

HOUSE BILL No. 4869

June 20, 2013, Introduced by Reps. Glardon, Santana, Crawford, Hooker, Haines, Singh,
Darany, Zorn, Graves, Foster and Brown and referred to the Committee on Health Policy.

A bill to amend 1978 PA 368, entitled
"Public health code,"
by amending the heading of part 135 and sections 13501, 13505,
13506, 13511, 13515, 13517, 13521, 13522, 13525, 13535, and 13536
(MCL 333.13501, 333.13505, 333.13506, 333.13511, 333.13515,
333.13517, 333.13521, 333.13522, 333.13525, 333.13535, and
333.13536), sections 13501 and 13522 as amended by 1994 PA 100
and section 13521 as amended by 1989 PA 56, and by adding part
135a; and to repeal acts and parts of acts.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

PART 135

~~RADIATION~~ RADIOACTIVE MATERIAL CONTROL

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

(A) "DEPARTMENT" MEANS THE DEPARTMENT OF ENVIRONMENTAL QUALITY.

(B) ~~(a)~~—"General license" means a license, effective pursuant to ~~UNDER~~ rules promulgated by the department without the filing of an application OR ISSUANCE OF A LICENSE, to transfer, acquire, own, possess, or use quantities of, or devices or equipment utilizing, radioactive material.

(C) ~~(b)~~—"Ionizing radiation" means ALL RADIATIONS CAPABLE OF PRODUCING IONS DIRECTLY OR INDIRECTLY IN THEIR PASSAGE THROUGH MATTER, INCLUDING ALL OF THE FOLLOWING:

(i) ELECTROMAGNETIC RADIATIONS INCLUDING gamma rays and x-rays. ~~7~~

(ii) PARTICULATE RADIATIONS INCLUDING alpha particles, beta particles, ~~high-speed~~ electrons, neutrons, protons, ~~high-speed~~ ions, and other ~~high-speed~~ nuclear particles.

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

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

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

(D) ~~(f)~~—"Person" means a ~~person~~ THAT TERM as defined in section 1106 or a STATE OR LOCAL governmental entity. PERSON DOES NOT INCLUDE THE DEPARTMENT OR A FEDERAL GOVERNMENTAL ENTITY.

(E) ~~(g)~~ "Radioactive material" means a solid, liquid, or gas material ~~which~~ **THAT** emits ionizing radiation spontaneously, **INCLUDING ACCELERATOR-PRODUCED, BY-PRODUCT, NATURALLY OCCURRING, SOURCE, AND SPECIAL NUCLEAR MATERIALS.**

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

(F) ~~(i)~~ "Registration" means registration of a ~~source of~~ ionizing radiation **RADIOACTIVE MATERIAL OR DEVICES OR EQUIPMENT UTILIZING RADIOACTIVE MATERIAL** in writing with the department.

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

(G) ~~(k)~~ "Specific license" means a license issued **BY THE DEPARTMENT** to use, manufacture, produce, transfer, receive, acquire, own, or possess quantities of, or devices or equipment utilizing, radioactive material.

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

Sec. 13505. A person shall not manufacture, produce, transport, transfer, dispose of, acquire, own, possess, or use a radioactive material ~~or other source of ionizing radiation unless~~ **THE PERSON IS** licensed, registered, or exempted **UNDER THIS PART OR IS LICENSED, REGISTERED, OR EXEMPTED** by the department in accordance with rules promulgated ~~pursuant to~~ **BY THE DEPARTMENT UNDER** this part. ~~or unless exempted by this part.~~

Sec. 13506. ~~Sections~~ **EXCEPT AS OTHERWISE PROVIDED IN THIS**

1 **SECTION, SECTIONS** 13505 and 13515 to 13536 do not apply to the
2 following sources or conditions: ~~, except as noted:~~

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

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

13 (A) ~~(e)~~ A radioactive material while being transported under
14 the jurisdiction of and in conformity with regulations adopted by
15 the **UNITED STATES** nuclear regulatory commission, **THE UNITED**
16 **STATES DEPARTMENT OF ENERGY**, or the United States department of
17 transportation, or their successors, specifically applicable to
18 the transportation of ~~such~~ **THE** radioactive material.

19 ~~—— (d) Sound waves, radio waves, and visible, infrared, or~~
20 ~~ultraviolet light.~~

21 (B) ~~(e)~~ A production **FACILITY** or utilization facility ~~, as~~
22 ~~defined in the federal atomic energy act of 1954, 42 U.S.C. 2011~~
23 ~~to 2281, or a source of ionizing radiation~~ **RADIOACTIVE MATERIAL**
24 used in or in connection with the operation of a production
25 **FACILITY** or utilization facility pursuant to a license from the
26 ~~federal~~ **UNITED STATES** nuclear regulatory commission or **ITS**
27 ~~successor thereto~~ **AGENCY**. However, the department may collect

1 radiation data and perform environmental monitoring in connection
2 with the operation of the facility ~~in accordance with~~ **PURSUANT TO**
3 this part. **AS USED IN THIS SUBDIVISION, "PRODUCTION FACILITY" AND**
4 **"UTILIZATION FACILITY" MEAN THOSE TERMS AS DEFINED IN 42 USC**
5 **2014.**

6 (C) ~~(f)~~ A source material, by-product material, or special
7 nuclear material over which the ~~federal~~ **UNITED STATES** nuclear
8 regulatory commission or ~~a~~ **ITS** successor ~~thereto~~ **AGENCY** has
9 exclusive regulatory jurisdiction under the ~~federal~~ atomic energy
10 act of 1954, **42 USC 2011 TO 2297H-13**, which jurisdiction has not
11 been transferred to this state pursuant to an agreement under ~~Act~~
12 ~~No. 54 of the Public Acts of 1965, being sections 3.801 and 3.802~~
13 ~~of the Michigan Compiled Laws 1965 PA 54, MCL 3.801 TO 3.802.~~

14 Sec. 13511. (1) The governor may enter into agreements with
15 the federal government, other states, or interstate agencies,
16 whereby the department shall perform for or on a cooperative
17 basis with the federal government, other states, or interstate
18 agencies inspections, environmental monitoring, or other
19 functions relating to control of ~~sources of ionizing radiation~~
20 **RADIOACTIVE MATERIAL.**

21 (2) An agreement entered into ~~pursuant to~~ **UNDER** subsection
22 (1) does not transfer, delegate, or impose upon the department
23 any power, authority, or responsibility that is not fully
24 consistent with this part.

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

1 of state departments acting within their statutory authorities.

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

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

9 Sec. 13517. (1) The department may enter at all reasonable
10 times upon private or public property upon which ~~sources of~~
11 ~~ionizing radiation~~ **RADIOACTIVE MATERIALS** are reasonably believed
12 to be located, with the permission of the owner or custodian
13 ~~thereof~~ **OF THE PROPERTY**, to determine if there is compliance with
14 or violation of this part or a rule **PROMULGATED UNDER THIS PART**
15 or **COMPLIANCE WITH OR A VIOLATION OF A** license **OR REGISTRATION**
16 **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 **OR REGISTRATION**
20 **ISSUED UNDER THIS PART** is being committed on private or public
21 property or that there exists on the property evidence of a
22 violation, and permission to enter ~~thereon~~ **ON THE PROPERTY** is
23 denied by the owner or custodian ~~thereof~~ **OF THE PROPERTY**, the
24 department may ~~apply to the proper judicial officer~~ **MAKE AN**
25 **AFFIDAVIT FOR A SEARCH WARRANT** under ~~Act No. 189 of the Public~~
26 ~~Acts of 1966, being sections 780.651 to 780.659 of the Michigan~~
27 ~~Compiled Laws 1966 PA 189, MCL 780.651 TO 780.659, for a warrant~~

1 commanding the sheriff or a law enforcement officer, with the aid
 2 of the department, to search the property and seize any ~~source of~~
 3 ~~ionizing radiation~~ **RADIOACTIVE MATERIAL** that is possessed,
 4 controlled, or used wholly or partially in violation of this part
 5 or a rule **PROMULGATED UNDER THIS PART** or **IN VIOLATION OF A**
 6 **license OR REGISTRATION ISSUED UNDER THIS PART**, or any evidence
 7 of a violation of this part, ~~or a rule, or license, OR~~
 8 **REGISTRATION.**

9 Sec. 13521. (1) The department shall promulgate rules
 10 ~~providing for general~~ **UNDER THE ADMINISTRATIVE PROCEDURES ACT OF**
 11 **1969 AS REQUIRED IN THIS PART. THE DEPARTMENT SHALL INCLUDE ALL**
 12 **OF THE FOLLOWING IN RULES PROMULGATED UNDER THIS PART:**

13 **(A) GENERAL** or specific licenses or registration, or
 14 exemption from licensing or registration, for radioactive
 15 materials. ~~and other sources of ionizing radiation. The rules~~
 16 ~~shall provide for amendment,~~

17 **(B) AMENDMENT, RENEWAL,** suspension, or revocation of
 18 licenses **OR REGISTRATIONS.** ~~In connection with those rules, the~~

19 **(2) THE** department may ~~promulgate~~ **INCLUDE IN** rules ~~to~~
 20 ~~establish~~ **PROMULGATED UNDER THIS PART** requirements for record
 21 keeping, permissible levels of exposure, notification and reports
 22 of accidents, protective measures, technical qualifications of
 23 personnel, handling, transportation, storage, waste disposal,
 24 posting and labeling of hazardous sources and areas, surveys, and
 25 monitoring.

26 **(3) (2)** ~~The~~ **DEPARTMENT SHALL NOT INCLUDE IN** rules ~~shall not~~
 27 **PROMULGATED UNDER THIS PART ANY** limit **ON** the intentional exposure

1 of patients to radiation for the purpose of lawful therapy or
 2 research conducted by licensed health professionals.

3 ~~—— (3) The department shall promulgate rules specifying the~~
 4 ~~minimum training and performance standards for an individual~~
 5 ~~using a radiation machine for mammography as set forth in section~~
 6 ~~13523.~~

7 Sec. 13522. (1) In promulgating rules ~~pursuant to~~ **UNDER** this
 8 part, the department shall avoid requiring dual licensing,
 9 ~~insofar as~~ **IF** practical. Rules promulgated by the department may
 10 provide for recognition of other state or federal licenses **OR**
 11 **REGISTRATIONS** as the department considers desirable, subject to
 12 **LICENSE AND** registration requirements prescribed by the
 13 department.

14 (2) A person who, on the effective date of an agreement
 15 under ~~Act No. 54 of the Public Acts of 1965, being sections 3.801~~
 16 ~~to 3.802 of the Michigan Compiled Laws 1965 PA 54, MCL 3.801 TO~~
 17 **3.802**, possesses a license issued by the federal government for a
 18 ~~source of ionizing radiation~~ **RADIOACTIVE MATERIAL** of the type for
 19 which the state assumes regulatory responsibility under the
 20 agreement, is considered to possess an identical license issued
 21 ~~pursuant to~~ **UNDER** this part, which license expires either 90 days
 22 after receipt of a written notice of termination from the
 23 department or on the date of expiration stated in the federal
 24 license, whichever occurs first.

25 (3) ~~(2)~~ The department may promulgate rules to establish a
 26 schedule of fees to be paid by applicants for licenses **OR**
 27 **REGISTRATION** for radioactive materials, ~~and~~ devices and equipment

utilizing the radioactive materials, **AND RENEWALS OF LICENSES OR REGISTRATIONS.**

~~(3) Except as otherwise provided in this subsection, the department may promulgate rules to establish a schedule of fees to be paid by an applicant for a license for other sources of ionizing radiation and the renewal of the license, and by a person possessing sources of ionizing radiation that are subject to registration. The registration or registration renewal fee for a radiation machine registered under this part is \$45.00 for the first veterinary or dental x ray or electron tube and \$25.00 for each additional veterinary or dental x ray or electron tube annually, or \$75.00 annually per nonveterinary or nondental x ray or electron tube. The department shall not assess a fee for the amendment of a radiation machine registration certificate. In addition, the department shall assess a fee of \$100.00 for each follow up inspection due to noncompliance during the same year. The department may accept a written certification from the licensee or registrant that the items of noncompliance have been corrected instead of performing a follow up inspection. If the department does not inspect a source of ionizing radiation for a period of 5 consecutive years, the licensee or registrant of the source of ionizing radiation does not have to pay further license or registration fees as to that source of ionizing radiation until the first license or registration renewal date following the time an inspection of the source of ionizing radiation is made.~~

(4) A fee collected under this part shall be deposited in

1 the state treasury and credited to the general fund of this
2 state.

3 ~~—— (5) Except as otherwise provided in subsection (6), 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 mammography~~
8 ~~authorization, per radiation machine \$ 100.00~~

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

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

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

22 ~~—— (8) The department shall adjust on an annual basis the fees~~
23 ~~prescribed by subsections (3) and (5) by an amount determined by~~
24 ~~the state treasurer to reflect the cumulative annual percentage~~
25 ~~change in the Detroit consumer price index, not to exceed 5%. As~~
26 ~~used in this subsection, "Detroit consumer price index" means the~~
27 ~~most comprehensive index of consumer prices available for the~~

1 ~~Detroit area from the bureau of labor statistics of the United~~
2 ~~States department of labor.~~

3 Sec. 13525. A municipality or a department, agency, or
4 official of a municipality ~~may~~ **SHALL** not license, regulate, or
5 require the registration of a radioactive material. ~~or other~~
6 ~~source of ionizing radiation.~~

7 Sec. 13535. A person who violates this part or a rule
8 promulgated under this part or who fails to obtain or comply with
9 conditions of licensure or registration under this part is guilty
10 of a misdemeanor, punishable by imprisonment for not more than
11 180 days, or a fine of not more than \$10,000.00, or both. A court
12 may fine a person not more than \$2,000.00 for each violation of
13 this part. Each day a violation continues ~~shall be~~ **IS** a separate
14 violation.

15 Sec. 13536. If, after thorough investigation by the
16 department, it is the judgment of the department that a person
17 has engaged in or is about to engage in an act or practice ~~which~~
18 **THAT** constitutes a violation of this part or **OF** a rule
19 **PROMULGATED** or order **ISSUED UNDER THIS PART**, the attorney
20 general, at the request of the department, shall ~~make application~~
21 **APPLY** to the appropriate circuit court for an order enjoining the
22 act or practice or for an order directing compliance with this
23 part or a rule **PROMULGATED** or order issued ~~pursuant to~~ **UNDER** this
24 part.

25 **PART 135A**

26 **RADIATION MACHINE CONTROL**

27 **SEC. 13551. (1) AS USED IN THIS PART:**

1 (A) "DEPARTMENT" MEANS THE DEPARTMENT OF LICENSING AND
2 REGULATORY AFFAIRS.

3 (B) "IONIZING RADIATION" MEANS ALL RADIATIONS CAPABLE OF
4 PRODUCING IONS DIRECTLY OR INDIRECTLY IN THEIR PASSAGE THROUGH
5 MATTER, INCLUDING ALL OF THE FOLLOWING:

6 (i) ELECTROMAGNETIC RADIATIONS INCLUDING GAMMA RAYS AND X-
7 RAYS.

8 (ii) PARTICULATE RADIATIONS INCLUDING ALPHA PARTICLES, BETA
9 PARTICLES, ELECTRONS, NEUTRONS, PROTONS, AND OTHER NUCLEAR
10 PARTICLES.

11 (C) "MAMMOGRAPHY" MEANS RADIOGRAPHY OF THE BREAST FOR THE
12 PURPOSE OF ENABLING A PHYSICIAN TO DETERMINE THE PRESENCE, SIZE,
13 LOCATION, AND EXTENT OF CANCEROUS OR POTENTIALLY CANCEROUS TISSUE
14 IN THE BREAST. MAMMOGRAPHY INCLUDES INTERVENTIONAL MAMMOGRAPHY.

15 (D) "MAMMOGRAPHY AUTHORIZATION" MEANS AUTHORIZATION UNDER
16 SECTION 13573 TO USE A RADIATION MACHINE FOR MAMMOGRAPHY.

17 (E) "MAMMOGRAPHY INTERPRETING PHYSICIAN" MEANS A PHYSICIAN
18 WHO MEETS THE APPLICABLE REQUIREMENTS OF SECTION 13574 AND WHO
19 INTERPRETS THE RESULTS OF A MAMMOGRAPHIC EXAMINATION.

20 (F) "MAMMOGRAPHY SYSTEM" MEANS THE RADIATION MACHINE USED
21 FOR MAMMOGRAPHY; AUTOMATIC EXPOSURE CONTROL DEVICES; IMAGING
22 SYSTEMS; IMAGE PROCESSOR; DARKROOM; AND VIEWBOXES.

23 (G) "PERSON" MEANS A PERSON AS DEFINED IN SECTION 1106 OR A
24 GOVERNMENTAL ENTITY.

25 (H) "PHYSICIAN" MEANS AN INDIVIDUAL WHO IS LICENSED OR
26 OTHERWISE AUTHORIZED UNDER ARTICLE 15 TO ENGAGE IN THE PRACTICE
27 OF MEDICINE OR OSTEOPATHIC MEDICINE AND SURGERY.

(I) "RADIATION MACHINE" MEANS A MACHINE OR DEVICE THAT PRODUCES IONIZING RADIATION IN ENERGIES OR INTENSITIES SUBJECT TO REGULATION BY DEPARTMENT RULE.

(J) "RADIATION MACHINE ADVISORY COMMITTEE" OR "COMMITTEE" MEANS THE RADIATION MACHINE ADVISORY COMMITTEE CREATED IN SECTION 13581.

(K) "RADIATION MACHINE CONTROL FUND" OR "FUND" MEANS THE RADIATION MACHINE CONTROL FUND CREATED BY SECTION 13562.

(L) "RADIOGRAPHY" MEANS THE MAKING OF A FILM OR OTHER RECORD OF AN INTERNAL STRUCTURE OF THE BODY BY PASSING X-RAYS THROUGH THE BODY TO ACT ON FILM OR OTHER IMAGE RECEPTOR.

(M) "REGISTRATION" MEANS REGISTRATION OF A RADIATION MACHINE IN WRITING WITH THE DEPARTMENT.

(N) "STEREOTACTIC BREAST BIOPSY" MEANS THE IMAGING OF A BREAST PERFORMED IN AT LEAST 2 PLANES TO LOCALIZE A TARGET LESION DURING INVASIVE INTERVENTIONS FOR BIOPSY PROCEDURES.

(O) "STEREOTACTIC BREAST BIOPSY PHYSICIAN" MEANS A PHYSICIAN WHO CONDUCTS STEREOTACTIC BREAST BIOPSY.

(2) IN ADDITION, ARTICLE 1 CONTAINS GENERAL DEFINITIONS AND PRINCIPLES OF CONSTRUCTION APPLICABLE TO ALL ARTICLES IN THIS CODE.

SEC. 13555. A PERSON SHALL NOT MANUFACTURE, PRODUCE, TRANSPORT, TRANSFER, DISPOSE OF, ACQUIRE, OWN, POSSESS, OR USE A RADIATION MACHINE UNLESS THE RADIATION MACHINE IS REGISTERED OR EXEMPTED BY THIS PART OR BY THE DEPARTMENT IN ACCORDANCE WITH RULES PROMULGATED BY THE DEPARTMENT UNDER THIS PART.

SEC. 13556. EXCEPT AS OTHERWISE PROVIDED IN THIS SECTION,

1 SECTIONS 13555 AND 13565 TO 13586 DO NOT APPLY TO THE FOLLOWING
2 SOURCES OR CONDITIONS:

3 (A) ELECTRICAL OR OTHER EQUIPMENT OR MATERIAL NOT INTENDED
4 PRIMARILY TO PRODUCE RADIATION THAT, BY NATURE OF DESIGN, DOES
5 NOT PRODUCE RADIATION AT THE POINT OF NEAREST APPROACH AT A
6 WEEKLY RATE HIGHER THAN 1/10 THE APPROPRIATE LIMIT GENERALLY
7 ACCEPTED BY THE MEDICAL PROFESSION FOR ANY CRITICAL ORGAN
8 EXPOSED. THE PRODUCTION TESTING OR PRODUCTION SERVICING OF THE
9 EQUIPMENT IS NOT EXEMPT UNDER THIS SUBDIVISION.

10 (B) A RADIATION MACHINE DURING PROCESS OF MANUFACTURE OR IN
11 STORAGE OR TRANSIT. THE PRODUCTION TESTING OR PRODUCTION
12 SERVICING OF THE RADIATION MACHINE IS NOT EXEMPT UNDER THIS
13 SUBDIVISION.

14 (C) NON-IONIZING RADIATION SOURCES OR DEVICES.

15 SEC. 13561. (1) THE GOVERNOR MAY ENTER INTO AGREEMENTS WITH
16 THE FEDERAL GOVERNMENT, OTHER STATES, OR INTERSTATE AGENCIES,
17 WHEREBY THE DEPARTMENT SHALL PERFORM FOR OR ON A COOPERATIVE
18 BASIS WITH THE FEDERAL GOVERNMENT, OTHER STATES, OR INTERSTATE
19 AGENCIES INSPECTIONS OR OTHER FUNCTIONS RELATING TO CONTROL OF
20 RADIATION MACHINES.

21 (2) AN AGREEMENT ENTERED INTO UNDER SUBSECTION (1) DOES NOT
22 TRANSFER, DELEGATE, OR IMPOSE UPON THE DEPARTMENT ANY POWER,
23 AUTHORITY, OR RESPONSIBILITY THAT IS NOT FULLY CONSISTENT WITH
24 THIS PART.

25 SEC. 13562. (1) THE RADIATION MACHINE CONTROL FUND IS
26 CREATED WITHIN THE STATE TREASURY. THE STATE TREASURER MAY
27 RECEIVE MONEY OR OTHER ASSETS FROM ANY SOURCE FOR DEPOSIT INTO

1 THE FUND.

2 (2) THE STATE TREASURER SHALL DIRECT THE INVESTMENT OF THE
3 RADIATION CONTROL FUND. THE STATE TREASURER SHALL CREDIT TO THE
4 FUND INTEREST AND EARNINGS FROM FUND INVESTMENTS.

5 (3) MONEY IN THE RADIATION CONTROL FUND AT THE CLOSE OF THE
6 FISCAL YEAR SHALL REMAIN IN THE FUND AND SHALL NOT LAPSE TO THE
7 GENERAL FUND.

8 (4) THE DEPARTMENT IS THE ADMINISTRATOR OF THE RADIATION
9 CONTROL FUND FOR AUDITING PURPOSES.

10 (5) THE DEPARTMENT SHALL EXPEND MONEY FROM THE FUND, UPON
11 APPROPRIATION, ONLY FOR THE PURPOSE OF CARRYING OUT ITS POWERS
12 AND DUTIES UNDER THIS PART.

13 SEC. 13565. (1) THE DEPARTMENT IS DESIGNATED AS THE
14 RADIATION MACHINE CONTROL AGENCY OF THIS STATE.

15 (2) IN THE MANNER REQUIRED BY RULES PROMULGATED UNDER THIS
16 PART, THE DEPARTMENT SHALL REQUIRE REGISTRATION OF RADIATION
17 MACHINES.

18 (3) THE DEPARTMENT SHALL DEVELOP AND CONDUCT PROGRAMS FOR
19 EVALUATION AND CONTROL OF HAZARDS ASSOCIATED WITH THE USE OF
20 RADIATION MACHINES.

21 SEC. 13566. IF THE DEPARTMENT FINDS THAT AN EMERGENCY EXISTS
22 REQUIRING IMMEDIATE ACTION TO PROTECT OCCUPATIONAL OR PUBLIC
23 HEALTH AND SAFETY, THE DEPARTMENT SHALL ISSUE AN ORDER, WITH OR
24 WITHOUT NOTICE OR HEARING, RECITING THE EXISTENCE OF THE
25 EMERGENCY AND PROVIDING FOR THE PROTECTION OF THE PUBLIC HEALTH
26 AND SAFETY. NOTWITHSTANDING ANY PROVISION OF THIS ACT OR THE
27 ADMINISTRATIVE PROCEDURES ACT OF 1969 TO THE CONTRARY, THE ORDER

1 IS EFFECTIVE IMMEDIATELY. A PERSON TO WHOM THE ORDER IS DIRECTED
2 SHALL COMPLY WITH THE ORDER IMMEDIATELY. HOWEVER, UPON REQUEST,
3 THE DEPARTMENT SHALL GRANT THE PERSON A HEARING ON THE ORDER OR
4 ON AN ISSUE CONCERNING THE ORDER WITHIN 15 DAYS AFTER RECEIPT OF
5 THE REQUEST. ON THE BASIS OF THE FINDINGS OF FACT AND CONCLUSIONS
6 OF LAW MADE AT THE HEARING, THE DEPARTMENT SHALL CONTINUE,
7 MODIFY, OR REVOKE THE ORDER WITHIN 30 DAYS AFTER THE HEARING.

8 SEC. 13567. (1) THE DEPARTMENT MAY ENTER AT ALL REASONABLE
9 TIMES UPON PRIVATE OR PUBLIC PROPERTY UPON WHICH RADIATION
10 MACHINES ARE REASONABLY BELIEVED TO BE LOCATED, WITH THE
11 PERMISSION OF THE OWNER OR CUSTODIAN OF THE PROPERTY, TO
12 DETERMINE IF THE RADIATION MACHINE IS IN COMPLIANCE WITH THIS
13 PART AND THE RULES PROMULGATED UNDER THIS PART.

14 (2) IF THE DEPARTMENT HAS PROBABLE CAUSE TO BELIEVE THAT A
15 VIOLATION OF THIS PART OR A RULE PROMULGATED UNDER THIS PART IS
16 BEING COMMITTED ON PRIVATE OR PUBLIC PROPERTY OR THAT THERE
17 EXISTS ON THE PROPERTY EVIDENCE OF A VIOLATION, AND PERMISSION TO
18 ENTER ON THE PROPERTY IS DENIED BY THE OWNER OR CUSTODIAN OF THE
19 PROPERTY, THE DEPARTMENT MAY MAKE AN AFFIDAVIT FOR A SEARCH
20 WARRANT UNDER 1966 PA 189, MCL 780.651 TO 780.659, COMMANDING THE
21 SHERIFF OR A LAW ENFORCEMENT OFFICER, WITH THE AID OF THE
22 DEPARTMENT, TO SEARCH THE PROPERTY AND SEIZE THE RADIATION
23 MACHINE THAT IS POSSESSED, CONTROLLED, OR USED WHOLLY OR
24 PARTIALLY IN VIOLATION OF THIS PART OR A RULE PROMULGATED UNDER
25 THIS PART, OR EVIDENCE OF A VIOLATION OF THIS PART OR A RULE
26 PROMULGATED UNDER THIS PART.

27 SEC. 13571. (1) THE DEPARTMENT SHALL PROMULGATE RULES UNDER

1 THE ADMINISTRATIVE PROCEDURES ACT OF 1969 AS PROVIDED IN THIS
2 PART. THE DEPARTMENT SHALL INCLUDE IN RULES PROMULGATED UNDER
3 THIS PART REQUIREMENTS FOR THE REGISTRATION OF RADIATION
4 MACHINES. THE DEPARTMENT MAY INCLUDE IN RULES PROMULGATED UNDER
5 THIS PART REQUIREMENTS FOR EXEMPTION FROM REGISTRATION, RECORD
6 KEEPING, PERMISSIBLE LEVELS OF EXPOSURE, NOTIFICATION AND REPORTS
7 OF ACCIDENTS, PROTECTIVE MEASURES, TECHNICAL QUALIFICATIONS OF
8 PERSONNEL, HANDLING, POSTING AND LABELING OF HAZARDOUS MACHINES,
9 DEVICES, AND AREAS, SURVEYS, AND MONITORING.

10 (2) THE DEPARTMENT SHALL NOT INCLUDE IN RULES PROMULGATED
11 UNDER THIS PART ANY LIMIT ON THE INTENTIONAL EXPOSURE OF A
12 PATIENT TO RADIATION FOR THE PURPOSE OF LAWFUL THERAPY OR
13 RESEARCH CONDUCTED BY A LICENSED HEALTH PROFESSIONAL.

14 (3) THE DEPARTMENT SHALL INCLUDE IN RULES PROMULGATED UNDER
15 THIS PART THE MINIMUM TRAINING AND PERFORMANCE STANDARDS FOR AN
16 INDIVIDUAL USING A RADIATION MACHINE FOR MAMMOGRAPHY AS SET FORTH
17 IN SECTION 13573.

18 (4) THE DEPARTMENT SHALL INCLUDE IN RULES PROMULGATED UNDER
19 THIS PART THE MINIMUM TRAINING AND PERFORMANCE STANDARDS FOR AN
20 INDIVIDUAL USING A RADIATION MACHINE FOR HUMAN SCREENING OR FOR
21 DIAGNOSTIC OR THERAPEUTIC PURPOSES.

22 SEC. 13572. (1) EXCEPT AS OTHERWISE PROVIDED IN THIS
23 SUBSECTION, THE DEPARTMENT MAY INCLUDE IN RULES PROMULGATED UNDER
24 THIS PART A SCHEDULE OF FEES TO BE PAID BY AN APPLICANT FOR THE
25 REGISTRATION OF A RADIATION MACHINE. THE REGISTRATION FEE OR
26 REGISTRATION RENEWAL FEE FOR A RADIATION MACHINE REGISTERED UNDER
27 THIS PART IS \$72.01 FOR THE FIRST VETERINARY OR DENTAL X-RAY OR

1 ELECTRON TUBE AND \$39.94 FOR EACH ADDITIONAL VETERINARY OR DENTAL
 2 X-RAY OR ELECTRON TUBE ANNUALLY, OR \$120.07 ANNUALLY PER
 3 NONVETERINARY OR NONDENTAL X-RAY OR ELECTRON TUBE. THE DEPARTMENT
 4 SHALL NOT ASSESS A FEE FOR THE AMENDMENT OF A RADIATION MACHINE
 5 REGISTRATION CERTIFICATE. IN ADDITION, THE DEPARTMENT SHALL
 6 ASSESS A FEE OF \$160.13 FOR EACH FOLLOW-UP INSPECTION DUE TO
 7 NONCOMPLIANCE DURING THE SAME YEAR. THE DEPARTMENT MAY ACCEPT A
 8 WRITTEN CERTIFICATION FROM THE REGISTRANT THAT THE ITEMS OF
 9 NONCOMPLIANCE HAVE BEEN CORRECTED INSTEAD OF PERFORMING A FOLLOW-
 10 UP INSPECTION. IF THE DEPARTMENT DOES NOT INSPECT A RADIATION
 11 MACHINE FOR 5 CONSECUTIVE YEARS, THE REGISTRANT OF THE RADIATION
 12 MACHINE DOES NOT HAVE TO PAY FURTHER REGISTRATION FEES FOR THAT
 13 RADIATION MACHINE UNTIL THE FIRST REGISTRATION RENEWAL DATE AFTER
 14 THE RADIATION MACHINE IS INSPECTED.

15 (2) THE DEPARTMENT SHALL TRANSMIT A FEE COLLECTED UNDER THIS
 16 PART TO THE STATE TREASURER FOR DEPOSIT IN THE RADIATION MACHINE
 17 CONTROL FUND.

18 (3) THE DEPARTMENT SHALL ASSESS THE FOLLOWING NONREFUNDABLE
 19 FEES IN CONNECTION WITH MAMMOGRAPHY AUTHORIZATION:

20 (A) INSPECTION, PER RADIATION MACHINE..... \$ 160.13

21 (B) REINSPECTION FOR REINSTATEMENT OF
 22 MAMMOGRAPHY AUTHORIZATION, PER RADIATION MACHINE..... \$ 160.13

23 (4) EXCEPT AS OTHERWISE PROVIDED IN SUBSECTION (1), THE
 24 DEPARTMENT SHALL NOT WAIVE A FEE REQUIRED UNDER THIS SECTION.

25 (5) THE DEPARTMENT SHALL ADJUST ON AN ANNUAL BASIS THE FEES

1 PRESCRIBED BY SUBSECTIONS (1) AND (3) BY AN AMOUNT DETERMINED BY
2 THE STATE TREASURER TO REFLECT THE CUMULATIVE ANNUAL PERCENTAGE
3 CHANGE IN THE DETROIT CONSUMER PRICE INDEX, NOT TO EXCEED 5%. AS
4 USED IN THIS SUBSECTION, "DETROIT CONSUMER PRICE INDEX" MEANS THE
5 MOST COMPREHENSIVE INDEX OF CONSUMER PRICES AVAILABLE FOR THE
6 DETROIT AREA FROM THE BUREAU OF LABOR STATISTICS OF THE UNITED
7 STATES DEPARTMENT OF LABOR.

8 SEC. 13573. (1) A PERSON SHALL NOT USE A RADIATION MACHINE
9 TO PERFORM MAMMOGRAPHY UNLESS THE RADIATION MACHINE IS REGISTERED
10 WITH THE DEPARTMENT UNDER DEPARTMENT RULES FOR REGISTRATION OF
11 RADIATION MACHINES AND IS SPECIFICALLY AUTHORIZED UNDER THIS
12 SECTION FOR USE FOR MAMMOGRAPHY.

13 (2) THE DEPARTMENT SHALL AUTHORIZE A RADIATION MACHINE FOR
14 USE FOR MAMMOGRAPHY IF THE RADIATION MACHINE, THE PERSONNEL
15 OPERATING THE RADIATION MACHINE, AND THE FACILITY IN WHICH THE
16 RADIATION MACHINE IS USED MEET ALL OF THE FOLLOWING STANDARDS:

17 (A) THE RADIATION MACHINE AND THE FACILITY IN WHICH THE
18 RADIATION MACHINE IS USED MEET ANY OF THE FOLLOWING REQUIREMENTS,
19 AS APPLICABLE:

20 (i) IS ACCREDITED IN MAMMOGRAPHY BY THE AMERICAN COLLEGE OF
21 RADIOLOGY OR OTHER MAMMOGRAPHY ACCREDITATION ORGANIZATION
22 APPROVED BY THE DEPARTMENT.

23 (ii) IS ACCREDITED IN STEREOTACTIC BREAST BIOPSY BY THE
24 AMERICAN COLLEGE OF RADIOLOGY, THE AMERICAN COLLEGE OF SURGEONS,
25 OR OTHER STEREOTACTIC BREAST BIOPSY ACCREDITATION ORGANIZATION
26 APPROVED BY THE DEPARTMENT. A RADIATION MACHINE THAT USES A
27 SPECIALLY DESIGNED ADD-ON DEVICE FOR STEREOTACTIC BREAST BIOPSY

1 MUST ALSO MEET THE REQUIREMENTS OF SUBPARAGRAPH (i) .

2 (B) THE RADIATION MACHINE, THE FILM OR OTHER IMAGE RECEPTOR
3 USED IN THE RADIATION MACHINE, AND THE FACILITY IN WHICH THE
4 RADIATION MACHINE IS USED MEET THE REQUIREMENTS SET FORTH IN
5 DEPARTMENT RULES FOR RADIATION MACHINES.

6 (C) THE RADIATION MACHINE IS SPECIFICALLY DESIGNED TO
7 PERFORM MAMMOGRAPHY.

8 (D) THE FACILITY IN WHICH THE RADIATION MACHINE IS USED DOES
9 ALL OF THE FOLLOWING:

10 (i) BEFORE THE DATE THAT A RADIATION MACHINE IS USED ON
11 PATIENTS AND AT LEAST ANNUALLY AFTER THAT DATE, HAS A QUALIFIED
12 MEDICAL PHYSICIST PROVIDE ON-SITE CONSULTATION TO THE FACILITY,
13 INCLUDING, BUT NOT LIMITED TO, A COMPLETE EVALUATION OF THE
14 ENTIRE MAMMOGRAPHY SYSTEM TO ENSURE COMPLIANCE WITH THIS PART AND
15 THE RULES PROMULGATED UNDER THIS PART.

16 (ii) MAINTAINS FOR AT LEAST 7 YEARS RECORDS OF THE
17 CONSULTATION REQUIRED IN SUBPARAGRAPH (i) AND THE FINDINGS OF THE
18 CONSULTATION.

19 (iii) DESIGNATES A PHYSICIAN AS THE LEAD INTERPRETING
20 PHYSICIAN. THE LEAD INTERPRETING PHYSICIAN IS RESPONSIBLE FOR
21 ENSURING THAT THE FACILITY MEETS THE REQUIREMENTS OF RULES
22 PROMULGATED UNDER THIS PART REGARDING THE QUALITY ASSURANCE
23 PROGRAM, QUALITY CONTROL TESTING, AND MEDICAL OUTCOMES AUDIT. THE
24 LEAD INTERPRETING PHYSICIAN MUST MEET THE APPLICABLE REQUIREMENTS
25 OF SECTION 13574.

26 (E) THE RADIATION MACHINE IS USED ACCORDING TO DEPARTMENT
27 RULES ON PATIENT RADIATION EXPOSURE AND RADIATION DOSE LEVELS.

1 (F) EACH INDIVIDUAL WHO OPERATES THE RADIATION MACHINE CAN
2 DEMONSTRATE TO THE DEPARTMENT THAT HE OR SHE IS SPECIFICALLY
3 TRAINED IN MAMMOGRAPHY AND MEETS THE STANDARDS REQUIRED BY THE
4 RULES PROMULGATED UNDER SECTION 13571(3).

5 (G) THE RESULTS OF EACH MAMMOGRAPHIC EXAMINATION PERFORMED
6 WITH THE RADIATION MACHINE ARE INTERPRETED BY A MAMMOGRAPHY
7 INTERPRETING PHYSICIAN.

8 (3) THE DEPARTMENT MAY ISSUE A NONRENEWABLE TEMPORARY
9 AUTHORIZATION FOR A RADIATION MACHINE FOR USE FOR MAMMOGRAPHY IF
10 ADDITIONAL TIME IS NEEDED TO ALLOW SUBMISSION OF EVIDENCE
11 SATISFACTORY TO THE DEPARTMENT THAT THE RADIATION MACHINE, THE
12 PERSONNEL OPERATING THE RADIATION MACHINE, AND THE FACILITY IN
13 WHICH THE RADIATION MACHINE IS USED MEET THE STANDARDS SET FORTH
14 IN SUBSECTION (2) FOR APPROVAL FOR MAMMOGRAPHY. A TEMPORARY
15 AUTHORIZATION GRANTED UNDER THIS SUBSECTION IS EFFECTIVE FOR NO
16 MORE THAN 12 MONTHS. THE DEPARTMENT MAY WITHDRAW A TEMPORARY
17 AUTHORIZATION BEFORE ITS EXPIRATION IF THE RADIATION MACHINE, THE
18 PERSONNEL OPERATING THE RADIATION MACHINE, OR THE FACILITY IN
19 WHICH THE RADIATION MACHINE IS USED DOES NOT MEET 1 OR MORE OF
20 THE STANDARDS SET FORTH IN SUBSECTION (2).

21 (4) TO OBTAIN MAMMOGRAPHY AUTHORIZATION FROM THE DEPARTMENT,
22 THE PERSON WHO OWNS OR LEASES A RADIATION MACHINE OR AN
23 AUTHORIZED AGENT OF THE PERSON SHALL APPLY TO THE DEPARTMENT FOR
24 MAMMOGRAPHY AUTHORIZATION ON AN APPLICATION FORM PROVIDED BY THE
25 DEPARTMENT AND SHALL PROVIDE ALL OF THE INFORMATION REQUIRED BY
26 THE DEPARTMENT AS SPECIFIED ON THE APPLICATION FORM. A PERSON WHO
27 OWNS OR LEASES MORE THAN 1 RADIATION MACHINE USED FOR MAMMOGRAPHY

1 SHALL OBTAIN MAMMOGRAPHY AUTHORIZATION FOR EACH RADIATION
2 MACHINE. THE DEPARTMENT SHALL PROCESS AND RESPOND TO A
3 MAMMOGRAPHY AUTHORIZATION APPLICATION WITHIN 30 DAYS AFTER THE
4 DATE OF RECEIPT OF THE APPLICATION. UPON DETERMINING TO GRANT
5 MAMMOGRAPHY AUTHORIZATION FOR A RADIATION MACHINE, THE DEPARTMENT
6 SHALL ISSUE A CERTIFICATE OF REGISTRATION SPECIFYING MAMMOGRAPHY
7 AUTHORIZATION FOR EACH AUTHORIZED RADIATION MACHINE. A
8 MAMMOGRAPHY AUTHORIZATION IS EFFECTIVE FOR 3 YEARS CONTINGENT
9 UPON THE RADIATION MACHINE FOR WHICH THE MAMMOGRAPHY
10 AUTHORIZATION IS ISSUED, THE PERSONNEL OPERATING THE RADIATION
11 MACHINE, AND THE FACILITY IN WHICH THE RADIATION MACHINE IS
12 OPERATED MAINTAINING CONTINUED ACCREDITATION AS REQUIRED UNDER
13 SUBSECTION (2) (A) .

14 (5) WITHIN 90 DAYS AFTER INITIAL MAMMOGRAPHY AUTHORIZATION
15 OF A RADIATION MACHINE UNDER THIS SECTION, THE DEPARTMENT SHALL
16 INSPECT THE RADIATION MACHINE. AFTER THAT INITIAL INSPECTION, THE
17 DEPARTMENT SHALL ANNUALLY INSPECT THE RADIATION MACHINE AND MAY
18 INSPECT THE RADIATION MACHINE MORE FREQUENTLY. THE DEPARTMENT
19 SHALL MAKE REASONABLE EFFORTS TO COORDINATE THE INSPECTIONS UNDER
20 THIS SECTION WITH THE DEPARTMENT'S OTHER INSPECTIONS OF THE
21 FACILITY IN WHICH THE RADIATION MACHINE IS LOCATED.

22 (6) AFTER EACH SATISFACTORY INSPECTION BY THE DEPARTMENT,
23 THE DEPARTMENT SHALL ISSUE A CERTIFICATE OF RADIATION MACHINE
24 INSPECTION OR A SIMILAR DOCUMENT IDENTIFYING THE FACILITY AND
25 RADIATION MACHINE INSPECTED AND PROVIDING A RECORD OF THE DATE
26 THE RADIATION MACHINE WAS INSPECTED. THE FACILITY SHALL POST THE
27 CERTIFICATE OR OTHER DOCUMENT NEAR THE INSPECTED RADIATION

1 MACHINE.

2 (7) THE DEPARTMENT MAY WITHDRAW THE MAMMOGRAPHY
3 AUTHORIZATION FOR A RADIATION MACHINE IF IT DOES NOT MEET 1 OR
4 MORE OF THE STANDARDS SET FORTH IN SUBSECTION (2).

5 (8) THE DEPARTMENT SHALL PROVIDE NOTICE AND AN OPPORTUNITY
6 FOR A HEARING IN CONNECTION WITH A DENIAL OR WITHDRAWAL OF
7 MAMMOGRAPHY AUTHORIZATION.

8 (9) UPON A FINDING THAT A DEFICIENCY IN A RADIATION MACHINE
9 USED FOR MAMMOGRAPHY OR A VIOLATION OF THIS PART OR THE RULES
10 PROMULGATED UNDER THIS PART SERIOUSLY AFFECTS THE HEALTH, SAFETY,
11 AND WELFARE OF INDIVIDUALS UPON WHOM THE RADIATION MACHINE IS
12 USED FOR MAMMOGRAPHY, THE DEPARTMENT MAY ISSUE AN EMERGENCY ORDER
13 SUMMARILY WITHDRAWING THE MAMMOGRAPHY AUTHORIZATION FOR THE
14 RADIATION MACHINE. THE DEPARTMENT SHALL INCORPORATE ITS FINDINGS
15 IN THE ORDER AND SHALL PROVIDE NOTICE AND AN OPPORTUNITY FOR A
16 HEARING WITHIN 5 BUSINESS DAYS AFTER ISSUANCE OF THE ORDER. THE
17 ORDER IS EFFECTIVE DURING THE PROCEEDINGS.

18 (10) IF THE DEPARTMENT WITHDRAWS THE MAMMOGRAPHY
19 AUTHORIZATION FOR A RADIATION MACHINE, THE RADIATION MACHINE
20 SHALL NOT BE USED FOR MAMMOGRAPHY. AN APPLICATION FOR
21 REINSTATEMENT OF A MAMMOGRAPHY AUTHORIZATION SHALL BE FILED AND
22 PROCESSED IN THE SAME MANNER AS AN APPLICATION FOR MAMMOGRAPHY
23 AUTHORIZATION UNDER SUBSECTION (4), EXCEPT THAT THE DEPARTMENT
24 SHALL NOT ISSUE A REINSTATED CERTIFICATE OF MAMMOGRAPHY
25 AUTHORIZATION UNTIL THE DEPARTMENT RECEIVES THE REINSPECTION FEE
26 REQUIRED UNDER SECTION 13572(3), INSPECTS THE RADIATION MACHINE,
27 AND DETERMINES THAT IT MEETS THE STANDARDS SET FORTH IN

1 SUBSECTION (2). THE DEPARTMENT SHALL CONDUCT AN INSPECTION
2 REQUIRED UNDER THIS SUBSECTION WITHIN 60 DAYS AFTER RECEIVING A
3 PROPER APPLICATION FOR REINSTATEMENT OF A MAMMOGRAPHY
4 AUTHORIZATION.

5 (11) IN ADDITION TO THE PENALTIES PROVIDED IN SECTION 13585
6 AND THE REINSPECTION FEE REQUIRED UNDER SECTION 13572(3), IF A
7 PERSON VIOLATES SUBSECTION (1), THE DEPARTMENT MAY IMPOSE AN
8 ADMINISTRATIVE FINE AGAINST THE OWNER OF THE RADIATION MACHINE
9 OR, IF A LESSEE OF THE RADIATION MACHINE HAS EFFECTIVE CONTROL OF
10 THE RADIATION MACHINE, THE LESSEE, OF NOT MORE THAN \$500.00 FOR
11 EACH CALENDAR WEEK IN WHICH A MAMMOGRAPHY IS PERFORMED IN
12 VIOLATION OF SUBSECTION (1). IF A PERSON CONTINUES TO VIOLATE
13 SUBSECTION (1) FOR A PERIOD OF 2 WEEKS AFTER A FINE IS IMPOSED
14 UNDER THIS SUBSECTION, THE DEPARTMENT SHALL POST A CONSPICUOUS
15 NOTICE ON THE UNAUTHORIZED RADIATION MACHINE AND AT THE ENTRY TO
16 THE FACILITY WHERE THE RADIATION MACHINE IS LOCATED WARNING THE
17 PUBLIC THAT THE FACILITY IS PERFORMING MAMMOGRAPHY USING A
18 RADIATION MACHINE THAT IS A SUBSTANTIAL HAZARD TO THE PUBLIC
19 HEALTH.

20 (12) THE DEPARTMENT MAY PROMULGATE RULES NECESSARY TO
21 IMPLEMENT THIS SECTION IN CONSULTATION WITH THE RADIATION MACHINE
22 ADVISORY COMMITTEE.

23 SEC. 13574. (1) BEFORE A PHYSICIAN INDEPENDENTLY INTERPRETS
24 THE RESULTS OF A MAMMOGRAPHIC EXAMINATION, THE PHYSICIAN MUST
25 MEET ALL OF THE FOLLOWING REQUIREMENTS:

26 (A) MEET 1 OF THE FOLLOWING REQUIREMENTS:

27 (i) BE CERTIFIED IN RADIOLOGY OR DIAGNOSTIC RADIOLOGY BY THE

1 AMERICAN BOARD OF RADIOLOGY OR THE AMERICAN OSTEOPATHIC BOARD OF
2 RADIOLOGY.

3 (ii) BE CERTIFIED OR DETERMINED TO BE QUALIFIED IN RADIOLOGY
4 OR DIAGNOSTIC RADIOLOGY BY ANOTHER PROFESSIONAL ORGANIZATION
5 APPROVED BY THE DEPARTMENT.

6 (iii) IF NOT CERTIFIED OR QUALIFIED UNDER SUBPARAGRAPH (i) OR
7 (ii), HAVE BEEN ELIGIBLE FOR CERTIFICATION OR QUALIFICATION UNDER
8 SUBPARAGRAPH (i) OR (ii) FOR LESS THAN 3 YEARS, AND HAVE HAD 3
9 MONTHS OR MORE OF DOCUMENTED FORMAL TRAINING IN THE
10 INTERPRETATION OF THE RESULTS OF MAMMOGRAPHIC EXAMINATIONS AND IN
11 TOPICS RELATED TO MAMMOGRAPHY. THE FORMAL TRAINING DESCRIBED IN
12 THIS SUBPARAGRAPH MUST INCLUDE INSTRUCTION IN RADIATION PHYSICS,
13 INCLUDING RADIATION PHYSICS SPECIFIC TO MAMMOGRAPHY, RADIATION
14 EFFECTS, AND RADIATION PROTECTION. THE INTERPRETATION COMPONENT
15 OF THE FORMAL TRAINING DESCRIBED IN THIS SUBPARAGRAPH MUST HAVE
16 BEEN UNDER THE DIRECT SUPERVISION OF A PHYSICIAN WHO MEETS THE
17 REQUIREMENTS OF SUBPARAGRAPH (i) OR (ii).

18 (B) HAVE 60 HOURS OR MORE OF DOCUMENTED MEDICAL EDUCATION IN
19 MAMMOGRAPHY, INCLUDING INSTRUCTION IN THE INTERPRETATION OF THE
20 RESULTS OF MAMMOGRAPHIC EXAMINATIONS AND EDUCATION IN BASIC
21 BREAST ANATOMY, PATHOLOGY, PHYSIOLOGY, TECHNICAL ASPECTS OF
22 MAMMOGRAPHY, AND QUALITY ASSURANCE AND QUALITY CONTROL IN
23 MAMMOGRAPHY. THE 60 HOURS OF MEDICAL EDUCATION DESCRIBED IN THIS
24 SUBDIVISION MUST BE CATEGORY 1 HOURS AND AT LEAST 15 HOURS OF THE
25 CATEGORY 1 HOURS MUST HAVE BEEN ACQUIRED WITHIN THE 3 YEARS
26 IMMEDIATELY PRECEDING THE DATE THE PHYSICIAN QUALIFIES AS A
27 MAMMOGRAPHY INTERPRETING PHYSICIAN UNDER THIS SECTION. THE

1 DEPARTMENT SHALL CONSIDER THE HOURS AN INDIVIDUAL SPENT IN
2 RESIDENCY SPECIFICALLY DEVOTED TO MAMMOGRAPHY AS EQUIVALENT TO
3 CATEGORY 1 HOURS AND ACCEPT THOSE RESIDENCY HOURS IF DOCUMENTED
4 IN WRITING BY AN APPROPRIATE REPRESENTATIVE OF THE TRAINING
5 INSTITUTION. A PHYSICIAN WHO IS CERTIFIED OR OTHERWISE QUALIFIED
6 UNDER SUBDIVISION (A) (i) OR (ii) IS CONSIDERED TO HAVE MET THE
7 REQUIREMENT OF THIS SUBDIVISION.

8 (C) HAVE INTERPRETED OR MULTIREAD AT LEAST 240 MAMMOGRAPHIC
9 EXAMINATIONS WITHIN THE 6-MONTH PERIOD IMMEDIATELY PRECEDING THE
10 DATE THAT THE PHYSICIAN BECOMES CERTIFIED OR OTHERWISE QUALIFIED
11 UNDER SUBDIVISION (A) (i) OR (ii). THE INTERPRETING OR MULTIREADING
12 REQUIREMENT OF THIS SUBDIVISION MUST HAVE BEEN UNDER THE DIRECT
13 SUPERVISION OF A PHYSICIAN WHO MEETS THE REQUIREMENTS OF
14 SUBDIVISION (A) (i) OR (ii). A PHYSICIAN WHO BECOMES CERTIFIED OR
15 QUALIFIED AS DESCRIBED IN SUBDIVISION (A) (i) OR (ii) AT THE FIRST
16 ALLOWABLE TIME, AS DEFINED BY THE CERTIFYING OR QUALIFYING
17 ORGANIZATION, MUST HAVE INTERPRETED OR MULTIREAD AT LEAST 240
18 MAMMOGRAPHIC EXAMINATIONS UNDER THE DIRECT SUPERVISION OF A
19 PHYSICIAN WHO MEETS THE REQUIREMENTS OF SUBDIVISION (A) (i) OR (ii)
20 IN ANY 6-MONTH PERIOD DURING THE LAST 2 YEARS OF A DIAGNOSTIC
21 RADIOLOGY RESIDENCY. A PHYSICIAN WHO QUALIFIED AS A MAMMOGRAPHY
22 INTERPRETING PHYSICIAN UNDER 1994 PA 100 BEFORE THE EFFECTIVE
23 DATE OF THE AMENDATORY ACT THAT ADDED THIS SECTION IS CONSIDERED
24 TO HAVE MET THE REQUIREMENT OF THIS SUBDIVISION.

25 (2) BEGINNING 1 YEAR AFTER THE EFFECTIVE DATE OF THE
26 AMENDATORY ACT THAT ADDED THIS SECTION, IN ADDITION TO ANY OTHER
27 REQUIREMENTS OF THIS SECTION, BEFORE A PHYSICIAN INDEPENDENTLY

1 CONDUCTS A STEREOTACTIC BREAST BIOPSY, THE PHYSICIAN MUST MEET
2 ALL OF THE FOLLOWING REQUIREMENTS:

3 (A) COMPLY WITH THE STANDARDS APPLICABLE TO A STEREOTACTIC
4 BREAST BIOPSY PHYSICIAN AS ESTABLISHED FOR THE STEREOTACTIC
5 BREAST BIOPSY ACCREDITATION PROGRAM OF THE AMERICAN COLLEGE OF
6 RADIOLOGY OR BY ANOTHER STEREOTACTIC BREAST BIOPSY ACCREDITATION
7 ORGANIZATION APPROVED BY THE DEPARTMENT.

8 (B) MAINTAIN ANNUAL RECORDS TRACKING THE NUMBER OF
9 STEREOTACTIC BREAST BIOPSIES CONDUCTED AND THE NUMBER OF CANCERS
10 FOUND.

11 (3) A MAMMOGRAPHY INTERPRETING PHYSICIAN SHALL MAINTAIN HIS
12 OR HER QUALIFICATIONS BY MEETING THE CONTINUING EXPERIENCE AND
13 EDUCATION REQUIREMENTS OF 21 CFR 900.12(A)(1)(ii) AND (iv). A
14 STEREOTACTIC BREAST BIOPSY PHYSICIAN SHALL MAINTAIN HIS OR HER
15 QUALIFICATIONS BY MEETING THE CONTINUING EXPERIENCE AND EDUCATION
16 REQUIREMENTS OF THE APPLICABLE ACCREDITATION PROGRAM APPROVED BY
17 THE BOARD.

18 SEC. 13575. A MUNICIPALITY OR A DEPARTMENT, AGENCY, OR
19 OFFICIAL OF A MUNICIPALITY SHALL NOT LICENSE, REGULATE, OR
20 REQUIRE THE REGISTRATION OF A RADIATION MACHINE.

21 SEC. 13581. A RADIATION MACHINE ADVISORY COMMITTEE IS
22 CREATED IN THE DEPARTMENT. NOTWITHSTANDING SECTION 2215, THE
23 COMMITTEE IS CREATED ON AN ONGOING BASIS. THE DIRECTOR SHALL
24 APPOINT MEMBERS TO THE COMMITTEE. MEMBERS OF THE COMMITTEE SERVE
25 AT THE PLEASURE OF THE DIRECTOR. THE COMMITTEE SHALL FURNISH TO
26 THE DEPARTMENT TECHNICAL ADVICE THE COMMITTEE CONSIDERS DESIRABLE
27 OR THE DEPARTMENT MAY REASONABLY REQUEST ON MATTERS RELATING TO

1 THE RADIATION MACHINE CONTROL PROGRAM UNDER THIS PART.

2 SEC. 13585. A PERSON WHO VIOLATES THIS PART OR A RULE
3 PROMULGATED UNDER THIS PART OR WHO FAILS TO OBTAIN OR COMPLY WITH
4 A CONDITION OF REGISTRATION UNDER THIS PART IS GUILTY OF A
5 MISDEMEANOR PUNISHABLE BY IMPRISONMENT FOR NOT MORE THAN 180
6 DAYS, OR A FINE OF NOT MORE THAN \$10,000.00, OR BOTH. A COURT MAY
7 FINE A PERSON NOT MORE THAN \$2,000.00 FOR EACH VIOLATION OF THIS
8 PART. EACH DAY A VIOLATION CONTINUES IS A SEPARATE VIOLATION.

9 SEC. 13586. IF, AFTER THOROUGH INVESTIGATION BY THE
10 DEPARTMENT, IT IS THE JUDGMENT OF THE DEPARTMENT THAT A PERSON
11 HAS ENGAGED IN OR IS ABOUT TO ENGAGE IN AN ACT OR PRACTICE THAT
12 CONSTITUTES A VIOLATION OF THIS PART OR A RULE PROMULGATED OR
13 ORDER ISSUED UNDER THIS PART, THE ATTORNEY GENERAL, AT THE
14 REQUEST OF THE DEPARTMENT, SHALL APPLY TO THE APPROPRIATE CIRCUIT
15 COURT FOR AN ORDER ENJOINING THE ACT OR PRACTICE OR FOR AN ORDER
16 DIRECTING COMPLIANCE WITH THIS PART OR A RULE PROMULGATED OR
17 ORDER ISSUED UNDER THIS PART.

18 Enacting section 1. Sections 13523 and 13531 of the public
19 health code, 1978 PA 368, MCL 333.13523 and 333.13531, are
20 repealed.