equivalent standards, as
28 determined by the department, in addition to any other requirement
29 established by the department under section 13571(4). An individual

1 who is granted a certification from the department as a nuclear
2 medicine technologist under this subsection may operate radiation
3 machines for the detection of radiation and computed tomography
4 radiation machines for attenuated correction and anatomical
5 localization.

6 (4) To be granted a certification from the department under
7 this part to operate a radiation machine as a radiologist
8 assistant, an individual shall hold a current certification from
9 the department as a radiographer and demonstrate to the department
10 that he or she meets the requirements for certification and
11 registration as a radiologist assistant from the American Registry
12 of Radiologic Technologists, radiology practitioner assistant from
13 the Certification Board of Radiology Practitioner Assistants, or
14 equivalent standards, as determined by the department, in addition
15 to any other requirement established by the department under
16 section 13571(4). An individual who is granted a certification from
17 the department as a radiologist assistant under this subsection may
18 operate radiography and fluoroscopy radiation machines. A
19 radiologist assistant shall not perform image interpretation,
20 render a diagnosis, or prescribe a medication or therapy, but may
21 perform activities in the areas of patient care, patient
22 management, and radiography and fluoroscopy procedures under the
23 supervision of a radiologist.

24 (5) To be granted a certification from the department under
25 this part to operate a computed tomography radiation machine for
26 diagnostic purposes, an individual shall demonstrate all of the
27 following to the department:

28 (a) That he or she holds a current certification from the
29 department as a radiographer, a radiation therapist, a nuclear

1 medicine technologist, or a radiologist assistant.

2 (b) That he or she meets the requirements for certification
3 and registration in computed tomography from the American Registry
4 of Radiologic Technologists, the Nuclear Medicine Technologists
5 certification board, or equivalent standards, as determined by the
6 department.

7 (c) That he or she meets any other requirement established by
8 the department under section 13571(4).

9 Sec. 13576. (1) To be granted a certification from the
10 department under this part as a limited X-ray machine operator, an
11 individual shall meet the prerequisite qualifications, receive
12 training, and demonstrate competence as follows:

13 (a) He or she shall complete at least 48 hours of didactic
14 instruction in a formal program, approved by the department, as
15 prescribed in subsection (3).

16 (b) He or she shall achieve a passing score of 70% on the
17 certification examination for the limited scope of practice in
18 radiography developed by the American Registry of Radiologic
19 Technologists and approved by the department in at least 1 but no
20 more than 3 of the limited scope categories of chest, extremities,
21 skull/sinus, spine, or podiatric. A facility needing to perform
22 examinations in addition to any 3 of these categories shall employ
23 a radiographer. A passing score on the basic chiropractic X-ray
24 technology examination given through the American Chiropractic
25 Registry of Radiologic Technologists and approved by the department
26 is considered to meet the requirements of this subdivision for
27 limited scope spinal radiography.

28 (c) He or she shall complete the clinical experience
29 requirements prescribed in subsection (4). An individual who has

1 been actively working as a medical X-ray operator for at least 6
2 months before the effective date of this part is exempt from the
3 requirements of this subdivision. The individual shall document
4 completion of the didactic training requirements in subdivision (a)
5 and the examination requirements in subdivision (b) within 3 years
6 after the effective date of this part.

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

11 (e) He or she shall meet any other requirement established by
12 the department under section 13571(4).

13 (2) A limited X-ray machine operator is limited in scope of
14 practice to only the examinations listed in this subsection and to
15 performing radiography without the use of contrast media or
16 fluoroscopy. A limited X-ray machine operator may perform only the
17 following specific X-ray examinations:

18 (a) The following X-ray examinations of the extremities:

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

29 (b) The following X-ray examinations of the spine:

1 (i) Cervical spine.....AP, lateral, odontoid, non-
2 trauma, swimmer's non-trauma.

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

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

6 (c) PA, AP, lateral, oblique, decubitus, and apical lordotic
7 X-ray examinations of the chest.

8 (d) Dorsalis pedis and lateral X-ray examinations of the
9 ankle.

10 (e) The following X-ray examinations of the skull and sinus:

11 (i) Entire skull.

12 (ii) Paranasal sinuses.

13 (iii) Facial bones.

14 (iv) Mandible and temporomandibular joint.

15 (3) An individual seeking certification from the department
16 under this part as a limited X-ray machine operator shall complete
17 a minimum of 48 hours of didactic training in a formal training
18 course. After successful completion of the course, the individual
19 shall pass an examination appropriate to his or her scope of
20 practice and complete the clinical experience requirements
21 prescribed in subsection (4). The formal training course is subject
22 to department approval and must provide instruction in all of the
23 following subjects:

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

25 (i) Patient protection.

26 (ii) Personnel protection.

27 (iii) Radiation exposure and monitoring.

28 (b) Equipment operation and maintenance including all of the
29 following:

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 of radiographs.
 9 (d) Patient care including all of the following:

10 (i) Legal and professional responsibilities.
 11 (ii) Patient education, safety, and comfort.
 12 (iii) Prevention and control of infection.
 13 (iv) Patient monitoring.
 14 (e) Radiographic procedure positioning.

15 (4) An individual who completes the requirements of subsection
 16 (3) shall complete 1 month of clinical training during which time
 17 he or she may perform the X-ray examinations allowed under
 18 subsection (2) only under the direct supervision of the physician
 19 in charge, or a radiographer. An individual described in this
 20 subsection must be trained in proper imaging procedures as listed
 21 below:

22 (a) Selection of appropriate radiographic image receptor size.
 23 (b) Selection of appropriate technique factors.
 24 (c) Use of correct source-to-image distance.
 25 (d) Establishment of proper direction of central ray.
 26 (e) Execution of proper patient position.
 27 (f) Collimation of the X-ray beam as appropriate.
 28 (g) Providing gonadal shielding if appropriate.
 29 (h) Using correct radiographic image markers.

- 1 (i) Giving proper patient instruction.
- 2 (j) Placing patient information correctly on the radiographic
- 3 image.
- 4 (k) Completing examination in a timely manner.
- 5 (l) Obtaining desired anatomy and positioning results on the
- 6 radiographic image.
- 7 (m) Obtaining appropriate contrast and density on the
- 8 radiographic image.
- 9 (n) Identifying visible motion or radiographic image artifacts
- 10 and repeating exam if needed.

11 Sec. 13585. A person who violates this part or a rule
12 promulgated under this part or who fails to obtain or comply with a
13 condition of registration or certification under this part is
14 guilty of a misdemeanor punishable by imprisonment for not more
15 than 180 days or a fine of not more than \$10,000.00, or both. Each
16 day a violation continues is a separate violation.

17 Sec. 13586. If, after thorough investigation by the
18 department, it is the judgment of the department that a person has
19 engaged in or is about to engage in an act or practice that
20 constitutes a violation of this part or a rule or order promulgated
21 or issued under this part, the attorney general, at the request of
22 the department, shall apply to the appropriate circuit court for an
23 order enjoining the act or practice or for an order directing
24 compliance with this part or a rule or order promulgated or issued
25 under this part.

26 Enacting section 1. Sections 13523, 13524, 13527, and 13531 of
27 the public health code, 1978 PA 368, MCL 333.13523, 333.13524,
28 333.13527, and 333.13531, are repealed.