DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

GOVERNMENTAL ENTITY DECLARATION

Form Approved: OMB No. 0910-0309
Expiration Date: May 31, 2029
See OMB Statement on Reverse.

FACILITY NAME AND ADDRESS	FACILITY IDENTIFICATION NUMBER (from FDA certificate) I.R.S. EMPLOYEE IDENTIFICATION NUMBER (EIN)

Facility Operation

		Yes	No
1.	Is the entire salary of all on-site personnel of the mammography facility paid directly by a Federal department, State, district, territory, possession, Federally-recognized Indian tribe, city, county, town, village, municipal corporation or similar political organization or subpart thereof?	☐	☐
2.	Is the building, office, or other space occupied by the mammography facility owned by, rented by, or leased to a Federal department, State, district, territory, possession, Federally-recognized Indian tribe, city, county, town, village, municipal corporation or similar political organization or subpart thereof?	☐	☐
3.	Is the facility's mammography equipment owned by, rented by, or leased to a Federal department, State, district, territory, possession, Federally-recognized Indian tribe, city, county, town, village, municipal corporation or similar political organization or subpart thereof?	☐	☐
4.	Does a Federal department, State, district, territory, possession, Federally-recognized Indian tribe, city, county, town, village, municipal corporation or similar political organization or subpart thereof have the ultimate authority to make day-to-day decisions concerning the management and operation of the mammography facility?	☐	☐

If you answered "yes" to all of the above questions, your facility qualifies as a governmental entity exempt from inspection fees. Please check ONE option below that best describes the entity that operates this facility:

☐ Federal department ☐ State, district, territory, or possession ☐ Federally-recognized Indian tribe
☐ City, county, town, village, municipal corporation or similar political organization or subpart thereof

Funding Under the Breast and Cervical Cancer Mortality Prevention Act of 1990* (www.cdc.gov/cancer/nbccedp)

		Yes	No
5.	Were at least 50% of the mammography screening examinations provided during the preceding 12 months funded under the Breast and Cervical Cancer Mortality Prevention Act of 1990, 42 U.S.C. 300k et seq.?	☐	☐

If you answered "yes" to question 5 above, your facility qualifies as a governmental entity exempt from inspection fees. Please provide the following information:

6. Total number of mammography screening examinations in preceding 12 months: _____

7. Number of mammography screening examinations provided during the preceding 12 months funded by grants under the Breast and Cervical Cancer Prevention Act of 1990: _____

*A facility providing Medicare/Medicaid services without meeting the governmental entity criteria described above *does not* qualify as a governmental entity. Additionally, FDA does not recognize other breast cancer or mammography grants/programs under the governmental entity exemption.

I attest that, to the best of my knowledge and belief, the information provided in this Declaration is true and correct and that the mammography facility identified above qualifies as a governmental entity under the definitions set forth on reverse of this form. I understand that FDA may request additional information to substantiate the statements made in this Declaration. I also understand that persons who knowingly make false statements to the government are subject to civil and criminal penalties.

Signature and address of Chief Financial or Operating Officer (or equivalent)

Signature of Chief Financial or Operating Officer *(or equivalent)*			Date
Printed Name	Title	Phone Number	
Street	City	State	ZIP Code

If your facility is claiming Governmental Entity (GE) status, please complete the GE Declaration form (Form 3422) [PDF] and submit it electronically to MQSAUserFeeSupport@fda.hhs.gov.

Instructions for Completion of Governmental Entity Declaration

This form is used to attest that a mammography facility qualifies as a "governmental entity" that is exempt from payment of inspection fees assessed under the Mammography Quality Standards Act of 1992.

A governmental entity is a mammography facility subject to inspection under section 354(g)(1) of the Public Health Service Act, 42 U.S.C. 263b(g)(1), that meets either of the following criteria--

(1) the facility is operated by any Federal department, State, district, territory, possession, Federally-recognized Indian tribe, city, county, town, village, municipal corporation or similar political organization or subpart thereof. The entire salary of all on-site personnel of the mammography facility must be paid directly by a particular form of government as listed above. All of the facility's mammography equipment must be owned, rented by, or leased by a particular form of government as listed above. The facility's ultimate authority to make day-to-day decisions concerning the management and operation of the mammography facility must come from a particular form of government as listed above. All of these requirements must be met in order for a facility to be considered a governmental entity. The particular form of government also must be listed on the Governmental Entity Declaration form (Form 3422) in the space provided.

(2) the facility provides services under the Breast and Cervical Cancer Mortality Prevention Act of 1990, 42 U.S.C. 300k *et seq.* **(www.cdc.gov/cancer/nbccedp)** and at least 50% of the mammography screening examinations provided during the preceding 12 months were funded under that statute. FDA does not recognize a facility providing Medicare/Medicaid services without meeting the governmental entity criteria described above. Additionally, other breast cancer or mammography programs/ grants are not recognized under the governmental entity exemption.

See 60 F.R. 14584 (March 17, 1995).

A facility that believes it qualifies as a governmental entity, as defined above, must complete this Declaration, have it signed by the facility's Chief Financial Officer or Chief Operating Officer (or equivalent responsible person), and return it within 30 days to the following address:

If your facility is claiming Governmental Entity (GE) status, please complete the GE Declaration form (Form 3422) [PDF] and submit it electronically to MQSAUserFeeSupport@fda.hhs.gov.

If this Declaration is not returned within 30 days, your facility will be categorized as subject to payment of inspection fees. Each such facility will be billed for all inspections conducted under 42 U.S.C. 263b (g)(1).

If FDA disallows a facility's claim that it is a governmental entity, FDA will notify the facility and will send a bill for all prior unpaid inspections.

If FDA determines that a facility is not a governmental entity, but the facility believes it qualifies for exemption by the definition of governmental entity set forth above, the facility may appeal FDA's determination by explaining and certifying the basis for its belief in a letter directed to the FDA Ombudsman, c/o Mammography Quality Standards Act Program, FDA, P.O. Box 6057, Columbia, MD 21045-6057. Any appeal must be postmarked within 30 days of the original billing date of the first inspection of the facility. The FDA Ombudsman will review a facility's claim that it is a governmental entity and will ordinarily reach a decision within 60 days. If the Ombudsman determines that a facility does not qualify as a governmental entity, the Ombudsman will provide a statement of the grounds for that determination. The Ombudsman's decision will constitute the agency's final decision on the matter.

IMPORTANT. This form must be signed by the Chief Financial Officer or Chief Operating Officer (or equivalent responsible person) of the facility claiming governmental entity status. If the Declaration is not returned within 30 days, your facility will be categorized as subject to payment of inspection fees. FDA may ask for additional documentation to substantiate a facility's claim that it is a governmental entity. Persons who knowingly make false statements to the government are subject to civil and criminal penalties.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average .5 hour (30 minutes) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."