## DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

## COVERNMENTAL ENTITY DECLARATION

Form Approved: OMB No. 0910-0909 Expiration Bale: October 31, 2022 See OMB Statement on Reverse.

GOVERNMENTAL ENTITY DECLARATION		OBS CINIS CLEANING WITHOUT COSC.			
FACILITY NAME AND ADDRESS		FACILITY IDENTIFICATION NUMBER (from FDA certificate)			
		T.R.S. EMPLOYEE IDENTIFICATION NUMBER			
Facility Operation	- Shirth			Van	Ma
1. Is the entire salary of all on-site personnel of the mammagraphy facility paid directly by a Federal department district, territory, possession, Federally-recognized Indian tribe, city, county, town, village, municipal corporational political organization or subpart thereof?					No
2. Is the building, office, or other space occupied by the mammography facility owned by, rented by, or leased to a F department, State, district, territory, passession, Federally-recognized Indian tribe, city, county, town, village, more corporation or similar political organization or subpart thereof?					No
<ol> <li>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, mwn, village, manicipal corporation or similar political organization or subpart thereof?</li> </ol>				itory,	No
4. Does a Pederal department. State, district, territory, possession, Federally-recognized Indian tribe, city, ananty, 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 management political.					No
If you answered "yes" to all of the above questions, your facility qualifies as a povernmental entity even at from inspection fies. Please check ONE a prior below that best describes the entity that operates this facility:					
Federal department	ciel, tectitory, or possession poration or similar political orga	Federally-recognization or subjust thereo		ne I	
Fonding Under the Breast and Cervical Can ( www.ede.gov/gancer/abscealt)	cer Mortality Prevention	Act of 1990*		•	
5. Were at least 50% of the manusography serective Breast and Cervical Cancer Mortality Pres			iths funded un	Yes	(%)
If you answered "yes" to question 5 where, you themse provide the fillowing information:			inspection fo	S.V.	
6. Total number of mammography screening exa	minations in preceding 12 mon	us:			
<ol> <li>Number of mammography screening examinat months fonded by grants under the Breast and</li> </ol>					
*A facility providing Medicarchtodicaid services widom meeting ant recognize offer breat caucer or rearming traphy grams/progres			connumbed curity.	Additionally, FDA	does
Tattest that, to the heat of my knowledge and belief, facility identified above qualifies as a governmental request additional information to substantiate the statements to the government are subject to civil and	entity under the definitions set atements made in this Declarati	forth on reverse of this fo	rm. I understa	and that FDA it	ay
Signature and addre	se of Chief Financial or Ope	rating Officer (or equive	lent)		
Signature of Chief Financial or Operating Officer (or equivalent)			Dute		
Printed Name	c Title		Phone Number		
Sleet	City	State		II' Code	
Return within 30 days to the following address:					
M€ <del>Plo</del>	SA Governmental Entity Decla  Mammography Quality Assu.  Box 6057	ration			
r.o.	A. ISTA STORE COCE				

Columbia, MT) 21045-6057

## 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 onsite personnel of the mammography facility must be paid directly by a particular form of government as listed above. At 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 alecisions 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 1996, 42 U.S.C. 300k et seq. (www.cdc.gov/winver/who.gov/p) and at least 50% of the mammegraphy 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 mammegraphy programs/grants are not recognized under the governmental entity exemption.

See 50 F.R. 14584 (March 17, 1995).

A facility that believes it qualifies as a governmental entity, as defined above, must complete this beataration, 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:

MQSA Governmental Entity Declaration
FDA:Mammography Quality Assurance Program
P.O. Box 6057
Columbia, MD 21045-6057

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 Assurance 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 divid and criminal penalties.

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

## \*DO NOT SEND YOUR COMPLETED FORM TO THE PRASTAFF EMAIL ADDRESS BELOW.\*

The hurden 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, gother and regiment like 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 hydren, to:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Aux (PRA) Stuff
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"An agency may not conduct or springer, and version is not respired to respond to, a collection of information unless it displays a currently valid OMB number."