

# Compilation of Responses Facilities Closing/Medical Records Survey

Work Product of the CRCPD H-11 Committee on Mammography

December 15, 2004

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## Survey Questions for Facilities Closing/Medical Records

### Responses from 36 states:

**AL AZ CT DE FL HI IA ID IL KS LA MA ME MI MO MS MT NC  
ND NJ NV NY OH OR PA RI SC SD TN TX UT VT WA WI WV  
WY**

Oklahoma did not complete the survey but sent the following response: "They have no specific requirements for any of these areas except those covered by the Federal MQSA rules, and that the Oklahoma State Department of Health regulated anything to do with diagnostic x-ray systems."

**The following states provided attachments: AZ DE FL HI MA ME  
MO NC ND NV NY OH SC TN VT WA WV.** Copies are available upon request.  
Delaware's material was submitted on a CD.

Some of the questions were to be answered only if they had a specific answer to an earlier question. The individuals who completed these surveys sometimes responded to a question even if their previous answer did not meet the selection criteria. My opinion is that the states go out of their way to be responsive. I elected to provide their comments, as opposed to providing comments only if the selection criteria were met. There also were a number of unsolicited comments, which I have included in this report as well.

### Notification of Closing Requirements

#### 1. Does your State require facilities to notify your radiation control agency when they close?

26	Yes	AL AZ CT DE HI IA ID IL KS LA MA ME MI MO ND NJ NV NY PA RI SC SD TN TX WA WI WV [Ohio answered Yes and No-their comments are below]
8	No	FL MS MT NC OR UT VT WY [Ohio answered Yes and No-their comments are below]

*If yes, would you please send us a copy of the regulation, refer us to the agency/organization that can send us a copy of the regulation, or give us a web site address where we might download these regulations?*

Here is the information you seek:

AL 420-3-26-05(3)(e) Report of Discontinuance. Every registrant who permanently discontinues the use of, or permanently disposes of all his x-ray producing machines at an installation, shall notify the Agency within thirty (30) days of

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- such action.
- AZ See regulation R12-1-206B. Must notify agency if any x-ray unit taken out of service. Facilities which close notify agency to inactivate facility registration, which requires an annual fee for each x-ray tube.
- CT DNA, 3/15 email sent re Q1--answered yes but nothing else
- DE Part B. They Sent CD containing Rad Control Regs & RT certification regs
- HI Admin Rules, Chapter 11-45, Section 11-45-25
- IA [idph.state.ia.us](http://idph.state.ia.us)
- ID <http://www2.state.id.us/adm/adminrules/rules/idapa16/0227.pdf>
- IL WWW.STATE.IL.US/IEMA, 32 Ill. Adm. Code 320.20
- KS 28-35-161. Discontinuance of use. If a registrant ceases to use a registrable item or items, for any reason, the registrant or the duly authorized representative of the registrant's estate shall give written notice to the department of the cessation of use. The notice shall be provided within 30 days of the date that the registrant ceases to use the registrable item or items, and shall state the date on which use of the item or items were disposed.
- LA LAC 33:XV.209: Notification of changes (can be found on the LA DEQ website)
- MA [www.state.ma.us/dph/rcp](http://www.state.ma.us/dph/rcp)
- MI We have a general requirement about notifying us whenever a change is made that affects the accuracy of the registration certificate that we issue. The legal citation is R325.5188m, Rule 188 in Part 4 of our rules. That part is viewable on-line on our website. Go to [www.michigan.gov/rss](http://www.michigan.gov/rss) and, in the Facility Information box, click on Michigan's Ionizing Radiation Rules, then select Part 4 of the Rules. This requirement is not specific enough to be effective with respect to mammography facilities, or most other facilities for that matter.
- MO 19 CSR 20 - 10.030(2). Registration of sources of ionizing radiation
- NJ NJ DEP- Bureau of Radiological Health (BRH) regulations do not apply to facility closings; however, BRH regulations do require facilities to notify our office when registered ionizing-producing machines are sold, relocated or disposed. The regulation is N.J.A.C. 7:28-3.9. A web link to the regulation can be found at <http://www.nj.gov/dep/rpp/njrules.htm>
- NV See NAC 459.166 (2); available @ [www.leg.state.nv/nac-459.html](http://www.leg.state.nv/nac-459.html)

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- NY 16.50(I) p.72 on enclosed Part 16/ State Sanitary Code
- OH No & Yes – According to rule 3701:1-38-03 of the Ohio Administrative Code (OAC), handlers of RGE to register with the Ohio Department of Health (ODH). Furthermore, these rules require any transfer of ownership, transfer of RGE or disposal of RGE Ohio to be reported. If a registrant does not notify the ODH, we consider the registration to be current and will expect compliance with any applicable rules. Please see this link for clarification.  
[http://www.odh.state.oh.us/Rules/Final/Chap1\\_38/Fr38\\_03.PDF](http://www.odh.state.oh.us/Rules/Final/Chap1_38/Fr38_03.PDF)
- PA PA Code Title 25, Chap. 216 reference 216.4(a). Go to our web site for the pertinent regulation @ [www.pacode.com](http://www.pacode.com)
- RI [www.rules.state.ri.us/rules/](http://www.rules.state.ri.us/rules/) check Rules and Regulations for the Control of Radiation plus various Health dept regulations,. Section B.6 “report of changes”/xray registrations.
- SC We use this requirement for any change affecting the facility's status.  
[Www.scdhec.net/hr/](http://www.scdhec.net/hr/) (Part 2)
- SD 44:03:01:06. Annual license renewal. The licensee shall notify the department in writing within 30 days after any change which makes the location or other information on machines, devices, or other radiation sources no longer accurate. The license shall be renewed annually during the month of January on forms supplied by the department. Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 26 SDR 96, effective January 23, 2000. General Authority: SDCL 34-21-4.1, 34-21-15. Law Implemented: SDCL 34-21-22.
- TN "State Regulations for Protection Against Radiation" (SRPAR)1200-2-10-.24(5) and 1200-2-10-.24(6){COPY ATTACHED}
- TX <http://www.tdh.state.tx.us/radiation/default.htm>
- WI Required to notify us of any change in the registration within 30 days of the change. This includes closing. (No one does this but it's on the books)
- WV Radiological Health Rules64-CSR-23. 5.9. Report of Changes, 5.9.a. Except as provided in Subdivision 5.9.b. the registrant shall notify the agency in writing within ten (10) days after any change which renders the information on registration no longer accurate. In the case of disposition of radiation sources, such notification shall specify the recipient of these sources.

## **2. If a regulation exists, does it apply to regular facility closings as well as bankrupt facilities?**

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25	Yes	AL AZ DE HI IA ID IL KS LA MA ME MI MO ND NJ NV NY PA RI SD TN TX WA WI WV
2	No	NC WY
3	Don't Know	SC MT VT

**Unsolicited Comments:**

DE: But not for specific bankruptcy;

MO: Website for state radiation control regs: [www.sos.mo.gov/adrules/csr/current/19csr/19c20-10.pdf](http://www.sos.mo.gov/adrules/csr/current/19csr/19c20-10.pdf);

OH: There is no provision for closing (bankrupt or otherwise) facilities in the RGE rules – we would work with these types of situations on a case-by-case basis.

**3. Does your state handle bankrupt facilities any differently than regular facility closings?**

4	Yes	AL LA TN UT
28	No	AZ CT DE FL HI IA ID IL KS MA ME MI MO MS NC ND NJ NV NY OH OR PA RI SD TX WA WI WV
If yes, how:		
AL	Once the court appoints a person to handle the assets, we stop tracking the equipment.	
LA	We notify the legal division	
TN	Notify Administration and Office of General Counsel	
UT	Administrative rules require that radioactive material licensees (general and specific) notify the Agency immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11, Bankruptcy, of the United States Code. There is not a similar requirement for persons that have registered x-ray systems at their facility.	

**Did not answer Yes but provided comments:**

OH Again, these types of situations would be worked through on a case-by-case basis. We do attempt to recoup any monies owed the ODH and follow through with the disposition of the RGE;

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SC Again, these types of situations would be worked through on a case-by-case basis. We do attempt to recoup any monies owed the ODH and follow through with the disposition of the RGE.

**4. If your radiation control agency is notified of a closing, is there any State follow-up on closed facilities? (close-out inspections, letters, forms required to be sent in, etc.)**

23	Yes	AL AZ CT DE IA ID IL KS LA MI MO MS ND NY OH OR PA RI SC TN TX UT WV
10	No	FL HI IA ME NC NJ NV SD WA WI

Comments:

- AL A determination is made about where the x-ray machines are going. If personnel monitoring records are involved, we determine where they are going to be transferred to.
- AZ R12-1-206B. A written notification is requested for file
- CT Letter sent on disposition of equipment (sold to new facility or disposal)
- DE Update database & file
- IA Answered Y&N. Yes on mammography facilities
- ID We require some documentation of disposition of x-ray machine.
- IL Mammography facilities are notified of the record retention requirement and must complete the closure form notifying the Agency of record
- LA We ask that a letter stating dispersal of the unit be sent in.
- MA For mammo facilities, they must tell us where the films are being stored and they must send back their state license.
- MO Close-out (on-site) inspection
- MS Inquire where x-ray machine moved or disposed
- ND Change of Status Notification - copy accompanying
- NJ We require facilities to file disposal forms with our Bureau. BRH Disposal forms can be downloaded from the web link below. <http://www.nj.gov/dep/rpp/brh/brhdown.htm>
- NY Disposition form for x-ray (attached). Occasional closeout for radioactive

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materials and to seal x-ray units. NYS Labor Dept regulated non-medical facilities; NYS Environmental Conservation Dept regulates waste.

- OH The RGE rules do not recognize a 'closed' or 'open' facility status. If the RGE is still on-site, then it must remain registered and meet compliance with the rules. There is a provision to inspection of RGE, if it has been rendered inoperable (satisfactory to the ODH). Please reference rule 3701:1-38-04(B).  
[http://www.odh.state.oh.us/Rules/Final/Chap1\\_38/Fr38\\_04.PDF](http://www.odh.state.oh.us/Rules/Final/Chap1_38/Fr38_04.PDF)
- OR Require information regarding disposition of x-ray machines.
- PA Reference PA Code, Title 25 Chap. 216 reference 216.4(a)(b) to notify in writing. A form is also available upon request that replaces a formal letter and indicates the disposition of the equipment. As long as they have a radiation producing machine, it is registered and active in our system. When they get rid of all machines, we inactivate their account.
- RI Rad Control Office must ensure that x-ray equipment has been properly transferred and registered by recipient. OR registration remains in effect
- SC All facilities that notify us of closing must submit this information in writing
- TN The Location / Disposition of the radiation machine(s)
- TX We require the facility to give an address where the patient records will be kept and instructions on how patients may obtain the records after the facility closes. If more than six months have passed, since the most recent routine inspection, a close-out inspection will be conducted.
- UT Follow-up is performed for those radioactive material licensees that have closed. Actions may include conducting inspections, taking enforcement actions or sending letters.
- VT Did not answer Y or N. Just commented: Only if radioactive materials were used at the facility
- WV Canceled registration letter is mailed to address on file or other specified
- WY The State of Wyoming does not have a health radiation safety program at this time.

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## 5. Does your state require or remind the facility to notify the accreditation body of its intention to close?

16	Yes	AL AZ CT FL IA IL KS MA ME MO MS ND NV PA RI SC
15	No	DE HI ID LA MI NC NJ NY OR TX UT WA WI WV WY
3	Don't Know	SD TN VT
Unsolicited Comments:		
AL	Only for MQSA	
AZ	Agency does not require, but reminds facility to notify ACR	
FL	Remind	
MO	Facility is reminded to notify the FDA and the ACR	
NY	Most MQSA facilities are reminded if they continue to appear on the FDA's active list.	
OH	Y&N Indirectly – these issues are usually brought to the attention of an MQSA inspector. This inspector should remind the facility to notify ACR. In addition, the inspector would contact the FDA, according to FDA policy . . . the FDA, in turn, would notify the ACR.	
PA	Yes, per our Mammography Quality Standards Act, (MQSA) contract on Page 8, under facility status change, we have our MQSA inspectors remind the facilities to contact their accreditation body, and in PA it is the American College of Radiology (ACR).	

## 6. Is any other state agency/organization notified when a facility closes?

10	Yes	AZ KS LA ND NJ NY PA RI VT WI
16	No	AL CT FL HI IA ID IL MA MI MO MS NC OR SC SD WY
9	Don't Know	DE ME NV OH TN TX UT WA WV
Unsolicited Comments:		
AZ	Some (Medical facilities) must notify Health Services. We do not notify them, but our registration is required.	
MO	Hospitals are required to notify the hospital licensing branch of the Dept of Health when they close.	
NY	Labor Dept for non medical; NY City is notified for facilities within city. Dept of Environmental Conservation is notified is they regulate the facility.	

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PA	Health care facilities in PA are under the state Dept. of Health, (DOH). Reference PA Code Title 28, Health & Safety, Chap. 127 and specifically 127.35, (Patient Care Records), and Chap. 115, (Medical Record Services), specifically 115.23c (Preservation of Medical Records)...if a hospital discontinues operation, it shall make known to the Dept. (DOH), where its records are stored.
RI	Typically program in Chronic Disease that administers mammography screening activities in state. <a href="http://www.health.ri.gov/disease/cancer/canwcs.htm">http://www.health.ri.gov/disease/cancer/canwcs.htm</a>

**7. Are facilities required to notify a different State agency/organization when they close?**

10	Yes	AZ FL HI KS LA ND NJ PA RI VT
9	No	ID IL MA MO MS NC SC SD WY
16	Don't Know	AL CT DE IA ME MI NV NY OH OR TN TX UT WA WI WV
Identify:		
AZ		See #6 above.
FL		Medical licensing boards
HI		For certain services, closure notification is rendered to: State Health Planning & Development agency, 1177 Almcea St., Rm 402, Honolulu, HI 96813 808/586-4524
KS		<a href="http://kdhe.state.ks.us/bhfr/">kdhe.state.ks.us/bhfr/</a>
LA		Louisiana Department of Health and Hospitals
ND		If the facility is a Hospital, Rural Health Clinic or Ambulatory Surgical Center - CONTACT: ND Department of Health, Division of Health Facilities; State Capital, Judicial Wing; 600 E. Boulevard Avenue, Room 20; Bismarck, ND 58505-0200 1/800-770-2675, Roger Unger & Bruce Pritschet, Directors
NJ		Both Dept of Law and Public Safety, Division of Consumer Affairs, Board of Medical Examiners & the Dept. of Health and Senior Services, Division of Health Care Quality and Oversight have regulations regarding Facility Closings. BME regulations regarding this issue are N.J.A.C. 13:35-6.5; BME contact is: Executive Director Mr. William Roeder., New Jersey State Board of Medical Examiners, P.O. Box 183, Trenton, NJ 08625-0183. Telephone: 609-826-7100. DHSS regulations regarding this topic can be found @ N.J.A.C. 8:43A-13.6 & N.J.A.C. 8:43G-15.1. DHSS contact is John Calabria email: <a href="mailto:john.calabria@doh.state.nj.us">john.calabria@doh.state.nj.us</a> , (609) 292-8773. The link for DHSS regulations is listed below.



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	<a href="http://www.nj.gov/health/hcsa/hcsadmin.htm">http://www.nj.gov/health/hcsa/hcsadmin.htm</a>
PA	Yes, regarding Medical Records, (See item #6 above). Commonwealth of PA, Dept. of Health, Health & Welfare Bldg., Harrisburg, PA 17108. The website is pacode.com for Title 28, Health & Safety, reference Chap. 115.23c and Chap. 127.35.
RI	Uncertain it would depend on type of facility, if hospital etc they would need to inform Facilities Regulation/Health dept- web site per regulations per above. Links below have some info. Re: notification and requirements. <a href="http://www.health.ri.gov/hsr/facilities/Home.htm">http://www.health.ri.gov/hsr/facilities/Home.htm</a> <a href="http://www.health.ri.gov/hsr/professions/professions_reg.htm">http://www.health.ri.gov/hsr/professions/professions_reg.htm</a>
VT	Don't know which specific ones

## Retention Requirements

### 8. Does your State have any regulations requiring retention of records including mammography films?

25	Yes	AZ FL HI IA ID IL MA ME MI MO MS MT ND NY OR PA RI SC SD TN TX VT WA WI WV
11	No	AL CT DE KS LA NC NJ NV OH UT WY
0	Don't Know	
Unsolicited Comments:		
AZ		R12-1-614.D.1.2. See copy
FL		Mammo only
MO		Required to maintain records of all mammograms for at least 60 months 19 CSR 20-11.020(2). Mammo regs: <a href="http://www.sos.state.mo.us/adrules/csr/current/19csr/19c30-11">www.sos.state.mo.us/adrules/csr/current/19csr/19c30-11</a> .
PA		Yes, reference PA Code, Title 28 Health & Safety Chap. 115 reference 115.23(a) Medical records...shall be kept on file for a minimum of 7 years following the discharge of a patient. Regarding mammography films...the MQSA federal regulations would not supersede the PA Code and retention is 5 years for MQSA. Note that under MQSA, it is 5 years unless it is a first mammogram, then it is 10 years. This pertains to both the films and the reports. Also reference Chap. 127 and specifically 127.35, Patient Care Records, ...reports...shall be part of the patient's medical record and shall conform to the requirements of Chap. 115.
SD		Only hospital based units are required to retain records for ten years.

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TN	Only for Radiation Dosimetry and Survey Records, not "mammography films".
WV	Ref. Radiological Health Rules 64-CSR-23. 7.11.c. Additional Facility Requirements. (mammography only) 7.11.c.7. Image Retention. Clinical images shall be retained for a minimum of five (5) years

**9. If no to question 8, does another State agency/organization have any regulations requiring retention of records including mammography films?**

10	Yes	AZ CT DE FL KS LA ME NJ PA WY
3	No	MO NC SD
5	Don't Know	AL NV OH TN UT

Unsolicited Comments:

- AZ Commented: R12-1-614.D.1.2, A.R.S. – 12-2291 & A.R.S. – 12-2297
- DE Added "FDA"; \*Answered the question even though they did not answer no to question 8:
- FL Answered no to question 8 but answered Y to Q9, and commented "all medical records."
- IL Answered y to q8 and q9.
- ME Answered no to question 8 but yes to Q9
- MO Answered Y to Q8 and Q9 and commented: the hospital licensing section requires the retention of all x-ray reports for a period of 10 years for hospitals only.
- OH Commented: Don't Know – but, I don't think so . . . 3701-83-11(E) does require "Health Care Facilities" to maintain medical records for six years – but, mammography does not fall under these rules. If you want to look anyway, here's the link:  
[http://www.odh.state.oh.us/Rules/Final/Chap83/Fr83\\_1st.htm](http://www.odh.state.oh.us/Rules/Final/Chap83/Fr83_1st.htm);
- PA Answered yes to Q8 and answered Yes to Q9. Their response to Q9 included: (See item #8 above) PA Code Title 28, Chap. 115 reference 115.23(a) and Chap. 127 reference 127.35.

**10. If a regulation exists, does it apply to regular facility closings as well as bankrupt facilities?**

21	Yes	AL AZ FL HI IA ID IL LA MA ME MI MO ND NJ PA RI SD TX WA WI WV
4	No	DE NC NY SC
8	Don't Know	CT KS MS MT NV OR TN VT

Note: Alabama and Louisiana answered No to Q8--that they have no regulations requiring retention of records, but Yes to Q10.

Unsolicited Comments:

AZ	Both
FL	Each licensing board

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NY	Just general regulations
RI	As part of general policy facilities that have been closing and did provide xray services, they have informed Radiation Control of location of records ie transfer to other physician or a records holding company. Generally we ask this of facility when we understand that they will be closing. Links in item 7 can provide some additional insight.

**11. If another State agency/organization has regulations requiring retention of records including mammography films, please provide name of agency/organization, address, telephone number(s), contact individual(s), web site(s), e-mail address(es), etc.**

Your response:	
AZ	Unknown
CT	Connecticut Department of Public Health - Contact Ann Marie Montermerlon (860/509-7416)
DE	FDA
FL	Each licensing board
IL	<a href="http://www.state.il.us/idph">www.state.il.us/idph</a>
KS	<a href="http://www.kdhe.state.ks.us/bhfr/">http://www.kdhe.state.ks.us/bhfr/</a>
LA	LA Dept. of Health and Hospitals Medicare/Medicaid division
MA	Health Care Quality may have some since they license facilities
ME	See attached
MO	Mr. Terry Wenkel 573/526-0229, Bureau of Healthcare Oversight - unit of Health Facility Regulation. Hospitals: 19 CSR 30-20.021 (3) (D)
ND	See question #7
NJ	Same as above for BME and DHSSBME regulations on record retention can be found at 13:35-2.6(h) & 13:35-6.5DHSS regulations on record retention can be found at N.J.S.A. 26:8-5 & N.J.A.C. 8:43A & 8:43G
NV	Not aware of other requirements
NY	See attached regulation – Section 17 Public Health law. For hospitals see website: <a href="http://www.health.state.ny.us/nysdoh/rules/405.htm">www.health.state.ny.us/nysdoh/rules/405.htm</a>
OR	DHS Office of Public Health Systems, Health Facility Licensing, 800 NE Oregon Street, Suite 640, Portland,OR 97232
PA	The website is pacode.com, Title 28, Chap. 115 reference 115.23(a) and Chap. 127 reference 127.35.
RI	as per above, at specified web sites above specifically <a href="http://www.health.ri.gov/disease/cancer/canwcs.htm">http://www.health.ri.gov/disease/cancer/canwcs.htm</a>
WI	Department of Regulation and Licensing, PO Box 8935 Madison, WI

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	53708-8935 web@drl.state.wi.us They cover records retention for dentists, chiropractors and MD's
WY	No other state agency

**12. If your State agency or another State agency/organization has any regulations requiring retention of records including mammography films, we are also interested in getting policies, procedures, and forms relating to these regulations. Would you please send us a copy of the policies, procedures and forms, and/or give us a web site address where we might download the material?**

Here is the information you seek:	
AZ	Informal procedure used. Closing facility is asked about future retrieval & noted at facility for inquires from patients and other facilities.
CT	I'll have one of my staff get that info for you
FL	<a href="http://www.doh.state.fl.us/mga/medical/me_home">www.doh.state.fl.us/mga/medical/me_home</a>
HI	HI Revised Statutes, Cahpter 622, Section 622-58
ID	<a href="http://www3.state.id.us/cgi-bin/newidst?sctid=390130094.K">http://www3.state.id.us/cgi-bin/newidst?sctid=390130094.K</a>
IL	<a href="http://www.state.il.us/iema">www.state.il.us/iema</a> 32 Ill. Adm.Code 370.90
KS	<a href="http://www.kdhe.state.ks.us/bhfr/">http://www.kdhe.state.ks.us/bhfr/</a>
MA	We do not have a written policy. When a facility calls to tell us they are closing, we tell them to send back the license, notify the ACR, and per our regulations, tell us where the films will be stored so patients can retrieve their films.
MS	hospitals, minimum standards. <a href="http://www.msdh.state.ms.us/msdhsite/index.htm/30,0,83,60.html">Www.msdh.state.ms.us/msdhsite/index.htm/30,0,83,60.html</a>
ND	Information forthcoming
NJ	The contacts for BME & DHSS provided above can speak to their policies and procedures
NY	Section 17 with website on bottom of paper
PA	Refer to the website pacode.com, Title 28, Chap. 115 and Chap. 127.35.
RI	The web sites indicated above might have information you seek <a href="http://www.health.ri.gov/disease/cancer/canwcs.htm">http://www.health.ri.gov/disease/cancer/canwcs.htm</a> no forms just regulations
SC	<a href="http://www.scdhec.net/hr/">www.scdhec.net/hr/</a> (Part 5)
SD	44:04:09:08. Retention of medical or care records. A health care facility must retain medical or care records for at least ten years after the last date of patient or resident care. Records of minors must be retained until the minor reaches the age of majority plus an additional two years, but no less than ten years. Initial, annual, and significant-change resident assessment records, as required in §§ 44:04:06:15 and 44:04:06:16, must be retained for ten years

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	effective January 1, 2000. Source: 19 SDR 172, effective May 19, 1993; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000; 27 SDR 59, effective December 17, 2000; 28 SDR 83, effective December 16, 2001. General Authority: SDCL 34-12-13. Law Implemented: SDCL 34-12-13.
WI	No forms available
WV	<a href="http://www.wvdhhr.org/rtia/radiological_health.asp">http://www.wvdhhr.org/rtia/radiological_health.asp</a>
WY	No regulations exist

## Maintaining Access to Medical Records

### 13. Does your State have any requirements for maintaining access to patient records when one mammography facility is bought out/taken over by another?

14	Yes	AZ FL IA ID IL MA MI MO ND NJ PA RI SD WI
11	No	CT DE ME NC NY OR SC TX UT WA WY
10	Don't Know	AL HI KS LA MS NV OH TN VT WV
Unsolicited Comments		
AZ		Same regulation
FL		Medical records act
MO		19 CSR 20-11.020(2) Requirements for suppliers of mammo services
NY		Nothing specific. Generally the facility is requested to issue a public notice in a local newspaper, specifying where the records will be kept.
OH		Don't Know – but, here's a link to the Ohio State Medical Association's web site regarding maintaining medical records: <a href="http://www.osma.org/public/Medical-Records.cfm">http://www.osma.org/public/Medical-Records.cfm</a>
PA		Yes, the Dept. of Health, (DOH), regulations PA Code, Title 28, Chap. 115, reference 115.23c regarding hospital closings and Chap. 127, reference 127.35 (Patient care records). For MQSA, refer to federal regulations 21 CFR 900 or subsequent policies.
RI		See response to item 7 regulations for facilities regulation, physicians and dentist.
WI		Only the FDA regs

### 14. If yes to question 13, who assumes responsibility of those patients' records from the first facility, and who is that information made known to (you, the

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**patients, and their physicians)?**

14. If yes to question 13, who assumes responsibility of those patients' records from the first facility, and who is that information made known to (you, the patients, and their physicians)?

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	Your Response:
AZ	Generally new owners take responsibility. If not, see #12. Some facilities notify all patients of closure & either have the patient pick up records or forward them to whom the patient chooses.
FL	Patient notification by posting in newspaper
IA	idph.state.ia.us
ID	Purchaser of the facility has responsibility of maintaining records.
IL	The new facility will be responsible for record retention, unless the new facility will not be performing mammography, which in that case the former facility is responsible for retention of their mammography records
MA	The facility that buys out the other facility is responsible
MI	Don't know
MO	The original mammography service provider must maintain files or transfer records to patient or patient's primary care provider
ND	The decision to assume responsibility is made as part of the notification but not specifically required of one or the other facility. As mentioned earlier for specific types of facilities, the facility must notify the State. Patients and Physicians???
NJ	BME requires facilities to notify patients when records are transferred to another facility. BME also requires physicians to advertise in a regional newspaper for three months after closing. Finally, BME requires physicians to make reasonable attempts to directly contact all patients treated within six months of the closing of the facility.
PA	Reference DOH regulations PA Code, Title 28, Chap. 115 reference 115.28, ownership...medical records are the property of the hospital. Also, Chap. 115, reference 115.23c regarding hospital closings...it is the responsibility of the hospital, (first facility), to make known to the Dept. (DOH) as to where the records are stored...for retrieval services for 5 years after closure. Prior to destruction, a public notice shall be made.
RI	Review specific regulations from facilities reg. and professional see response to item 7.
SD	44:04:09:11. Disposition of medical or care records on closure of facility or transfer of ownership. If a health care facility ceases operation, the facility must provide for safe storage and prompt retrieval of medical or care records and the patient or resident indexes specified in § 44:04:09:10. The health care facility may arrange storage of medical or care records with another health care facility of the same licensure classification, transfer medical or care records to another health care provider at the request of the patient or resident, relinquish medical records to the patient or resident or the patient's or resident's parent or legal guardian, or arrange storage of remaining medical records with a third party vendor who undertakes such a storage activity. At least 30 days before closure, the health care facility must notify the department in writing indicating the provisions for the safe preservation

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	<p>of medical or care records and their location and publish in a local newspaper the location and disposition arrangements of the medical or care records.</p> <p>If ownership of the health care facility is transferred, the new owner shall maintain the medical or care records as if there was not a change in ownership. Source: 19 SDR 172, effective May 19, 1993; 27 SDR 59, effective December 17, 2000. General Authority: SDCL 34-12-13. Law Implemented: SDCL 34-12-13. Cross-Reference: Storage of medical or care records, § 44:04:09:09</p>
WI	All three

**15. Does your State have any requirements regarding the transfer of patients' records to, and release from, non-medical storage facilities?**

8	Yes	AZ IA MA MO NJ PA SD WI
11	No	DE HI ID IL MI NC ND SC TX UT WY
15	Don't Know	AL CT FL KS LA ME MS NV NY OH OR TN VT WA WV
Unsolicited Comments		
AZ		Same regulation – post closure some facilities hire private storage to assume availability of records
MO		no distinction made in regulations for "non-medical storage facility." 19 CSR 20-11.020(3)
NY		Nothing different than Section 17
PA		Yes, the DOH regulations, PA Code Title 28. See Chap. 115, reference 115.22 storage of medical records and reference 115.23(a) preservation of medical records and reference 115.23c closures and overall Chap. 127 reference 127.35 patient care records, (radiology interpretations).
RI		Not specifically but contained in regulations referenced per licensing entities in item 7. fees that can be charged for records etc



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## Maintaining Digital Images

### 16. Does your State have any special requirements or regulations for retention of digital images?

3	Yes	MA WI WV
23	No	AZ CT DE HI IA ID IL LA ME MO MS NC ND NJ NV NY PA SC SD TX UT WA WY
8	Don't Know	AL FL KS OH OR RI TN VT
Unsolicited Comment:		
AZ		No digital specific regs
MO		No special requirements for digital images. Some regs apply for retention, storage and availability of records - digital or film
NY		They are considered a medical record
PA		No – Refer to the MQSA federal regulations, 21 CFR 900, for policy updates to include new modalities for mammography studies. Also, under the DOH regulations, PA Code, Title 28, Chap. 115 reference 115.26, “automation of medical records” – they have encouraged innovations in medical record formats, however, “digital” is so new, the regulations are lacking information on this modality.
RI		Nothing specific at this time implied in some instances
WV		Ref. Radiological Health Rules 64-CSR-23. 7.11.c. Additional Facility Requirements. (mammography only) 7.11.c.7. Image Retention. Clinical images shall be retained for a minimum of five (5) years.

### 17. If yes to question 16, can they be stored on disk?

3	Yes	MA WI WV
1	No	PA
5	Don't Know	FL RI TN VT WA
<p>Note:</p> <p>AZ answered no to Q16 and Yes to Q17.</p> <p>DE answered N to Q16 and N to Q17.</p> <p>NY Although NY answered No to Q 16, they answered "Yes-guidance only" to Q17.</p> <p>PA Although PA answered No to Q16, they provided the following: Refer to item #16 above and best to reference the MQSA regulation, 21 CFR 900, updated policies. (Note that digital images can be stored on hard drive with several back-up systems).</p> <p>TX Although TX answered No to Q16, they answered yes to Q17.</p>		

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**18. If yes to question 17, is there a requirement for being able to retrieve images from the disks?**

2	Yes	WI WV
2	No	AZ MA
5	Don't Know	DE FL RI TN VT WA (These states did not answer Yes to Q17)
<p>Note:  DE answered N to Q16, N to Q17.  NY answered No to Q16, but they answered Q17 and Q18 "Yes-guidance only"  PA Best to reference the MQSA regulation, 21 CFR 900, updated policies.  RI General text of physicians and facilities regulations implies that retrieval is necessary</p>		

**19. If your State agency or another State agency/organization have any regulations on retention of digital images, could you send us a copy of your regulations, procedures, and policies for retention of digital images or give us a web site address where we might download these items?**

Here is the information you seek:	
IL	The record retention is the same as for standard mammography radiographs.
NJ	I am not aware of any specific regulations regarding digital records.
PA	This modality is too new for the DOH regulations-may be a policy under the MQSA regulations?
RI	links to other HEALTH regulations. Radiation Control regs do not speak directly to patient images but do address certain records retention on computer-digital media. Other licensing agency regs seem to imply. <a href="http://www.rules.state.ri.us/rules/">www.rules.state.ri.us/rules/</a> , <a href="http://www.health.ri.gov/hsr/facilities/Home.htm">http://www.health.ri.gov/hsr/facilities/Home.htm</a>
WI	s. 146.819, Wis. Stats. <a href="http://folio.legis.state.wi.us/cgi-bin/om_isapi.dll?clientID=995221&amp;infobase=stats.nfo&amp;j1=146.819&amp;jump=146.819&amp;softpage=Browse_Frame_Pg">http://folio.legis.state.wi.us/cgi-bin/om_isapi.dll?clientID=995221&amp;infobase=stats.nfo&amp;j1=146.819&amp;jump=146.819&amp;softpage=Browse_Frame_Pg</a>
WV	<a href="http://www.wvdhhr.org/rtia/radiological_health.asp">http://www.wvdhhr.org/rtia/radiological_health.asp</a>

## Follow-up Survey for Stereotactic Inspections

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**20. Does your State perform inspections of stereotactic mammography units?**

19	Yes	AL AZ CT FL IA ID IL MA ME MO NC NJ NV NY OH RI SC TN WA
14	No	DE HI KS LA MS ND OR PA SD UT VT WI WV WY
Unsolicited comments:		
FL	Verification of use	
LA	The Division of Radiological Health inspects all non-exempt radiation	
ME	Third party inspectors	
MI	We also inspect for other requirements. However, we do not typically cite a facility for phantom image shortcomings or for high mgd, but we do point those issues out to the facility.	
MO	State regs make no distinction between mammography, stereotactic or needle localization units	
NV	They are inspected as non mammography equipment	
PA	From our experience, there are several different types of stereotactic units in PA, for example, one may be similar in style to a mammography unit and used primarily for a breast biopsy on the patient with a patterned grid set-up etc. and another use is for specimens. These units are generally not inspected under state regulations and are not part of the MQSA	
RI	Limited inspections	
TN	The Division of Radiological Health inspects all non-exempt radiation machines possessed by any person in the State of TN	
TX	We perform an inspection aimed at confirming compliance with the radiation safety rules and confirming that the facility conducts any quality control tests recommended by the unit manufacturer.	

**If yes to question 20, please answer the following questions. If no, skip questions 21-24.**

**21. Is this just a mammography unit inspection, or do you also inspect the facility for other requirements, such as its quality assurance program?**

- AL      Inspections are limited to Alabama Rules which are not specific to mammography
- AZ      Unit inspection – Dose & HVL, ESE, Qualifications of Personnel and annual survey by medical physicist. Radiation protection
- CT      Just x-ray device inspection

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FL	Verification of use
IA	In rules idph.state.ia.us
ID	Partial inspection of x-ray source, but not stereotactic devices.
IL	The facility is inspected for quality assurance and physicist reports are reviewed.
MA	We inspect the whole program from QC to qualifications to physicists reports. We basically look to see that they are following the ACR program
ME	Both
MO	QA and personnel qualifications are checked
NC	We inspect unit and other requirements, no rules to back it.
NJ	In addition to the MQSA inspection, inspectors will conduct tests to verify compliance with New Jersey requirements as contained in N.J.A.C. 7:28-15.4
NV	Evaluated with other non mammography equipment
NY	Full QA inspection & equipment
OH	The unit and the quality assurance program
RI	Equipment insp.is limited to general mammo, if facility is doing sterotactic then inspection should also involve addressing issues in Rules and Regulations Relating to Quality Assurance Standards for Mammograms at <a href="http://www.rules.state.ri.us/rules/">www.rules.state.ri.us/rules/</a> “The facility shall meet the basic requirements of the voluntary ACR Stereotactic Breast Biopsy Accreditation Program in each facility where stereotactic breast biopsies are performed”
SC	Yes, see attached inspection form
TN	The only State of TN Radiation Control Regulations we use are "State Regulations for Protection Against Radiation (SRPAR)
TX	12 month intervals
WA	Medical physics report, dose, training of operators

Note: PA answered No to Q20 so they should have skipped Q21-24. Their response to this question was (See item #20 above.) regarding stereotactic units.

## **22. What is the inspection frequency for the stereotactic mammography units**

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## **and/or facilities?**

- AL Annually if also a MQSA facility, two to three years if not.
- AZ Annually
- CT Because of x-ray program staff shortage, we currently don't have a specific inspection frequency.
- FL Annual
- IA Once a year
- ID Same as regular mammography units.
- IL Stereotactic units are inspected annually.
- MA annually
- ME yearly
- MO Annually
- NC 2 to 3 years/ 2 if problems observed
- NJ Once every year for the 60 registered stereotactic facilities in NJ
- NV As time and staff permits
- NY 1 year/annual inspections
- OH 2 to 3 years depending on the results of the previous inspection and the type of facility
- RI Depends on registration category-generally 1-2 yr frequency
- SC Biannually
- TN All mammography equipment can be in either of two classes of radiation machines. If they are used in a private practicing physician's office (except a radiologist or orthopedic surgeon) then they are Class II and are to be inspected on a bi-annual basis. If they are not used in private practicing physician's office, then they are class III and are to be inspected on an annual basis.
- WA 3 years

Note: PA answered No to Q20 so they should have skipped Q21-24. Their response to this question was See item #20 above. MI also answered No to Q20 but answered "annual inspections are made" to Q22.

<b>23. What types of problems are most commonly found? (If you don't check a particular area, please indicate by noting "not checked.")</b>	<b>How often are these problems identified (as a</b>
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		<b>percentage of total number of facilities, units or personnel checked)?</b>
<b>Equipment</b>		____ Not checked
<b>Personnel</b>		____ Not checked
<b>Quality Control</b>		____ Not checked
<b>Other</b>		____ Not checked

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State	Equipment	Personnel	QC	Other
AL				Operator Protection / 1-2%
AZ	Not checked	Unqualified personnel 5%	Not checked	Not checked
FL	Not checked	Not checked	Not checked	Not checked
IA	Checked 05%	Checked 60%	Checked 30%	Checked 05%
IL	Not checked	Not checked	Failure to perform within the required schedule	Not checked
MA			5%	
ME	Rarely 1%	Never	Rarely 1%	
MO	Not checked	CME and no initial mammography training, % unk	Unknown	No annual or initial physicist survey, % unk
NC	High dose 275 mR and above / 10% or 50 facilities	Credentials not available / 50%	Some do no QC; Some do not even have a physicist report done (ever); Some do not own a phantom / 30%	Checking for needle accuracy. When asked what the parameters were for CA we got a wide variety of answers. We also noticed the dose was high where facilities were using very low kVp and not following manufacturer's instructions for establishing techniques.
NJ	0%	0%	Violations included failure to have annual physicist survey. Failure to provide safety instructions to all operators. / 6%	0%
NV	No major problems identified			
NY	Checked / 10 - 20%	Not checked	Checked / 20%	Checked: Medical Outcomes, Audits / 10%
OH	I am not privy to these statistics.			
PA *	Not checked	Not checked	Not checked	Not checked
RI			We only had one system at the time and item was during startup of accreditation process. Since that time specific attn to stereo other than confirming registration with Agency and ACR accreditation	
SC		Continued education for		

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State	Equipment	Personnel	QC	Other
		personnel <5%		
TN	Not checked	Not checked	Not checked	Not checked
TX	No significant problems have been found. Some get very close to the mean glandular dose limit of 300 mR. Collimation is sometimes a problem.	We have requirements for the technologist and physicist. No significant problems have been noted.	We require that the manufacturer's recommended procedures are followed. The manufacturer's recommendations are usually easy to comply with and no significant problems have been noted.	
WA				Medical physics annual review not done / 50%

### Comments:

- AZ Generally no problems are found
- CT I'll get back to you on question 23.
- MI We have not looked at violations cited to see what is typically cited and how often. However, it certainly would be helpful if FDA mandated ACR accreditation. Only a small percentage of stereotactic machines in this state are ACR accredited, unfortunately.
- OH I am not privy to these statistics
- PA PA did not answer Yes to Q20. They commented: See item #20 above regarding stereotactic units
- RI Due to newness of staff this area has not been a major inspection area. Previous, inspections addressed areas to ensure conformance with ACR accreditation requirements/Stereo and this will be focus as program and level of training expands.
- SC Continuing education for personnel
- TX No significant problems have been found. Some get very close to the mean glandular dose limit of 300 mR. Collimation is sometimes a problem.

Note: PA answered No to Q20 so they should have skipped Q21-24.

**24. Could you send us a copy of your regulations, procedures, policies, and test/inspection forms for stereotactic units and/or facilities (or give us a web site address where we can download these items)?**

- AL [www.adph.org/radiation](http://www.adph.org/radiation) See rules sections 1,3,5,6,10,13
- AZ Considered a type of mammography facility – no stereotactic specific regulations



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IA idph.state.ia.us

ID We don't have specific regulations for stereotactic units alone.

IL www.state.il.us.iema 32 Ill. Adm. Code 370.70

LA The Dynamic link for the entire "State Regulations for Protection Against

NC Will send you some information on separate document.

NJ Stereotactic facilities are covered under N.J.A.C. 7:28-15.4. This particular regulation can be found at the following web link:  
<http://www.nj.gov/dep/rpp/njrules.htm>

NV Mammography rules are found at [www./leg.state.nv/nac.457.html](http://www.leg.state.nv/nac.457.html). Other regulations are found at [www.leg.state.nv/nac.459.html](http://www.leg.state.nv/nac.459.html)

NY See attached QC guide & inspection form. Except for the medical outcomes audit, all tests similar to ACR requirements.

OH There are no special provisions for the inspection of stereotactic units at this time. When I answered that we check the unit and the QA program—it has nothing to do with the fact that the unit is a stereotactic unit (we have no stereotactic unit specific rules).

PA \* N/A (See item #20 above.)

RI regulations are at web sites previously noted for Radiation Control and Chronic Disease, mammography

SC scdhec.net/hr/ (Part 5)

SD n/a

TN The dynamic link for the entire "State Regulations for Protection Against Radiation" (SRPAR) is available at the TN Secretary of State's web site:  
<http://www.state.tn.us/sos/rules/1200/1200-02/1200.02.htm>

VT dna

WY NONE

\* Note: PA answered No to Q20 so they should have skipped Q21-24.

The survey forms were completed by:

AL Bradley Grinstead  
AZ Shanna Farish, Robert Cope  
CT Denny Galloway  
DE Robert Brinsfield  
FL Don Steiner  
HI Russ Takata  
IA Don Flater

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ID	David Eisentrager
IL	Marilyn Haycraft
KS	Tom Conley
LA	Jennifer Elee
MA	Karen Farris
ME	Linda Plusquellic
MI	Jim Camburn
MO	Gary Franklin & John Langston
MS	Herman Gaines
MT	Juan Stevens
NC	Jenny Rollins
ND	Warren Freier
NJ	Paul Orlando
NV	Stan Marshall & Paul Simpson
NY	Gerald O'Connor
OH	Dwight Leesburg
OR	Bob Rapcinski
PA	Stephen Williams
RI	Jack Ferruolo
SC	Aaron Gantt
SD	Robert Stahl & Gary Kaus
TN	Did not indicate who completed the survey
UT	Craig Jones
TX	Jerry Cogburn
UT	Craig Jones
VT	Carla White
WA	Mike Odlaug
WI	Mark Bunge
WV	Dan Hill
WY	Dewey Long

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