Nevada Radiation Control Program

Mammography Machine
Application for Certificate of Authorization

FACILITY NAME (CERTIFICATE ISSUED IN THIS NAME) | TELEPHONE NUMBER | *FAX* NUMBER | E-MAIL ADDRESS

MAILING ADDRESS | CITY | STATE | ZIP CODE

PHYSICAL ADDRESS (IF DIFFERENT) | CITY | STATE | ZIP CODE

NAME OF INDIVIDUAL COMPLETING FORM [1] | TITLE | TELEPHONE NUMBER | E-MAIL ADDRESS

NAME OF PHYSICIAN WHO SUPERVISES MACHINE OPERATION

LOCATION OF MAMMOGRAPHY PRACTICE

☐ private radiology office ☐ hospital ☐ multi-specialty clinic ☐ mobile unit, fixed use location

☐ mobile unit, multiple temporary locations [2] ☐ other _____ (SPECIFY LOCATION)

Number of mammography machines in use at the designated location? _____

Number of mammograms performed each month at this location? _____

Proportion of total mammograms performed for clinical indications? [3] _____ %

Are non-breast imaging studies performed at this location? ☐ Y ☐ N

[1] If not a member of organizational management, provide a letter from management which authorizes this individual to legally bind the organization.
[2] List use locations on supplemental attached sheet.
[3] Non-screening; ordered because of symptoms, findings, or prior history of breast cancer.

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PERSONNEL [4]

RADIOLOGIST	ABR CERTIFIED Y	ABR CERTIFIED N	YEAR OF ABR CERT	NEVADA LIC NO.	YEARS EXPERIENCE IN MAMMOGRAPHY	NAMED ON PRIOR CERT Y	NAMED ON PRIOR CERT N	DIGITAL QUALIFIED Y	DIGITAL QUALIFIED N
	☐	☐				☐	☐	☐	☐
	☐	☐				☐	☐	☐	☐
	☐	☐				☐	☐	☐	☐
	☐	☐				☐	☐	☐	☐
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	☐	☐				☐	☐	☐	☐
	☐	☐				☐	☐	☐	☐
	☐	☐				☐	☐	☐	☐

NAME OF RADIOLOGICAL PHYSICIST FOR FACILITY [5]	SPECIALTY BOARD CERTIFIED Y	SPECIALTY BOARD CERTIFIED N	YEAR OF SPECIALTY CERTIFICATION	SUBSPECIALTY BOARD CERTIFICATION Y	SUBSPECIALTY BOARD CERTIFICATION N	DIGITAL QUALIFIED Y	DIGITAL QUALIFIED N
	☐	☐		☐	☐	☐	☐
	☐	☐		☐	☐	☐	☐

[4] Name all physicians interpreting mammograms for this facility. Indicate if they are ABR certified radiologists and any special mammography training (*e.g.*, residency, fellowship, workshops, seminars, symposia, etc.). Provide the number of years of mammography interpretation experience for each.

[5] This physician supervises machine operation for purposes of this application.

NAME OF MAMMOGRAPHY TECHNOLOGIST	AART CERTIFIED OR STATE LICENSE IN GENERAL RADIOGRAPHY		NEVADA CERTIFICATION NO.	DIGITAL QUALIFIED	
	Y	N		Y	N
CHIEF TECHNOLOGIST	☐	☐		☐	☐
	☐	☐		☐	☐
SUPERVISING TECHNOLOGIST [6]	☐	☐		☐	☐
	☐	☐		☐	☐
	☐	☐		☐	☐

TECHNIQUES AND POSITIONS USED FOR NON-SYMPTOMATIC MAMMOGRAPHY

How many views per breast comprise a typical non-symptomatic exam? _____

☐ CC ☐ ML oblique ☐ ML (chest wall) ☐ 90° ML7 (contact) ☐ other _____ (SPECIFY)

Typical technique employed for a craniocaudad view of an average density (normal) compressed breast:

_____ kVp _____ mA _____ TIME _____ mAs Grid used? ☐ Y ☐ N

[6] For purposes of this application, the supervising technologist may or may not hold a Certification of Authorization for Mammography.

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EQUIPMENT [7]

Previous Health Division Radiation Producing Machine Registration or Certificate? ☐ Y ____________ ☐ N
CERTIFICATE NUMBER

Dedicated mammography machine? ☐ Y ☐ N

____________	____________	____________
MANUFACTURER	MODEL NUMBER	GENERATOR SERIAL NUMBER

____________	____________	____________
DATE OF MANUFACTURE	DATE INSTALLED	FOCUS RECEPTOR DISTANCE (cm)

Target material: ☐ W ☐ Mo ☐ Rh ☐ Ag ☐ other ____________

Previous Health Division Radiation Producing Machine Registration or Certificate? ☐ Y ____________ ☐ N
CERTIFICATE NUMBER

Dedicated mammography machine? ☐ Y ☐ N

____________	____________	____________
MANUFACTURER	MODEL NUMBER	GENERATOR SERIAL NUMBER

____________	____________	____________
DATE OF MANUFACTURE	DATE INSTALLED	FOCUS RECEPTOR DISTANCE (cm)

Target material: ☐ W ☐ Mo ☐ Rh ☐ Ag ☐ other ____________

Previous Health Division Radiation Producing Machine Registration or Certificate? ☐ Y ____________ ☐ N
CERTIFICATE NUMBER

Dedicated mammography machine? ☐ Y ☐ N

____________	____________	____________
MANUFACTURER	MODEL NUMBER	GENERATOR SERIAL NUMBER

____________	____________	____________
DATE OF MANUFACTURE	DATE INSTALLED	FOCUS RECEPTOR DISTANCE (cm)

Target material: ☐ W ☐ Mo ☐ Rh ☐ Ag ☐ other ____________

[7] Complete one section for each mammographic machine to be issued a certificate. Include in your application package a phantom image taken with each machine, and a copy of the post-installation physicist report.

IMAGE RECORDING SYSTEM

FILM/SCREEN [8]

FILM

☐ Agfa-Mamoray ☐ Dupont LDS ☐ Dupont LDT ☐ Dupont Microv ☐ Dupont MRF31
☐ Dupont SR329 ☐ Fuji-MI ☐ Kodak Mini-R ☐ Kodak OM ☐ Kodak TMM
☐ Konica, CM ☐ Other _____

SCREEN

☐ DuPont Lo Dose ☐ Dupont LD/2 ☐ Kodak Min-R (SSS) [9] ☐ Kodak Min-R Fast (DSS) [10]
☐ Kodak Min-R Medium (SSS) ☐ Kodak Min-R-RF ☐ Konica ☐ Monarch
☐ other _____

Is the above a change from system used from previous certificate? ☐ Y ☐ N

Digital system _____
IDENTIFY PRINTER SYSTEM

PROCESSOR [11]

MANUFACTURER	MODEL NUMBER	CHEMISTRY TYPE	OPEPRATING TEMP (C/F)	TIME IN DEVELOPER SOLUTION (SEC)

Dedicated to mammography only? ☐ Y ☐ N

MANUFACTURER	MODEL NUMBER	CHEMISTRY TYPE	OPEPRATING TEMP (C/F)	TIME IN DEVELOPER SOLUTION (SEC)

Dedicated to mammography only? ☐ Y ☐ N

[8] Identify each type. If film and screen do not bear the same brand, provide manufacturer's statement of compatibility.
[9] single-sided screen
[10] double-sided screen
[11] Complete one section for each processor.

QUALITY ASSURANCE PROGRAM [12]

MEDICAL HISTORY

Is a patient history taken as part of the mammographic study? ☐ Y ☐ N

If yes, indicate which of the following are included in the medical history:

- ☐ current breast symptoms (mass, nipple discharge, dimpling, etc.)
- ☐ family history (mother, sister, pre- or post-menopausal)
- ☐ age at onset and upon cessation of menses
- ☐ present menstrual status (pre-menopausal, peri-menopausal, post-menopausal)
- ☐ hormonal pharmaceuticals (birth control pills, menopausal symptoms, fertility drugs, etc., and when)
- ☐ prior malignancies (type and therapy)
- ☐ previous mammogram (when and where)
- ☐ benign breast disease
- ☐ age at first live birth
- ☐ nulliparity
- ☐ any previous breast surgery (type, at what age)

[12] The Q.A. program must meet the requirements of NAC Ch. 457 and 21 CFR 900.

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MAMMOGRAM REPORT

Does the report include all findings, mammographic/radiographic interpretation and clinical/medical examination?

☐ N/A (no clinical exam done) ☐ No, mammographic findings only ☐ Yes, all findings reported

In the absence of mammographic findings, is a recommendation made on the basis of the clinical/medical examination?

☐ N/A (no clinical exam done) ☐ No, mammographic findings only ☐ Yes, all findings reported

What mechanism is in place for follow-up of positive or equivocal results, and to assure that the patient's physician has received the report? [13]

If self-referred patients are seen, provide a copy of the written authorization from the Health Division granting this facility permission to conduct mammography without a prescription signed by a licensed practitioner of the healing arts.

Who receives reports for self-referred patients? (check all that apply)

☐ Each patient must supply the name of a care physician care provider.

☐ Patient may select a physician from an available pool to receive the report. [14]

☐ N/A — all patients are referred by physicians.

Which of these follow-up mechanisms are in place? (check all that apply)

☐ results of biopsies ☐ cancers with negative mammograms ☐ cancers with positive mammograms

☐ minimal cancers detected ☐ cancers detected by mammography alone ☐ cancers detected by physical exam alone

☐ cancers detected by both mammography and physical exam ☐ mammographic localizations with positive results

☐ positive mammograms without evidence of cancer

In what proportion of cases are additional views done? _____ % ☐ Additional imaging exam tests ordered? _____ %

Specify the types of additional exams ordered: _____

What is your facility's current film retention policy? _____ years In what form are results obtained? _____

FILM, MICROFILM COPIES, ETC.

What is done with the films and reports after this time period?

[13] NAC 457.345(4)(b)

[14] Provide copy of current list with application.

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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. Make check payable to: Nevada State Health Division

Applications that have SATISFIED ALL REQUIREMENTS may take up to two weeks for processing.

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

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RADIOLOGIST INFORMATION / CHANGES

_____ currently provides radiological services to _____

NAME OF RADIOLOGY GROUP — NAME OF FACILITY

as an integral part of their mammography services. These radiological services include interpretation of mammograms, and supervision of the quality assurance program, the radiological physicist and the mammographers involved in this program. This supervision includes on-site visitation at least monthly for observation of the performance of the mammographers as well as review of Q.A. documentation.

If at any time _____ no longer provides these services to _____ ,

NAME OF RADIOLOGY GROUP — NAME OF FACILITY

_____ will notify Nevada Division of Health within ten (10) work days. At that time, any existing

NAME OF CHIEF TECHNOLOGIST OR FACILITY ADMINISTRATOR

Mammography Certificate of Authorization will be withdrawn until the Health Division verifies eligibility for a Certificate. The originally issued Certificate of Authorization must be returned to the Health Division once the Radiology Group discontinues facility supervision.

PHYSICIST INFORMATION / CHANGES

_____ currently provides radiological services to _____

NAME OF PHYSICIST OR PHYSICIST GROUP — NAME OF FACILITY

as an integral part of their mammography services.

If at any time _____ no longer provides these services to _____ ,

NAME OF PHYSICIST OR PHYSICIST GROUP — NAME OF FACILITY

_____ will notify Nevada Division of Health within ten (10) work days. At that time the Chief

NAME OF CHIEF TECHNOLOGIST OR FACILITY ADMINISTRATOR

Technologist or Facility Administrator will inform the Health Division regarding interim professional coverage until a new Physicist or Physicist Group assumes responsibility. The Facility will enlist the mandated Physicist support before any repairs are completed, or before periodic evaluations requiring review by a physicist.

SUPERVISING RADIOLOGIST	ORIGINAL SIGNATURE	DATE
PHYSICIST OR PHYSICIST GROUP REPRESENTATIVE	ORIGINAL SIGNATURE	DATE
FACILITY CORPORATE REPRESENTATIVE	ORIGINAL SIGNATURE	DATE

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