GUIDANCE FOR SUBMISSION OF REQUESTS FOR RECONSIDERATION OF ADVERSE DECISIONS ON ACCREDITATION OF MAMMOGRAPHY FACILITIES UNDER THE MAMMOGRAPHY QUALITY STANDARDS ACT, 42 U.S.C. § 263(b)

This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations or both.

Mammography Standards Branch
Division of Mammography Quality and Radiation Programs
Office of Health and Industry Programs

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Comments and suggestions may be submitted at any time for Agency consideration to, Mammography Standards Branch, HFZ-240, 1350 Piccard Drive, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Al Van De Griek by telephone at (301) 594-0866 or by electronic mail at vdg@cdrh.fda.gov.

Additional Copies: World Wide Web/CDRH/DMQRP home page: http://www.fda.gov/cdrh/dmqrp.html, or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 400 when prompted for the document shelf number.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, MD 20850

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UNITED STATES FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF HEALTH AND INDUSTRY PROGRAMS
DIVISION OF MAMMOGRAPHY QUALITY AND RADIATION PROGRAMS

INTRODUCTION

This guidance document reflects the agency's current thinking on procedures for submission of requests for reconsideration of adverse decisions on accreditation, under the Mammography Quality Standards Act of 1992. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

A facility that has been denied accreditation is entitled to an appeal to the facility's accreditation body (AB). A facility should avail itself of the AB's appeal process before requesting reconsideration from the Food and Drug Administration (FDA).

If the facility cannot achieve satisfactory resolution of an adverse accreditation decision through its AB's appeal process, the facility may request reconsideration of that adverse decision by FDA through the Division of Mammography Quality and Radiation Programs (DMQRP).

NOTE: A facility cannot perform mammography services while an adverse accreditation decision is being appealed.

The appropriate procedure for requesting reconsideration of an adverse decision on accreditation to DMQRP is as follows:

APPEALS PROCEDURE

A facility should make its request for reconsideration to DMQRP, within 60 days of the AB's adverse appeals decision, at the following address:

Division of Mammography Quality and Radiation Programs (HFZ-240)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Dr.
Rockville, MD 20850
Attn: Standards Branch

The request for reconsideration should include 3 copies of the following records:

1. The AB's original denial of accreditation, including clinical or phantom image score sheets when applicable;

2. All information the facility submitted to the AB as part of the appeals process, including all original films submitted to the AB (additional copies of the films are not required);

3. A copy of the AB's adverse appeals decision including clinical or phantom image score sheets when applicable;

4. A statement of the bases for the facility's disagreement with the AB's decision.

The DMQRP will make a decision concerning the request for reconsideration within 60 days of receipt of all of the material specified above. The Division will provide the facility with written notification of its decision, and of the facility's options as a consequence of that decision.

A facility that is dissatisfied with DMQRP's decision following reconsideration is entitled to a formal hearing before the Departmental Appeals Board (DAB) of the Department of Health and Human Services. Copies of the applicable regulations (subpart D of 42 CFR part 498) for formal hearings will be supplied upon written request.