

TABLE 1.—ANNUAL INSPECTION FEE BY NUMBER OF UNITS

Number of Units	Fee
1	\$1,749
2	\$1,953
3	\$2,157
4	\$2,361
5	\$2,565
6	\$2,769
7	\$2,973
Followup Inspection Fee	\$991

FDA will continue to charge separately for annual and followup inspections. FDA believes it is more appropriate and equitable for the costs of followup inspections to be borne entirely by the facilities that require such inspections. FDA has again chosen to adopt a flat fee for followup inspections over an hourly rate that would vary the fee by the length of the inspection. This approach eliminates concerns about variations among inspectors and differential treatment of facilities. The fee schedule is subject to change each year to ensure that the aggregate amount of fees collected during any year equals the aggregate amount of costs for that year's facility inspections. FDA will monitor the adequacy of the fee on an annual basis to account for any major programmatic and budget changes.

FDA continues to use a uniform, national fee structure. The methodology adopted by FDA to determine inspection fees does not pass on the costs of inspecting governmental entities to other facilities. The entire cost of inspecting governmental entities has been and will continue to be borne by appropriated funds.

V. Facilities Subject to Payment of Inspection Fees

Under the MQSA, all certified mammography facilities except governmental entities, as determined by FDA, are subject to payment of inspection fees (see section 354(r) of the PHS Act). FDA will continue to use the definition that was previously developed and applied to determine whether a facility qualifies as a governmental entity for the purpose of determining whether a facility is exempt from payment of inspection fees under section 354(r) of the PHS Act. A facility may qualify as a governmental entity in

two ways. First, a facility may qualify if any Federal department, State, district, territory, possession, Federally-recognized Indian tribe, city, county, town, village, municipal corporation, or similar political organization does the following: (1) Operates the facility; (2) pays the entire salary of all onsite personnel for the facility; (3) owns, rents, or leases all of the facility's mammography equipment; and (4) has the ultimate authority to make day-to-day decisions concerning the management and operation of the facility.

Second, a facility may qualify as a governmental entity if the facility provides services under the Breast and Cervical Cancer Mortality Prevention Act of 1990 (www.cdc.gov/cancer/nbccedp) (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**) and at least 50 percent of the mammography screening examinations provided during the preceding 12 months were funded under that statute. Facilities providing mammography services using grants under other statutes will not qualify as a government entity. FDA does not recognize, as a governmental entity, a facility providing Medicare/Medicaid services unless that facility qualifies as a governmental entity as described in the previous paragraph.

VI. Billing and Collection Procedures

Within 30 days following inspection, FDA mails a bill and a "Governmental Entity Declaration" form (Form 3422) to the inspected facility. Facilities who believe they meet the governmental entity criteria complete the form and return it in lieu of the inspection fee payment. The bill sets forth the type of inspection conducted (annual or follow-

up), the fee to be paid, and the date payment is due (30 days after billing date). Inspection fees are billed to and collected from the party that operates the facility. If the facility is owned or controlled by an entity other than the operator, it is up to the parties to establish, through contract or otherwise, how the costs of facility inspections will be allocated.

If full payment is not received by the due date, a second bill is sent. At that time, interest begins to accrue at the prevailing rate set by the Department of the Treasury, a 6 percent late payment penalty is assessed in accordance with 45 CFR 30.13, and a \$20 administrative fee is assessed for each 30-day period that a balance remains due. If payment is not received within 30 days of a third and final bill, FDA may initiate action to collect unpaid balances (with interest and penalties), including the use of collection agencies, the reporting of delinquencies to commercial credit reporting agencies, and forwarding delinquent accounts to the Department of the Treasury, Treasury Offset Program. Any questions or concerns about the billing and collection procedures may be addressed to Billing Inquiries c/o Mammography Quality Assurance Program, P.O. Box 6057, Columbia, MD 21045, 1-800-838-7715.

VII. Request for Comments

Although the MQSA does not require FDA to solicit comments on fee exemption, assessment and collection, FDA is inviting comments from interested persons in order to have the benefit of additional views.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any