patients and staff, Medicare and Medicaid certification, costs to patients, sources of payment, patients' functional status and diagnoses. Data collection is planned for the period July-November, 1998. Survey design is in process now. Sample selection and preparation of layout forms will precede the data collection by several months. The total annual burden hours are 5,625.

Respondents	Number of respondents	Number of Responses/ Respondents	Average burden/response (in hours)	Total burden (in hours)
Agency Questionnaire	1350	1	0.333	450
Current Patient Sampling List	1350	1	0.333	450
Current Patient Questionnaire	1350	6	0.25	2025
Discharged Patient Sampling List	1350	1	0.50	675
Discharged Patient Questionnaire	1350	6	0.25	2025

2. (NIOSH) Occupational Asthma Identification Methods -0920–0350—Reinstatement—Over the last decade, Occupational Asthma (OA) has emerged as the most prevalent occupational respiratory disease, resulting in morbidity, disability, diminished productivity, and rarely, death. Prevention of OA has become one of the most important goals for NIOSH. This project addresses these issues by examining the potential of different asthma screening approaches as surveillance tools when employed serially over time among workers at risk, and also characterizes the occurrence of and risk factors for occupational asthma in various high risk industries.

The primary objective of the study is to examine the potential of different asthma screening approaches as surveillance tools when employed serially over time among workers at risk. A second major objective is to characterize the occurrence of and risk factors for occupational asthma in several industries, specifically workers rearing insects for agricultural pest control, wood product workers using isocyanates, and other occupational groups with different exposure profiles. A series of four groups of screening measures are applied to examine the potential of each measure in different situations. This includes a questionnaire (including an occupational history), lung function tests (shift spirometry, serial peak flow tests, airway responsiveness), inflammation and immunology tests (specific and nonspecific serum immunoglobulins, skin prick tests, nasal lavage for cellular and biochemical factors), and environmental measurements (gravimetric dusts, antigens, chemical vapors, viable organisms, endotoxins). Workers exposed to 1) high molecular weight sensitizing dusts, (insect particulate), 2) low molecular weight sensitizers, (methylene biphenyldiisocyanate, MDI), and 3) irritant but not sensitizing exposures, as well as a control group of unexposed workers, are followed for two years. The results should be useful in improving tools for recognition, monitoring, and surveillance of OA. In addition, risk factors for OA will be further delineated, which will assist in targeting OA prevention strategies for agricultural and other workers. Total annual burden hours are 2,251.

Form name	Number of respondents	Number of responses/ respondent	Average burden/response (in hours)	Total burden (in hours)
Initial questionnaire	250	1	0.333	83
Follow-up questionnaire	250	4	0.166	167
Occupational questionnaire/Skin Test	250	1	0.75	188
Spirometry	250	20	0.083	417
Peak flow tests	250	300	0.016	1,250
Blood test	250	3	0.083	63
Nasal Lavage	250	1	0.333	83

Dated: January 8, 1998.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–856 Filed 1–13–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94N–0335]

Medical Devices; Mammography Quality Standards Act of 1992; Inspection Fees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the new fees the agency will assess for inspections of mammography facilities starting on February 13, 1998. The Mammography Quality Standards Act of 1992 (the MQSA) requires FDA to assess and collect fees from mammography facilities to cover the costs of annual inspections required by the MQSA. Because these costs have increased since inspections began in 1995, FDA is raising the fees accordingly. This notice explains which facilities are subject to payment of inspection fees, provides information on the costs included in developing inspection fees, and provides information on the inspection, billing, and collection processes. This is the first increase in inspection fees under the MQSA since the initial fee was established in 1995.

DATES: Effective February 13, 1998, for all inspections conducted under 42 U.S.C. 263b(g). Submit written comments by March 16, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–123, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John L. McCrohan, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332, FAX 301–594–3306.

SUPPLEMENTARY INFORMATION:

I. Background

The MQSA amended Title III of the Public Health Services Act (the PHS Act) (42 U.S.C. 262 *et seq*.) by adding a new section 354 (42 U.S.C. 263b) to require uniform national quality standards for mammography facilities. The MQSA requires all mammography facilities, other than facilities of the Department of Veterans Affairs, to be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services as meeting quality standards. The MQSA requires FDA to establish and operate: (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.

The MQSA requires annual facility inspections to determine compliance with the quality standards. Section 354(r) of the PHS Act requires FDA to assess and collect fees for inspections of all mammography facilities, other than governmental entities as determined by FDA, to cover the costs of inspections. The original notice on the MQSA fees was published in the **Federal Register** of March 17, 1995 (60 FR 14584), and was effective with the initiation of the inspection program in January 1995. An updated resource review has demonstrated that the recoverable costs of the MQSA inspection program have increased since 1995, and that 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 February 13, 1998, 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, or a State operating under a delegation of authority from 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 final quality standards were recently published in the **Federal Register** on October 28, 1997 (62 FR 55852). Inspections will be conducted by inspectors who have met Federal training requirements and who are certified 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 42 U.S.C. 263b(g)(4)).

III. Costs Included in 1998 Inspection Fee

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 cost of annual and followup inspections conducted by FDA or a State acting under a delegation from 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 February 13, 1998. 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.

- Personnel costs of annual and followup inspections of mammography facilities, including administration and support.
- Purchase of equipment, development of instrument calibration procedures, calibration of instruments used in the inspections, and modification of training facilities and laboratories to support the MQSA operations.
- Design, programming, and maintenance of data systems necessary to schedule and track inspections and to collect data during inspections.
- Training and certification of inspectors (both FDA and State inspectors).
- Costs of billing facilities for fees due for annual and followup inspections and collecting facility payments.
- Tracking, coordination, and direction of inspections.
- Overhead and support attributable to facility inspections.

Because most scientific equipment 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, these costs will be recovered over the useful life of the asset. FDA has not and will not recover compliance costs (e.g. taking legal and administrative enforcement actions) in the fee.

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, will be subject to this 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 Starting February 13, 1998

The costs of the MQSA inspection program have grown since its startup year, while the inspection fee has been held constant since its inception in FY95. Beyond the inflationary increases that are to be expected over the course of 3 years, the increased costs in the inspection program are attributable to two major areas: The actual rate of inspections and the full-scale implementation costs of the data systems. These costs account for the major difference between the costs of the startup phase of the program in FY95 and the full-scale operation in FY98, and they are largely responsible for the fee increase.

Although state inspectors, under contract with FDA, technically began inspections in January 1995, the first round of inspections actually extended well into FY96, when the bulk of the inspector cadre was hired and trained. Thus, the FY98 costs of the inspection program are almost $4 million higher than the FY95 costs, because roughly 10,000 facilities will be inspected in FY98, more than twice as many as the 4,900 inspections conducted in FY95. In addition, FY98 costs reflect the full-scale oversight and scientific support necessary to manage a national inspection program that now utilizes 250 inspectors to inspect 10,000 facilities annually. Between FY95 and FY98, the State contracts and associated costs have grown 64 percent and this State activity accounts for 72 percent of the total FY98 inspection program budget.

The data systems component of the inspection program has increased by almost $800,000 over FY95 levels, and it accounts for 8 percent of the total FY98 inspection program budget. The development, implementation, and support of this integrated system required increased investment in data systems over the FY95 levels. In FY95, only the rudimentary components of the system were operational. The data system is now in the final stages of development and implementation. It includes the inspector laptop with customized inspection software and a communications system that integrates the field and headquarters components of the inspection program. The overall system enables electronic communication between the inspector and headquarters for communicating inspection results, initiating and tracking inspection followup, and conducting ongoing inspector/headquarters education regarding the inspection program.

The remaining 20 percent of the FY98 inspection program budget covers training, equipment calibration, inspection administration, billing, and the fee assessment.

FDA reviewed the past methodology for calculating the inspection fee, which accounted for differences in facility size. A similar method was adopted for calculating the 1998 fee. A facility's inspection fee will be based on the number of mammography units used by the facility. FDA data on inspected facilities indicates that there are roughly 10,112 total mammography facilities and approximately 12,720 mammography units. The number of mammography facilities identified as Government entities is around ten percent.

The total recoverable aggregate costs of the MQSA inspection program is estimated to be $12.8 million in FY 1998. This is below the $14 million authorized by Congress for collections in FY 1998. To recover the costs of the inspection program, the facility portion of the fee is $1,345 and the unit portion is $204, and these must be added according to the number of units at each facility. This new fee of $1,549 for a facility with one unit compares to the current fee of $1,178 for a facility with one unit.

The following fees will be assessed starting February 13, 1998, for facility inspections conducted after that date:

TABLE 1.—ANNUAL INSPECTION FEE BY NUMBER OF UNITS

Number of Units	Fee
1	$1,549
2	$1,753
3	$1,957
4	$2,161
5	$2,365
6	$2,569
7	$2,773
Followup Inspection Fee	
Fee	$878

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 notes, however, that the initial fees established in FY 1995 remained constant for a period of 3 years. The agency expects this new fee schedule to remain constant through FY 1999. FDA will monitor the adequacy of the fee on an annual basis.

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 42 U.S.C. 263b(r)).

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 42 U.S.C. 263b(r). A governmental entity is a mammography facility subject to inspection under section 354(g)(1) of the PHS Act (42 U.S.C. 263b(g)(1)), that meets either of the following criteria: (1) 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; or (2) provides services under the Breast and Cervical Cancer Mortality Prevention Act of 1990, 42 U.S.C. 300k *et. eq.*, and at least 50 percent of the mammography screening examinations provided during the preceding 12 months were funded under that statute. The first notice of fees for facilities provides additional background relating to this definition (see 52 FR 14585).

VI. Billing and Collection Procedures

Within 30 days following inspection, FDA mails a bill to the inspected facility (governmental entities do not receive bills). The bill sets forth the type of inspection conducted (annual or followup), 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 (currently, the prevailing rate is 13.75 percent), 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 and reporting of delinquencies to commercial credit reporting agencies.

Any questions or concerns about the billing and collection procedures may be addressed to Billing Inquiries c/o Mammography Quality Assurance Program, FA, P.O. Box 6057, Columbia, MD 21045–6057, 1–800–838–7715.

VII. Review and Appeals Procedures Regarding Qualifications as a Governmental Entity

FDA will review each declaration that a facility qualifies as a governmental entity. If FDA disallows a facility's claim that it is a governmental entity, a bill will be sent to the facility with payment due within 30 days.

If FDA determines that a facility is not a governmental entity, but the facility believes it qualifies for exemption under the definition of governmental entity set forth previously, 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, FA, P.O. Box 6057, Columbia, MD 21045–6057, postmarked within 30 days of FDA's notice to the facility that the facility does not qualify as a governmental entity. The FDA Ombudsman will review a facility's claim that it is a governmental entity and will normally reach a decision within 60 days. If the Ombudsman determines that a facility does not qualify as a governmental entity, the Ombudsman shall provide a statement of the grounds for that determination. The Ombudsman's decision will constitute the agency's final decision on the matter. During the time required for the Ombudsman's review, FDA's efforts to collect the fee will be suspended and all time-related penalties held in abeyance.

VIII. 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. FDA may consider altering its methodology of defining governmental entities, and assessing and collecting fees under the MQSA in future years. Each year's inspection experience provides additional data about differences among facilities and variations in costs by State, region, or other factors.

Interested persons may, on or before March 16, 1998, submit to the Dockets Management Branch (address above) written comments regarding this notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments and a full explanation of the costs included and the methodology employed in determining these fees are on file with the Dockets Management Branch (address above) and may be seen in that office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 23, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–881 1–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on January 28, 1998, 9:30 a.m. to 5 p.m.

Location: Parklawn Conference Center, conference rooms G and H, 5600 Fishers Lane, Rockville, MD.

Contact Person: Veronica J. Calvin, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12515. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss a premarket approval (PMA) supplement for a computerized automated Papanicolaou (PAP) smear reader that is indicated for use as a primary screener to select a subpopulation of smears that will be designated for no further review.

Procedure: On January 28, 1998, from 10:30 a.m. to 11:30 a.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 21, 1998. Oral presentations from the public will be