

assessment category: “Incomplete: Need additional imaging evaluation and/or prior mammograms for comparison.” As such, it is not clear how a facility would comply with both the Alternative Standard and the other applicable requirements in the amended regulations.

Moreover, as discussed in the MQSA small entity compliance guide, FDA has generally exercised enforcement discretion regarding the final assessment category wording where the variation in wording does not change the meaning of the assessment category (e.g., “benign finding” instead of “benign” or “suspicious abnormality” instead of “suspicious”), and FDA intends to continue such a practice. Thus, FDA has determined that Alternative Standard #11 is no longer needed, no longer appropriate, and may cause confusion, and so withdrawal of Alternative Standard #11 is justified by § 900.12.

FDA also has determined that withdrawal of Alternative Standard #12 is justified by § 900.12. Alternative Standard #12 allowed use of an additional assessment category “Post Procedure Mammograms for Marker Placement.” As of the effective date of the MQSA final rule (September 10, 2024), the nearly identical assessment statement “Post-Procedure Mammogram for Marker Placement” is included in the amended § 900.12(c)(1)(iv)(G). Because amended § 900.12(c)(1)(iv)(G) incorporates Alternative Standard #12, FDA has determined that the alternative is no longer needed, no longer appropriate, and may cause confusion, and so withdrawal of Alternative Standard #12 is justified by § 900.12.

Finally, FDA is amending Alternative Standard #8, which permitted interpreting physicians to provide a separate assessment of findings for each breast in the medical report instead of a single overall assessment of findings as set forth in § 900.12(c)(1)(iv). Specifically, the alternative permitted: “A separate assessment of findings for each breast, classified in one of the following categories,” instead of “A separate final assessment of findings for each breast, classified in one of the following categories.” This language is being amended to use the term “final assessment” to match the updated language in amended § 900.12(c)(1)(v). As a result of the amended § 900.12, amending Alternative Standard #8 is justified by § 900.12.

Dated: August 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) hereby gives notice that the National Vaccine Advisory Committee (NVAC) will hold an in-person meeting. The meeting will be open to the public and public comment will be heard during the meeting.

DATES: The meeting will be held September 12–13, 2024. The confirmed meeting times and agenda will be posted on the NVAC website at <http://www.hhs.gov/nvpo/nvac/meetings/index.html> as soon as they become available.

ADDRESSES: Instructions regarding attending this meeting will be posted online at <http://www.hhs.gov/nvpo/nvac/meetings/index.html> at least one week prior to the meeting. Pre-registration is required for those who wish to attend the meeting in person or participate in public comment. Please register at <http://www.hhs.gov/nvpo/nvac/meetings/index.html>.

FOR FURTHER INFORMATION CONTACT: Ann Aikin, Acting Designated Federal Officer, Office of Infectious Disease and HIV/AIDS Policy, U.S. Department of Health and Human Services, Tower Building, Room, 1101 Wootton Parkway, Rockville, MD 20852. Email: nvac@hhs.gov. Phone: 202–795–7697.

SUPPLEMENTARY INFORMATION: Pursuant to section 2101 of the Public Health Service Act (42 U.S.C. 300aa–1), the Secretary of HHS was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program’s responsibilities.

The Assistant Secretary for Health serves as Director of the National Vaccine Program.

During this meeting, the NVAC will hear presentations about implementation of the universal hepatitis B vaccine recommendations of adults aged 19–59 years and adults aged 60 years and older with risk factors for hepatitis B infection, new approaches for tuberculosis vaccine innovation, and research to inform future HIV vaccine development. The NVAC will also host panels on vaccine equity, provider payment, and planning for the development of the next national vaccine strategy.

Please note that agenda items are subject to change, as priorities dictate. Information on the final meeting agenda will be posted prior to the meeting on the NVAC website: <http://www.hhs.gov/nvpo/nvac/index.html>.

Members of the public will have the opportunity to provide comment at the NVAC meeting during the public comment period designated on the agenda. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Members of the public may also submit written comments. Written comments should not exceed three pages in length. Individuals planning to submit comments should email their written comments or their request to provide a comment during the meeting to nvac@hhs.gov at least five business days prior to the meeting.

Dated: August 19, 2024.

Ann Aikin,

Acting Designated Federal Official, Office of the Assistant Secretary for Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning