



Nevada Radiation Control Program

Mammography Machine

Application for Certificate of Authorization



Processing Timeframe

Applications that have SATISFIED ALL REQUIREMENTS take (2) weeks for processing, PLUS MAIL DELIVERY.

A valid certificate must be posted prior to operation of the mammography machine.

REGISTRANT INFORMATION

FACILITY NAME, (CERTIFICATE ISSUED IN THIS NAME)		TELEPHONE	FAX
MAILING ADDRESS	CITY	STATE	ZIP
PHYSICAL ADDRESS (IF DIFFERENT)	CITY	STATE	ZIP
NAME OF INDIVIDUAL COMPLETING FORM ¹	TITLE	TELEPHONE	E-MAIL

¹ If not a member of organizational management scan and attach a letter from management which authorizes this individual to legally bind the organization.

TYPE OF FACILITY

<input type="checkbox"/> Private Radiology Office	<input type="checkbox"/> Hospital	<input type="checkbox"/> Multi-Specialty Clinic	<input type="checkbox"/> Mobile unit, fixed use location
<input type="checkbox"/> Mobile unit, multiple temporary statewide locations ²		<input type="checkbox"/> Other _____ <small>SPECIFY TYPE AND LOCATION</small>	

² Include a supplemental sheet listing use locations and schedule of frequency, provide updates to the Division as requested.

EQUIPMENT

Previous Health Division Radiation Producing Machine Registration or Certificate? <input type="checkbox"/> Y <input type="checkbox"/> N _____		
Number of machines in use at this facility _____		<small>CERTIFICATE NUMBER</small>
Type of mammography machine to be registered ³	<input type="checkbox"/> F/S ⁴	<input type="checkbox"/> FFDM <input type="checkbox"/> DBT
MANUFACTURER _____		
MODEL _____		
CONTROL CONSOLE Serial No. _____		
DATE OF MANUFACTURE _____	DATE INSTALLED _____	FOCUS RECEPTOR DISTANCE (cm) _____
Target Material : <input type="checkbox"/> W <input type="checkbox"/> Mo <input type="checkbox"/> Rh <input type="checkbox"/> Ag <input type="checkbox"/> Other _____		
³ For additional machine(s) include addendum#1 with application.		
⁴ For Film Screen machines include addendum#2 with application.		

- Include a copy of the **Form FDA 2579**, Report of Assembly of a Diagnostic X-Ray System⁵.
- Include a copy of the Post Installation Physicist Report, (Summary Pages).
- Submit a Film of the Phantom Image QC for the machine via the Mail or, provide an image in any other manner approved by the Division. Contact the RCP for instructions.
- Include a copy of the facility Business License.

⁵ Or, attach justification of why the **Form FDA 2579** is unavailable.

ADDITIONAL REQUIREMENTS

- Commit to State, FDA and MQSA Requirements for **QUALITY ASSURANCE PROGRAM**.
NAC 457.300(1). Quality assurance and control: General requirements. ([NRS 457.065](#)) The operator of a facility shall:
Establish and maintain a program of quality assurance in accordance with the provisions of 21 C.F.R. § 900.12 for each machine and all other equipment at the facility used for mammography.
- Commit to State, FDA and MQSA Requirements for **REPORTS and RECORDS**.
NAC 457.313 Preliminary interpretation and reports of mammograms; standards for mammography records and reports; statement regarding breast density and other information to be provided to patient. ([NRS 457.065](#), [457.1857](#))

- Commit to State, FDA and MQSA Requirements if **SELF-REFERRED PATIENTS** are seen.
Provide a copy of the written Authorization from the Division to conduct annual screening in Healing Arts Mammography on patients age 40 and above and are asymptomatic of breast disease.
NAC 457.365(2). Mammographer: Prohibited acts. Except as otherwise authorized by the Division pursuant to [NAC 459.554](#), perform mammography without a prescription or order from the patient’s referring or responsible provider of care. The mammographer shall post a copy of the authorization of the Division in a conspicuous place near the machine.

- Name of Supervising Physician** _____
NAC 457.340 Physician who supervises operation of machine: Preparation, review and updating of manual of procedures; compliance with standards; notification of violation of chapter. ([NRS 457.065](#))

- Name of Supervising Technologist** _____

- Name of Radiological Physicist** _____

- Commit to State, FDA and MQSA **Requirements for Interpreting Physicians.**
NAC 457.345 Interpreter of mammograms: Prerequisites to certification of machine. ([NRS 457.065](#), [457.184](#))
 1. A person who is employed or retained by a facility for mammography to interpret mammograms must comply with the requirements of this section as a prerequisite to the issuance or renewal of any certificate for a machine located at the facility.
 2. The person:
 - (a) Must be a physician licensed pursuant to [chapter 630](#) or [633](#) of NRS; and
 - (b) Must satisfy the qualifications for an interpreting physician set forth in 21 C.F.R. § 900.12(a)(1).
 (Added to NAC by Bd. of Health, eff. 1-24-92; A 7-7-94; 11-1-95; R033-06, 6-28-2006)

INTERPRETING PHYSICIANS ⁵

RADIOLOGIST	Current Nevada License No.	Modality Training 8 hrs. FFDM	Modality Training 8 hrs. DBT	Continuing Experience 960 exams / 24 months	Continuing Education 15 Credits / 36 months
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

⁵ List all physicians interpreting mammograms for this facility and enter their current Nevada License number. Verify they meet the applicable requirements listed above. **Documentation is not required to be attached, it will be verified at time of inspection.** Signee is attesting to have verified these requirements. New Physician(s) credentials will be verified at time of inspection.

If additional Interpreting Physician worksheets are needed, print out addendum #3.

I attest that the information provided in this application is accurate and complete to the best of my knowledge.

NAME

TITLE

SIGNATURE

DATE

Current fee: \$551.00 per machine. Fee is non-refundable Per NAC 457.295.

Make check payable to: STATE OF NEVADA – RADIATION CONTROL PROGRAM.