

HOUSE BILL NO. 6105

August 17, 2020, Introduced by Rep. Wakeman 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



1 receptor.

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

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

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

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

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

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

21 ~~(a) Electrical or other equipment or material not intended~~
22 ~~primarily to produce radiation which, by nature of design, does not~~
23 ~~produce radiation at the point of nearest approach at a weekly rate~~
24 ~~higher than 1-~~

25 ~~10 the appropriate limit generally accepted by the medical~~
26 ~~profession for any critical organ exposed. The production testing~~
27 ~~or production servicing of the equipment is not exempt.~~

28 ~~(b) A radiation machine during process of manufacture or in~~
29 ~~storage or transit. The production testing or production servicing~~



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

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

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

10 (c) ~~(e)~~ A production **facility** or utilization facility ~~as~~
11 ~~defined in the federal atomic energy act of 1954, 42 U.S.C. 2011 to~~
12 ~~2281,~~ or a source of ionizing radiation used in or in connection
13 with the operation of a production **facility** or utilization facility
14 pursuant to a license from the federal ~~nuclear regulatory~~
15 ~~commission~~ **Nuclear Regulatory Commission** or **its** successor ~~thereto~~
16 **agency**. However, the department may collect radiation data and
17 perform environmental monitoring in connection with the operation
18 of the facility in accordance with this part. **As used in this**
19 **subdivision, "production facility" and "utilization facility" mean**
20 **those terms as defined in 42 USC 2014.**

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



1 Sec. 13515. (1) The department is designated as the radiation
2 control agency of this state and shall coordinate radiation control
3 programs of state departments acting within their statutory
4 authorities.

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

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

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

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



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

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

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

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

26 Sec. 13522. (1) In promulgating rules ~~pursuant to~~ **under** this
 27 part, the department shall avoid requiring dual licensing, insofar
 28 as practical. Rules promulgated by the department may provide for
 29 recognition of other state or federal licenses as the department



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

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

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



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

8 (a) "Department" means the department of labor and economic
9 opportunity.

10 (b) "Director" means the director of the department or his or
11 her designee.

12 (c) "Ionizing radiation" means gamma rays and X-rays, alpha
13 particles, beta particles, high-speed electrons, neutrons, protons,
14 high-speed ions, and other high-speed nuclear particles.

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

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

21 (f) "Mammography interpreting physician" means a physician who
22 meets the requirements set forth in section 13573(2)(g) and is
23 responsible for evaluating and interpreting mammographic 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,
28 microwaves, radio frequency fields, magnetic fields, and visible,
29 infrared, or ultraviolet light.



1 (i) "Non-ionizing radiation device" means a machine or device
2 that produces non-ionizing radiation in intensities or frequencies
3 subject to regulation by the department by rule.

4 (j) "Person" means that term as defined in section 1106 or a
5 governmental entity.

6 (k) "Radiation machine" means a machine or device that
7 produces ionizing radiation in energies or intensities subject to
8 regulation by the department by rule.

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

12 (m) "Registration" means registration of a radiation machine
13 in writing with the department.

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

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

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

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

29 (b) A radiation machine during process of manufacture or in

1 storage or transit. The production testing or production servicing
2 of the radiation machine is not exempt.

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

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

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

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

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

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

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

27 (5) The department shall require certification of individuals
28 who operate radiation machines for diagnostic, instructional, or
29 therapeutic purposes and who are not otherwise exempted from this

1 part.

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

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

22 (2) If the department has probable cause to believe that a
23 violation of this part or a rule promulgated under this part is
24 being committed on private or public property or that there exists
25 on the property evidence of such a violation, and permission to
26 enter on the property is denied by the owner or custodian of the
27 property, the department may make an affidavit for a search warrant
28 under 1966 PA 189, MCL 780.651 to 780.659. The search warrant
29 issued to the department under 1966 PA 189, MCL 780.651 to 780.659,

1 must command the sheriff or a law enforcement officer, with the aid
2 of the department, to search the property and seize the radiation
3 machine that is possessed, controlled, or used wholly or partially
4 in violation of this part or a rule promulgated under this part, or
5 evidence of a violation of this part or a rule promulgated under
6 this part.

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

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

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 13573.

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

28 Sec. 13572. (1) Except as otherwise provided in subsection
29 (2), the department may promulgate rules to establish a schedule of

1 fees to be paid by an applicant for the registration of a radiation
2 machine or a non-ionizing radiation device. The department shall
3 promulgate rules to establish a schedule of fees to be paid by an
4 applicant for certification to operate a radiation machine.

5 (2) The registration or registration renewal fee for a
6 radiation machine registered under this part is \$75.00 annually per
7 X-ray or electron tube. The department shall not assess a fee for
8 the amendment of a radiation machine registration certificate. In
9 addition, the department shall assess a fee of \$100.00 for each
10 follow-up inspection due to noncompliance during the same year. The
11 department may accept a written certification from the registrant
12 that the items of noncompliance have been corrected instead of
13 performing a follow-up inspection. If the department does not
14 inspect a radiation machine or non-ionizing radiation device for a
15 period of 5 consecutive years, the registrant of the radiation
16 machine or non-ionizing radiation device does not have to pay
17 further registration fees as to that radiation machine or non-
18 ionizing radiation device until the first registration renewal date
19 following the time an inspection of the radiation machine or non-
20 ionizing radiation device is made.

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

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

- 26 (a) Inspection, per radiation machine.....\$100.00
- 27 (b) Reinspection for reinstatement of
- 28 mammography authorization, per radiation machine..... \$100.00

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

3 (d) Each reevaluation of a radiation machine due
4 to failure during the previous evaluation, relocation
5 of the radiation machine, or similar changes that
6 could affect earlier evaluation results..... \$300.00.

7 (5) If an applicant for mammography authorization submits an
8 evaluation report issued by the American College of Radiology that
9 evidences compliance with section 13573(2)(a), the department shall
10 waive the fee under subsection (4) for department evaluation of
11 compliance with that provision.

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

14 (7) The department shall adjust on an annual basis the fees
15 prescribed in this section by an amount determined by the state
16 treasurer to reflect the cumulative annual percentage change in the
17 Detroit Consumer Price Index, not to exceed 5%. As used in this
18 subsection, "Detroit Consumer Price Index" means the most
19 comprehensive index of consumer prices available for the Detroit
20 area from the Bureau of Labor Statistics of the United States
21 Department of Labor.

22 Sec. 13573. (1) A person shall not use a radiation machine to
23 perform mammography unless the radiation machine is registered with
24 the department under department rules for registration of radiation
25 machines and is specifically authorized under this section for use
26 for mammography.

27 (2) The department shall authorize a radiation machine for use
28 for mammography if the radiation machine, the personnel operating
29 the radiation machine, and the facility in which the radiation

1 machine is used meet all of the following standards:

2 (a) The radiation machine and the facility in which the
3 radiation machine is used meet the criteria for the American
4 College of Radiology Mammography Accreditation Program dated August
5 1993 and amended 1995 (Res. 24, 53) and published by the American
6 College of Radiology in the documents entitled "ACR Standards for
7 the Performance of Screening Mammography", which documents and
8 criteria are incorporated by reference, excluding the physician
9 interpreter and the accreditation fee schedule. The department
10 shall make copies of those criteria available to the public and may
11 by rule adopt modified criteria. The department may accept an
12 evaluation report issued by the American College of Radiology as
13 evidence that a radiation machine, the personnel operating the
14 radiation machine, and the facility in which the radiation machine
15 is used meet those criteria. If at any time the department
16 determines that it will not accept any evaluation reports issued by
17 the American College of Radiology as evidence that a radiation
18 machine, the personnel operating the radiation machine, and the
19 facility in which the radiation machine is used meet those
20 criteria, the department shall promptly notify each person who has
21 registered a radiation machine used exclusively to perform
22 mammography under this part and the rules promulgated under this
23 part.

24 (b) The radiation machine, the film or other image receptor
25 used in the radiation machine, and the facility in which the
26 radiation machine is used meet the requirements set forth in
27 department rules for radiation machines.

28 (c) The radiation machine is specifically designed to perform
29 mammography.

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

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

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

10 (iii) Designates a physician licensed under part 170 or 175 as
11 the lead interpreting physician. The physician designated under
12 this subparagraph is responsible for the clinical aspects of the X-
13 ray examinations and other procedures related to mammography and is
14 also responsible for conducting an on-site visit to each
15 mammography station within the facility at least monthly for the
16 purpose of providing professional feedback regarding clinical image
17 quality and quality assurance procedures, for review of quality
18 control documentation, and for ensuring that safe operating
19 procedures are used in the delivery of mammographic services. If
20 the physician designated under this subparagraph practices
21 primarily outside of the facility, the physician shall keep a log
22 of each on-site visit signed by the physician. The chief
23 administrative officer of the facility or his or her designee may
24 request to view the log at any time. The physician designated under
25 this subparagraph shall meet the requirements of subdivision (g) (i)
26 and (v) .

27 (iv) Submits, as part of the application for authorization and
28 subsequent renewals, evidence of a surety bond, secured trust fund,
29 or other suitable secured instrument or mechanism that is approved

1 by the department and that ensures proper patient mammography
2 record and film handling and transfer in the event of facility
3 closure. The facility shall attest that the method of coverage
4 chosen will completely cover all costs involved and will be
5 adjusted, as needed, accordingly.

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

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

13 (g) The X-ray images of each mammographic examination
14 performed with the radiation machine are interpreted by a
15 mammography interpreting physician who is a physician licensed
16 under part 170 or 175 and who meets all of the following
17 requirements:

18 (i) Is certified in radiology or diagnostic radiology by the
19 American Board of Radiology or the American Osteopathic Board of
20 Radiology, has been eligible for certification in radiology or
21 diagnostic radiology for not more than 3 years, or is certified or
22 determined to be qualified in radiology or diagnostic radiology by
23 another professional organization approved by the department.

24 (ii) Has successfully completed not less than 3 months of
25 formal training in reading mammograms with instruction in medical
26 radiation physics, radiation effects, and radiation protection and
27 has documentation of successful completion of the training that is
28 satisfactory to the department. For purposes of this subparagraph,
29 the department may accept time spent in a residency program that



1 includes specific training in mammography if the individual has
2 documentation of the residency program that is satisfactory to the
3 department.

4 (iii) Has initial training that includes documented
5 interpretation of not less than 240 mammographic examinations in
6 the 6 months immediately preceding the performance of independent
7 interpretation.

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

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

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

26 (3) The department may issue a nonrenewable temporary
27 authorization for a radiation machine for use for mammography if
28 additional time is needed to allow submission of evidence
29 satisfactory to the department that the radiation machine, the

1 personnel operating the radiation machine, and the facility in
2 which the radiation machine is used meet the standards set forth in
3 subsection (2) for approval for mammography. A temporary
4 authorization granted under this subsection is effective for not
5 longer than 12 months. The department may withdraw a temporary
6 authorization before its expiration if the radiation machine, the
7 personnel operating the radiation machine, or the facility in which
8 the radiation machine is used does not meet 1 or more of the
9 standards set forth in subsection (2).

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

28 (a) Maintaining continued accreditation by the American
29 College of Radiology.

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

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

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

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

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

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

27 (9) On a finding that a deficiency in a radiation machine used
28 for mammography or a violation of this part or the rules
29 promulgated under this part seriously affects the health, safety,

1 and welfare of individuals on whom the radiation machine is used
2 for mammography, the department may issue an emergency order
3 summarily withdrawing the mammography authorization for the
4 radiation machine. The department shall incorporate its findings in
5 the order and shall provide an opportunity for a hearing within 5
6 working days after issuance of the order. The order is effective
7 during the proceedings.

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

21 (11) In addition to the penalties provided in section 13585
22 and the reinspection fee required under section 13572, if a person
23 violates subsection (1), the department may impose an
24 administrative fine against the owner of the radiation machine or,
25 if a lessee of the radiation machine has effective control of the
26 radiation machine, the lessee, of not more than \$500.00 for each
27 calendar week in which a mammography is performed in violation of
28 subsection (1). If a person continues to violate subsection (1) for
29 a period of 2 weeks after a fine is imposed under this subsection,



1 the department shall post a conspicuous notice on the unauthorized
2 radiation machine and at the entry to the facility where the
3 radiation machine is located warning the public that the facility
4 is performing mammography using a radiation machine that is a
5 substantial hazard to the public health.

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

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

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

26 (2) As used in this section, "dense breast tissue" means
27 heterogeneously or extremely dense breast tissue as defined in
28 nationally recognized guidelines or systems for breast imaging
29 reporting of mammography screening including, but not limited to,

1 the breast imaging reporting and data system established by the
2 American College of Radiology. If, after the effective date of the
3 amendatory act that added this section, new terms are defined in
4 revised guidelines or systems for breast imaging reporting of
5 mammography screening, and the department determines that those new
6 terms are more appropriate for the purposes of the information
7 required to be provided under this section, the department, by
8 order, may update the definition of dense breast tissue under this
9 subsection to use those new terms. On issuance, the department
10 shall forward an order issued under this subsection to the
11 legislature.

12 Sec. 13574. (1) A limited scope operator is limited in scope
13 of practice to only those procedures listed in subsection (3). A
14 limited scope operator shall meet the prerequisite qualifications,
15 receive training, and demonstrate competence as follows:

16 (a) Shall complete at least 48 hours of didactic instruction
17 in a formal program, approved by the department, as prescribed in
18 subsection (4).

19 (b) Shall achieve a passing score of 70% on the certification
20 examination for the limited scope of practice in radiography
21 developed by the American Registry of Radiologic Technologists and
22 approved by the department in at least 1 but no more than 3 of the
23 limited scope categories of chest, extremities, skull/sinus, spine,
24 or podiatric. A facility needing to perform examinations in
25 addition to any 3 of these categories shall employ a comprehensive
26 scope operator according to subsection (2). A passing score on the
27 basic chiropractic X-ray technology examination given through the
28 American Chiropractic Registry of Radiologic Technologists and
29 approved by the department is considered to meet the requirements



1 of this subdivision for limited scope spinal radiography.

2 (c) Shall complete the clinical experience requirements in
3 subsection (5). An individual who has been actively working as a
4 medical X-ray operator for at least 6 months before the effective
5 date of this part is exempt from the requirements of this
6 subdivision. The individual shall document completion of the
7 didactic training requirements in subdivision (a) and the
8 examination requirements in subdivision (b) within 3 years after
9 the effective date of this part.

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

14 (2) A comprehensive scope operator is not limited in scope of
15 practice for performing medical X-ray procedures. A comprehensive
16 scope operator must meet the prerequisite qualifications, receive
17 training, and demonstrate competence as follows:

18 (a) Shall meet the standards for issuance of a registration
19 certificate as a registered technologist from the American Registry
20 of Radiologic Technologists or other nationally recognized
21 accreditation body. These standards, entitled "Rules and
22 Regulations", as revised in February 1990, and "By-Laws", as
23 revised in September, 1989, published by the American Registry of
24 Radiologic Technologists, are incorporated by reference. These
25 standards are available from the radiation safety section of the
26 department at no charge. The standards are also available from the
27 American Registry of Radiologic Technologists, at no charge. A
28 determination by the American Registry of Radiologic Technologists
29 that an individual meets its respective standards for issuance of a

1 registration certificate is prima facie evidence to the department
2 that the individual complies with the standards.

3 (b) Shall, if the scope of practice includes specialties such
4 as computed tomography or radiation therapy, meet the standards for
5 issuance of advanced certification in that specialty from the
6 American Registry of Radiologic Technologists, as approved by the
7 department.

8 (3) A limited scope X-ray operator described in subsection (1)
9 shall perform only the following specific X-ray examinations:

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

- 11 (i) Hand and fingers..... PA, lateral, oblique.
- 12 (ii) Wrists..... PA, lateral, oblique.
- 13 (iii) Forearm..... AP, lateral.
- 14 (iv) Elbow..... AP, lateral.
- 15 (v) Humerus..... AP, lateral.
- 16 (vi) Foot and toes..... AP, lateral, oblique.
- 17 (vii) Ankle..... AP, lateral, oblique.
- 18 (viii) Tibia-fibula..... AP, lateral.
- 19 (ix) Knee..... AP, lateral.
- 20 (x) Femur..... AP, lateral.

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

- 22 (i) Cervical spine..... AP, lateral, odontoid, non-
23 trauma, swimmer's non-trauma.
- 24 (ii) Thoracic spine..... AP, lateral, swimmer's non-
25 trauma.
- 26 (iii) Lumbar spine..... AP, lateral, L5-S1 lateral.

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

- 1 (d) DP and lateral X-ray examinations of the ankle.
- 2 (e) The following X-ray examinations of the skull and sinus:
- 3 (i) Entire skull.
- 4 (ii) Paranasal sinuses.
- 5 (iii) Facial bones.
- 6 (iv) Mandible and temporomandibular joint.

7 (4) An individual described in subsections (1) and (2) shall
8 complete a minimum of 48 hours of didactic training in a formal
9 training course. After successful completion of the course, the
10 individual shall pass an examination appropriate to his or her
11 scope of practice and complete the clinical experience requirements
12 prescribed in subsection (5). The formal training course is subject
13 to department approval and shall provide instruction in all of the
14 following subjects:

- 15 (a) Radiation protection including all of the following:
 - 16 (i) Patient protection.
 - 17 (ii) Personnel protection.
 - 18 (iii) Radiation exposure and monitoring.
- 19 (b) Equipment operation and maintenance including all of the
20 following:
 - 21 (i) Radiographic unit components.
 - 22 (ii) Principles of X-ray production.
 - 23 (iii) Recognition of malfunctions.
- 24 (c) Image production and evaluation including all of the
25 following:
 - 26 (i) Selection of technique factors.
 - 27 (ii) Film processing and quality assurance.
 - 28 (iii) Evaluation of radiographs.

- 1 (d) Patient care including all of the following:
- 2 (i) Legal and professional responsibilities.
- 3 (ii) Patient education, safety, and comfort.
- 4 (iii) Prevention and control of infection.
- 5 (iv) Patient monitoring.
- 6 (e) Radiographic procedure positioning.
- 7 (5) An individual who completes the requirements of subsection
- 8 (4) shall complete 1 month of clinical training during which time
- 9 he or she may perform the X-ray examinations allowed under
- 10 subsection (3) only under the direct supervision of the physician
- 11 in charge, a comprehensive scope operator, or a limited scope
- 12 operator with not less than 3 years of experience. An individual
- 13 described in this subsection must be trained in proper imaging
- 14 procedures as listed below:
- 15 (a) Selection of appropriate film size.
- 16 (b) Selection of appropriate technique factors.
- 17 (c) Use of correct source-to-image distance.
- 18 (d) Establishment of proper direction of central ray.
- 19 (e) Execution of proper patient position.
- 20 (f) Collimation of the X-ray beam as appropriate.
- 21 (g) Providing gonadal shielding if appropriate.
- 22 (h) Using correct film markers.
- 23 (i) Giving proper patient instruction.
- 24 (j) Placing patient information correctly on the film.
- 25 (k) Completing examination in a timely manner.
- 26 (l) Obtaining desired anatomy and positioning results on the
- 27 film.
- 28 (m) Obtaining appropriate contrast and density on the film.
- 29 (n) Identifying visible motion or film artifacts and repeating

1 exam if needed.

2 Sec. 13581. The director shall appoint an ionizing radiation
3 advisory committee. Members of the committee serve at the pleasure
4 of the director. The committee shall furnish to the department
5 technical advice the committee considers desirable or the
6 department may reasonably request on matters relating to the
7 radiation machine control program.

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

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

23 Enacting section 1. Sections 13523, 13524, 13527, and 13531 of
24 the public health code, 1978 PA 368, MCL 333.13523, 333.13524,
25 333.13527, and 333.13531, are repealed.

