2025 Current Fiscal Year Report: National Mammography Quality Assurance Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2025

3. Committee or Subcommittee	3b. GSA Committee No.
National Mammography Quality Assurance Advisory Committee	1671

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	07/07/2023	07/07/2025	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Statutory (Congress Created)

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
42 U.S.C. 263b(n)	07/06/1991	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports	No Reports for this FiscalYear

17a. Open	17b. Closed	17c. Partially Closed	Other Activities	17d. Total
0	0	0	0	0

Meetings and Dates

No Meetings

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$0.00	$0.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$0.00	$0.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$0.00
18b(1). Travel and Per Diem to Non-Federal Members	$0.00	$0.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00
18c. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings)	$0.00	$0.00
18d. Other (all other funds not captured by any other cost category)	$0.00	$0.00
18e. Total Costs	$0.00	$0.00
19. Federal Staff Support Years (FTE)	0.00	0.00

20a. How does the Committee accomplish its purpose?

The National Mammography Quality Assurance Advisory Committee (NMQAAC) provides advice to the Agency on the following tasks: (1) developing appropriate quality standards and regulations for mammography facilities, (2) developing appropriate standards and regulation for bodies accrediting mammography facilities, (3)

developing regulations on sanctions, (4) developing procedures to monitor compliance with standards, (5) establishing a mechanism to investigate consumer complaints, (6) reporting new developments concerning breast imaging that should be considered in the oversight of mammography facilities, (7) determining whether there is a shortage of mammography facilities in rural and health professional shortage areas, (8) determining whether there will be a sufficient number of medical physicists after 1999, and (9) determining the costs and benefits of compliance with these requirements.

20b. How does the Committee balance its membership?

The Mammography Quality Standards Act of 1992 (MQSA) specifies that advisory committee members be selected from physicians, practitioners and other health professionals whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography. The Act also directs the appointment of four individuals from among national breast cancer consumer health organizations with expertise in mammography and at least two practicing physicians who provide mammography services. The current committee is composed of M.D.'s and Ph.D's who have expertise in the fields of medical physics, teleradiology, medical physicist, digital mammography, and diagnostic radiology. Consumer interests are represented by mammographers, radiologic technologists and health education specialists.

20c. How frequent and relevant are the Committee Meetings?

This committee is mandated by the

Mammography Quality Standards Act of 1992 (MQSA) to provide input in the promulgation of reasonable policies to execute the Act. Meetings are to be held annually. The committee held no meetings in FY 2024, however, activities and accomplishments of the Agency action are as follows: • Publication of Amended Final Rule to the Mammography Quality Standards Act of 1992 (MQSA) and the Federal Food, Drug, and Cosmetic Act (FD&C Act) • Collaboration with accreditation bodies to enhance the accreditation process in response to COVID-19 • Approval of accreditation body procedures and protocols that streamline the submission process for accreditation • Issuance of compliance actions such as Additional Mammography Reviews (AMRs), Patient and Provider Notifications (PPNs), and certificate actions (e.g., no longer in effect or revocation) • Approval of nine (9) manufacturer quality control manuals and fourteen (14) alternative standards • Development and upgrade of MPRISweb to MPRIS 2.0 • Update MQSA inspection paper invoices to electronic invoices • Development of virtual MQSA inspector training program No meeting is planned for FY 2025.

20d. Why can't the advice or information this committee provides be obtained elsewhere?
Committee members have backgrounds in academia, research, and/or clinical practice. Their advice and input is considered as part of FDA's regulatory decision-making and lends credibility to decisions that may face intense public scrutiny. The alternate means of accessing this advice would involve the recruitment of large numbers of scientists on a full-time basis at maximum rates of compensation.

20e. Why is it necessary to close and/or partially closed committee meetings?

N/A

21. Remarks

Although this committee did not meet in FY 2024, considerable time was devoted to appointing current members, maintaining associated records for these activities, and streamlining paper processes within FDA. In addition, time was spent in the routine care and maintenance of the committee: the development of a financial report for this website; updating the roster and number of vacancies on our website; completing the annual ethics report; reviewing financial disclosures of current members and potential nominees and providing ethics training. Since the Committee did not meet, no reporting was required. The Agency continues to publish a request for nominations in the Federal Register Notice, to receive nominations to fill the current and upcoming vacancies.

Designated Federal Officer

James P Swink Lead Public Health Analyst, Center for Devices and Radiological Health/FDA

Committee Members	Start	End	Occupation	Member Designation
Carson, Paul	07/13/2023	01/31/2027	Active Emeritus Professor of Radiology, University of Michigan, Ann Arbor, MI	Special Government Employee (SGE) Member
Destounis, Stamatia	07/13/2023	01/31/2027	Managing Partner, Elizabeth Wende Breast Care, LLC, Rochester, NY	Special Government Employee (SGE) Member
Epling, James	02/25/2022	01/31/2026	Assistant Clinical Professor, University of South Carolina School of Medicine, Greenville, SC	Special Government Employee (SGE) Member

Giger, Maryellen	07/13/2023	01/31/2027	A.N. Pritzker Distinguished Service Professor of Radiology, Committee on Medical Physics & the College, The Univ. of Chicago, Chicago, IL	Special Government Employee (SGE) Member
Goode, Allen	02/25/2022	01/31/2026	Chief Diagnostic Medical Physicist, Department of Radiology & Medical Imaging, University of Virginia Health Systems, Charlottesville, VA	Special Government Employee (SGE) Member
Grimm, Lars	02/25/2022	01/31/2026	Associate Professor, Division of Breast Imaging, Department of Radiology, Duke Unversity Medical Center, Durham, NC	Special Government Employee (SGE) Member
Hulme, Katie	02/25/2022	01/31/2026	Diagnostic Medical Physicist, The Cleveland Clinic Foundation, Beachwood, OH	Special Government Employee (SGE) Member
Malak, Sharp	02/25/2022	01/31/2025	Breast Imaging Radiologist, Department of Radiology, St. Bernards Healthcare, Jonesboro, AR	Special Government Employee (SGE) Member
Moseley, Tanya	07/13/2023	01/31/2027	Prof. of Diagnostic Radiology and Breast Surgical Oncology, The Univ. of Texas MD Anderson Cancer Ctr., Houston, TX	Special Government Employee (SGE) Member

Number of Committee Members Listed: 9

Narrative Description

FDA's strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public

health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The National Mammography Quality Assurance Advisory Committee (NMQAAC) supports FDA's strategic priorities by advising the Food and Drug Administration on the following items, thereby helping FDA meet Objective 3 of Empowering Consumers by improving and increasing FDA-initiated health benefit/risk information: (A) developing appropriate quality standards and regulations for mammography facilities; (B) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program; (C)developing regulations with respect to sanctions; (D) developing procedures for monitoring compliance with standards; (E) establishing a mechanism to investigate consumer complaints; (F) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities; (G) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; (H) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (I) determining the costs and benefits of compliance with these requirements.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments
NA

What are the cost savings associated with this committee?

	Checked if Applies
None	☐
Unable to Determine	☑
Under $100,000	☐
$100,000 - $500,000	☐
$500,001 - $1,000,000	☐
$1,000,001 - $5,000,000	☐
$5,000,001 - $10,000,000	☐
Over $10,000,000	☐
Cost Savings Other	☐

Cost Savings Comments
The utilization of the National Mammography Quality Assurance Advisory Committee enables the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the Committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?
87

Number of Recommendations Comments
The committee made 87 recommendations from FY03 through FY24.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
84%

% of Recommendations Fully Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA often accepts the recommendations from its committees, the advice is purely advisory in nature, therefore, the Agency has the option of not implementing the advice. This number

represents an approximation of the percentage of recommendations that the agency has fully implemented or plans to fully implement.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
10%

% of Recommendations Partially Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?
Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments
Most of the committee's recommendations deal with guidance. When the guidance has been finalized, the committee is sent copies of the guidance and the guidance is published as part of the public record. When appropriate, information is made available to the public. Actions related to guidance documents or other general matters or issues are available publicly when implemented. Please see https://www.fda.gov/.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☐
Issued new regulation	☑
Proposed legislation	☐
Approved grants or other payments	☐
Other	☑

Action Comments
Issued new or modified guidance.

Is the Committee engaged in the review of applications for grants?
No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	✓
Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	✓
Other	

Access Comments

N/A