GUIDANCE FOR REVIEW 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 Chet Trybus by telephone at (301) 594-3772 or by electronic mail at cgt@fdadr.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 402 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

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

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 a process for review and decision making for requests for reconsideration of adverse decisions on accreditation, under the Mammography Quality Standards Act of1992 (MQSA or the Act). 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.

Enforcement of MQSA is presently governed by interim regulations at 21 CFR Part 900. Final regulations at 21 CFR Part 900 will take effect on April 28, 1999. Both the interim and final regulations, at section 900.11, require that mammography facilities be accredited by an FDA approved AB, in order to be certified by FDA to perform mammography. In the event that a facility is denied accreditation, it may appeal that denial to the AB in accordance with the AB's procedures. In the event that the appeal is denied, the facility may further appeal to FDA by submitting a request for reconsideration of the adverse accreditation decision to the FDA.

FDA will provide a copy of "GUIDANCE FOR SUBMISSION OF REQUESTS FOR RECONSIDERATION OF ADVERSE DECISIONS ON ACCREDITATION OF MAMMOGRAPHY FACILITIES UNDER THE MAMMOGRAPHY QUALITY STANDARDS ACT" to facilities that inform the Food and Drug Administration (FDA) that they wish to request reconsideration of an adverse decision on accreditation by their accreditation body (AB). Facilities should submit requests for reconsideration in accordance with that guidance. The guidance may be requested by telephone at (301) 594-3332, by facsimile at (301) 594-3306, or by writing to:

> Division of Mammography Quality and Radiation Programs
> U.S. Food and Drug Administration
> 1350 Piccard Drive
> Rockville, Maryland 20850

REQUESTS FOR RECONSIDERATION PROCESSING

Requests for reconsideration will be reviewed and acted upon by the Division of Mammography Quality and Radiation Programs (DMQRP or the Division). Upon receipt of a request for reconsideration of an adverse accreditation decision, DMQRP (normally the liaison officer of the

AB that denied accreditation) will create a request for reconsideration case file and document log.[1] Receipt of the request will be recorded in the log, as will a complete list of the contents of the facility's submission. The disposition of all contents of the request shall be recorded in the log throughout the period that the request for reconsideration is under review.

The case file will be filed in the Division appeals file by facility name and FDA identification number. It will, at a minimum, contain a copy of:

1. the document log,

2. all documents and letters, including summary minutes of all meetings, gathered or generated during or as a result of review of the request for reconsideration, and

3. the original request for reconsideration.

Note that all clinical or phantom images submitted by the requester will be returned by registered mail or other equally secure means after final disposition of the case. This file will serve as an administrative record should a facility, whose appeal is denied, seek remedy from the Departmental Appeals Board.[2]

DMQRP will establish an ad hoc "Facility Accreditation Review Committee" (Committee) which will review the request for reconsideration. The Committee will normally consist of the liaison officer for the AB that made the adverse decision as chairperson, the Chief of the Mammography Standards Branch, at least one FDA radiologist who is a qualified mammography interpreting physician, and at least two other members of the Division. The chairperson will select the persons to serve on the Committee with the approval of the Chief of the Mammography Standards Branch. Following the procedure below, the Committee will make an initial decision and formulate a recommendation to the Division Director whether the denial of accreditation should be sustained or reversed.

The review procedure that follows is predicated on the belief that most requests for reconsideration will be submitted subsequent to failure of a facility to pass clinical image review by its accreditation body, and subsequent to a failed appeal to the AB. In the event that a request for reconsideration is received in which some other factor is the reason for the adverse accreditation decision, the Committee will select appropriate DMQRP staff to assist the Committee in its review of the request, and the procedure will be modified as necessary by the Committee.

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1 The log may be a paper document, a word processor document or a spreadsheet. If the log is a computer document, it must be backed up at all times, and a current copy should be retained in the case file.

2 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.

REVIEW PROCEDURE

1. The chairperson will prepare a letter to the appealing facility for the Division Director's signature, acknowledging receipt of the appeal.

2. The chairperson will give the clinical images provided by the appealing facility to the radiologist (or radiologists in sequence), who will score them independently and in writing, using the same eight criteria used by the accreditation bodies. Prior to scoring the images, the radiologist(s) will neither be told nor shown the evaluation results from the facility's AB, nor the scores of the other radiologists. Score sheets and clinical images will be returned to the chairperson.

3. The Committee will request in writing, from the facility's AB, a copy of the original score sheets for the initial and appeal reviews of the clinical images submitted with the request for reconsideration.

4. The chairperson will call a meeting of the Committee subsequent to the scoring of the images by the radiologists, to review the request for reconsideration and formulate a recommendation to Division management.

5. The radiologist(s) will present their findings to the Committee, and both their score sheets and AB's score sheets will be made available to all members of the Committee. The Committee will consider the accreditation body's score sheets and summary reports including any comments, the Committee radiologists score sheets and their comments, and the statement of the basis for the facility's disagreement with the AB's decision.

6. The Committee will then formulate a recommendation to affirm or deny the request for reconsideration, and prepare a summary of its finding for review by the Division Director who will make the final decision. Both the recommendation and final decision will be based upon objective criteria, e.g., the FDA radiologist's score sheets, to the extent possible.

7. When a final decision has been made, DMQRP will provide written notification to the facility and the AB over the Divisions Director's signature, and inform each of the available options. If the AB's decision to deny accreditation is upheld, the facility notification will also specify the facility's rights for further review by the Departmental Appeals Board, and how to request such review.