

Secretary of Health and Human Services, as meeting quality standards (section 354(b) and (d)(iv) of the PHS Act). The MQSA requires FDA to establish and operate the following: (1) A Federal certification and inspection program for mammography facilities, (2) regulations and standards for accreditation bodies, and (3) standards for equipment, personnel, quality assurance, and recordkeeping and reporting by mammography facilities (section 354(c), (e), (f), and (g) of the PHS Act). The MQSA requires annual facility inspections to determine compliance with the quality standards (section 354(g) of the PHS Act). Section 354(r) of the PHS Act requires FDA to assess and collect fees for inspections of mammography facilities, other than governmental entities as determined by FDA, to cover the costs of inspections.

An updated resource review has demonstrated that the recoverable costs of the MQSA inspection program have increased since 1998. In addition, the annual amount of fees collected under the current fee schedule has been well below the level authorized by Congress. Accordingly, the fees have been recalculated so that the aggregate amount of fees collected will equal the aggregate costs of the inspections conducted, as mandated by the MQSA.

Therefore, FDA is providing notice of the increased fees to be assessed starting on October 1, 2003, and additional information relating to those fees. Although the MQSA does not require FDA to solicit comments on fee assessment and collection, FDA is inviting comments from interested persons in order to have the benefit of additional views and information, as the agency continues to evaluate its fee assessment procedures.

II. Inspections Under the Mammography Quality Standards Act of 1992

Section 354(g)(1) of the PHS Act requires FDA, States as Certifier (SAC) States, or a State or local agency acting on behalf of the FDA, to conduct an annual inspection of each mammography facility. The purpose of the annual inspection is to determine facility compliance with quality standards established under the MQSA. Inspections will be conducted by inspectors who have met Federal training requirements and who are qualified by FDA.

Under ordinary circumstances, inspections will be conducted during the regular business hours of the facility

or at a mutually agreed time. FDA normally will provide 5 working days advance notice of each annual inspection. If a significant deficiency is identified during an inspection, FDA will provide information on necessary corrective action and, in appropriate cases, will schedule a followup inspection after the facility has had a reasonable time to correct the deficiency. FDA normally will provide 5 working days advance notice of each followup inspection. FDA may make unannounced inspections or may provide shorter notice if prompt action is necessary to protect the public health (see section 354(g)(4) of the PHS Act).

III. Costs Included in the Fees to Be Assessed Beginning on October 1, 2003

Section 354(r) of the PHS Act requires FDA to assess and collect fees from persons who own or lease mammography facilities, or their agents, to cover the costs of inspections conducted by FDA, SAC States, or a State or local agency acting on behalf of FDA. Section 354(r) limits FDA's discretion in setting inspection fees in three ways: (1) Fees must be set so that, for a given fiscal year (FY), the aggregate amount of fees collected will equal the aggregate costs of inspections conducted; (2) a facility's liability for fees must be reasonably based on the proportion of the inspection costs that relate to the facility; and (3) governmental entities, as determined by FDA, are exempt from payment of fees.

FDA has determined that the following categories of costs are recoverable under section 354(r) of the PHS Act and has included them in the fees to be assessed beginning on October 1, 2003. These categories represent the same costs that have been assessed in fees since the beginning of the inspection program. Facilities are not being assessed for any new costs associated with inspections.

Cost categories are as follows: (1) Personnel costs of annual and followup inspections of mammography facilities, including administration and support; (2) purchase of equipment, calibration of instruments used in the inspections, and modification and maintenance of training facilities and laboratories to support the MQSA operations; (3) design, programming, and maintenance of data systems necessary to schedule and track inspections and to collect data during inspections; (4) training and qualification of inspectors (both FDA and State inspectors); (5) costs of billing facilities for fees due for annual and

followup inspections and collecting facility payments; (6) tracking, coordination, and direction of inspections; and (7) overhead and support attributable to facility inspections.

Because most equipment used for inspections is durable and can be used for a period of years, it is not appropriate to recover the full costs of such expenditures in the year of purchase. To do so would result in the MQSA inspection fee varying widely from one year to the next. Instead, FDA recovers these costs over the useful life of the asset.

The recoverable portions of all fixed costs of the inspection program and appropriate variable costs are recovered in the annual inspection fee. This fee will vary depending on how many mammography units are used by a facility. All mammography facilities, except governmental entities, are subject to an inspection fee.

If the annual inspection of a facility identifies a deficiency that necessitates a followup inspection that facility will be assessed an additional fee to recover the costs of that additional inspection (unless it is a governmental entity). Facilities that do not require a followup inspection are not subject to this fee.

IV. Inspection Fees to be Assessed Beginning on October 1, 2003

FDA reviewed the past methodologies for calculating the inspection fee, which accounted for differences in facility size. The same method was adopted for calculating the fees FDA will assess beginning on October 1, 2003. A facility's inspection fee will be based on the number of mammography units used by the facility.

The total recoverable aggregate cost of the MQSA inspection program is estimated to be \$14.1 million in FY 2004. This is below the \$16.4 million authorized by Congress for collections in FY 2004. To recover the costs of the inspection program, the facility portion of the fee is \$1,545 and each unit portion is \$204. The cost of each additional unit must be added to the facility portion of the fee to determine the total inspection fee. This new fee of \$1,749 for a facility with one unit compares to the current fee of \$1,549 for a facility with one unit.

FDA will assess the following fees, beginning on October 1, 2003, for facility inspections, shown in table 1 of this document: