

Attachment J

(Adequate Response Letter to Facility)

[Date]

Name of responsible individual
Name of facility
Address

Section 1.02 Re: MQSA Inspection ID # _____

Dear (Addressee) :

Your facility was inspected on insert date of inspection here by a representative [{from the State of state name and name of state radiation control program under contract to the Food and Drug Administration} or {of the Food and Drug Administration}]. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in 42 U.S.C. 263b(f) and Title 21, Code of Federal Regulations (CFR), Section 900.12.

On insert date of facility response here, you responded by letter to the noncompliances found during the inspection [{for situations where letters are sent} as referenced in the Warning Letter dated date of letter]. Based on your response, your facility has now met the annual MQSA inspection requirement. The corrective action you have implemented will be evaluated during your next inspection.

Sincerely yours,

[name and title of district official]
____ District Office

cc:
State of _____ [radiation control office]
[street address]
[city, state, zip code]

bcc:
(district office)