EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN FOR HOSPITALS

Form name	Number of hospitals	Total burden hours	Average hourly wage rate*	Total cost burden
Pre/Post-Interview Protocol	6	156	$27.46	$4,284
Quarterly Update Protocol	6	36	27.46	989
Usability Testing Protocol	6	24	27.46	659
AHRQ QI Data Collection Tool	6	144	27.46	3,954
Total	24	360	NA	9,886

*Based upon the mean of the average wages, National Compensation Survey: Occupational wages in the United States, March 2009, "U.S. Department of Labor, Bureau of Labor Statistics." Used as an overall average wage rate across the various types of staff involved in the quality improvements.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total and annualized cost of this project to the government. The estimated total cost for the evaluation work is $209,827 over the two-year year project, with an annualized total cost of $104,914. These costs were developed based on estimates of staff days required, to which administrative expenses are applied, and based on airfare, hotel, and per diem costs for staff travel for the site visits at the end of the evaluation.

EXHIBIT 3—ESTIMATED COST OF THE EVALUATION

Cost component	Total cost	Annualized cost
Protocol Development	$40,278	$20,139
Data Collection Activities	91,104	45,552
Data Analysis	45,252	22,626
Publication of Results	24,370	12,185
Travel for Site Visits	8,823	4,412
Total	209,827	104,914

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: February 24, 2010.

Carolyn M. Clancy,

Director.

[FR Doc. 2010–4948 Filed 3–10–10; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0121]

Agency Information Collection Activities; Proposed Collection; Comment Request; Mammography Quality Standards Act Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the estimated reporting and recordkeeping burden associated with the Mammography Quality Standards Act requirements.

DATES: Submit written or electronic comments on the collection of information by May 10, 2010.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public

submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The Mammography Quality Standards Act Requirements—21 CFR Part 900 (OMB Control Number 0910–0309)—Extension

The Mammography Quality Standards Act requires the establishment of a Federal certification and inspection program for mammography facilities; regulations and standards for accreditation and certification bodies for mammography facilities; and standards for mammography equipment, personnel, and practices, including quality assurance. The intent of these regulations is to assure safe, reliable, and accurate mammography on a nationwide level.

Under the regulations, as a first step in becoming certified, mammography facilities must become accredited by an FDA-approved accreditation body. This requires undergoing a review of their clinical images and providing the accreditation body with information showing that they meet the equipment, personnel, quality assurance and quality control standards, and have a medical reporting and recordkeeping program, a medical outcomes audit program, and a consumer compliant mechanism. On the basis of this accreditation, facilities are then certified by FDA or an FDA-approved State certification agency and must prominently display their certificate. These actions are taken to ensure safe, accurate, and reliable mammography on a nationwide basis.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.3(b)(1)	0.33	1	0.33	1	0.33		
900.3(b)(3) full[1]	0.33	1	0.33	320	106	10,000	
900.3(b)(3) limited[2]	5	1	5	30	150		
900.3(d)(2)	0.1	1	0.1	30	3		
900.3(d)(5)	0.1	1	0.1	30	3		
900.3(e)	0.1	1	0.1	1	0.1		
900.3(f)(2)	0.1	1	0.1	200	20		$45
900.4(c)	2,894	1	2,894	1.5	4,341		
900.11(b)(1)							
900.11(b)(2) facility[3]							
900.4(c) AB[4]	5	1	5	421	2,105		$173,620
900.4(d)	2,894	1	2,894	.75	2,171		
900.11(b)(1)							
900.11(b)(2) facility[3]							
900.4(d) AB[4]	5	1	5	211	1,055		
900.4(e)	8,681	1	8,681	1	8,681		$8,681
900.11(b)(1)							
900.11(b)(2) facility[3]							

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.4(e) AB[4]	5	1	5	1,736	8,680		
900.4(f)	331	1	331	7	2,317		$77,640
900.4(h) facility[3]	8,681	1	8,681	1	8,681		$3,820
900.4(h) AB[4]	5	1	5	10	50		
900.4(i)(2)	1	1	1	16	16		
900.6(c)(1)	0.1	1	0.1	60	6		
900.11(b)(3)	5	1	5	.5	2.5		
900.11(c)	400	1	400	5	2,000		
900.12(c)(2)	8,681	4,942	42,901,502	.0833333	3,575,124		$19,500,000
900.12(c)(2) patient refusal[5]	87	1	87	.5	43.5		
900.12(h)(4)	7	1	7	1	7		
900.12(j)(1) facility[3]	8	1	8	200	1,600		$120
900.12(j)(1) AB[4]	8	1	8	320	2,560		$240
900.12(j)(2)	2	1	2	100	200		$3,875
900.15(c)	5	1	5	2	10		
900.15(d)(3)(ii)	1	1	1	2	2		
900.18(c)	2	1	2	2	4		
900.18(e)	2	1	2	1	2		
900.21(b)	0.33	1	0.33	320	106	$30,000	$174
900.21(c)(2)	0.1	1	0.1	30	3		
900.22(h)	5	200	1,000	.083	83		20
900.22(i)	2	1	2	30	60		
900.23	5	1	5	20	100		
900.24(a)	0.4	1	0.4	200	80		$42
900.24(a)(2)	0.15	1	0.15	100	15		$21
900.24(b)	1	1	1	30	30		
900.24(b)(1)	0.3	1	0.3	200	60		$42
900.24(b)(3)	0.15	1	0.15	100	15		$21
900.25(a)	0.2	1	0.2	16	3.2		
FDA Form 3422	700	1	700	.25	175		
Total					3,620,673	$40,000	$19,768,361

[1] One-time burden.
[2] Refers to accreditation bodies applying to accredit specific Full Field Digital Mammography units.
[3] Refers to the facility component of the burden for this requirement.
[4] Refers to the accreditation body component of the burden for this requirement.
[5] Refers to the situation where a patient specifically does not want to receive the lay summary of her exam.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.3(f)(1)	0.1	1	0.1	0	0		
900.4(g)	5	1	5	1	5		
900.12(a)(1)(i)(B)(*2*)	87	1	87	8	696		
900.12(a)(4)	8,681	4	34,724	1	34,724		
900.12(c)(4)	8,681	1	8,681	1	8,681	$28,000	
900.12(e)(13)	8,681	52	451,412	.083333	37,618		
900.12(f)	8,681	1	8,681	16	138,896		
900.12(h)(2)	8,681	2	17,362	1	17,362		
900.22(a)	5	1	5	1	5		
900.22(d)	5	1	5	1	5		
900.22(e)	5	1	5	1	5		
900.22(f)	3	1	3	1	3		
900.22(g)	5	1	5	1	5		$50
900.25(b)	5	1	5	1	5		
Total					238,010	$28,000	$50

The following sections of title 21 of the Code of Federal Regulations (CFR) were not included in the previously mentioned burden tables because they were considered usual and customary practice and were part of the standard of care prior to the implementation of the regulations. Therefore, they resulted in no additional reporting or recordkeeping burden: 21 CFR 900.12(c)(1) and (c)(3) and 21 CFR 900.3(f)(1).

Section 900.3(c) was not included in the previously mentioned burden tables because all four existing accreditation bodies are approved until late in 2013; so, no applicants will reapply during the requested information collection period. Section 900.24(c) was also not included in the previously mentioned burden tables because if a certifying state had its approval withdrawn, FDA would take over certifying authority for the affected facilities. Because FDA already has all the certifying state's electronic records, there wouldn't be an additional reporting burden.

Dated: March 8, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–5230 Filed 3–11–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0101]

Agency Information Collection Activities; Proposed Collection; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Form FDA 3356; Eligibility Determination for Donors; and Current Good Tissue Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements for FDA regulations related to human cells, tissues, and cellular and tissue-based products (HCT/Ps) involving establishment registration and listing using Form FDA 3356; eligibility determination for donors; and current good tissue practice (CGTP).

DATES: Submit written or electronic comments on the collection of information by May 10, 2010.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c)