



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.

PERSONNEL ⁴

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

| NAME OF RADIOLOGICAL PHYSICIST FOR FACILITY ⁵ | SPECIALTY BOARD CERTIFIED | | YEAR OF SPECIALTY CERTIFICATION | SUBSPECIALTY BOARD CERTIFICATION | | DIGITAL QUALIFIED | |
|--|---------------------------|-------|---------------------------------|----------------------------------|-------|-------------------|-------|
| | Y | N | | Y | N | Y | 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-SYMPOMATIC 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:

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

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

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.

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.

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

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