Paige Veigl, ARRT
Director of Radiology
Nocona General Hospital
100 Park Road
Nocona, Texas 76255
(940) 825-3235
FDA Facility # 171595

Dockets Management Branch
Food & Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852
(301) 827-6860

June 5, 2002

Please allow this letter to serve as our official petition to the FDA requesting that our 1999 MQSA inspection report and warning letter posted on the Internet also be accompanied by our facility's response letter.

Attached you will find the documents in question. As the response letter indicates, many of the items listed as being in violation were in fact already in place in our facility. Rather than observing that we merely failed to comply with the new regulations implemented in April 1999, the inspector merely wanted us to elaborate in a more detailed fashion within our already existing written policies. According to the MQSA/TDH inspector, her software did not allow her any variance to make such notations in the report, but rather left her no option but to issue an official violation.

We feel that to only post the warning letter and not include our response letter presents a misleading picture of our mammography program, of which we are quite proud.

It is my understanding that this warning letter will be available on your web site indefinitely, as appears to be true due to the fact that it has already been over two years since the date of that inspection.

Enclosed please find the petition itself as described in the Code of Federal Regulations, Title 21, Volume 1, citing 21CFR10.30.

Thank you for your consideration.

Sincerely,
Paige Veigl
Director of Radiology

02P-0267

CP 1

6/5/02

Dockets Management Branch
Food & Drug Administration
Department of Health and Human Services
Rooms 1-23
12420 Parklawn Dr.
Rockville, MD 20857

The undersigned submits this petition under 10.30, 10.33 and 10.35 of the Code of Federal Regulations, Title 21, Volume 1 to request the Commissioner of Food and Drugs to amend the Mammography Quality Standards Act 67-FR5446 (Public Law 102-539 & Public Law 102-248, Title 42, Chapter 6A), as pertaining to the Food and Drug Administration Freedom of Information Act (HFI-35).

A. Action Requested

I hereby request that the Mammography Quality Standards Act and the Food and Drug Administration Freedom of Information Act be amended to allow facilities' response letters to FDA Warning Letters to also be posted on the Internet as an attachment to the Warning letter itself.

B. Statement of Grounds

Pertaining to FDA Facility #171595, MQSA Inspection of October 1999, attached you will find relevant documents to the matter in question. As the response letter indicates, many of the items listed as being in violation were in fact already in place in our facility. Rather than observing that we failed to comply with the new relations implemented in April 1999, the inspector merely wanted us to elaborate in a more detailed fashion within our already existing written policies. According the MQSA/TDH inspector, her software did not allow her any variance to make such notations in the report, but rather left her no option but to issue an official violation.

Additionally, as again indicated in the response letter, we disagree with one of the violations regarding time frame between physicist's inspections. Despite the fact that this disagreement was voiced in the response letter, the FDA, to the best of our knowledge, performed no follow-up activity.

We feel that to only post the warning letter and not include our response letter presents a misleading picture of our mammography program, of which we are quite proud. To allow response letters to be posted online as attachments to Warning letters would be of benefit not only to our facility, but many others as well.

C. Certification

The undersigned certifies that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

(Signature)	Paige Veigl
(Name of Petitioner)	Paige Veigl, Director of Radiology Nocona General Hospital
(Mailing Address)	100 Park Road Nocona, Texas 76255
(Telephone Number)	(940) 825-3235

Paige Veigl, ARRT (R) (M)
Director of Radiology
Nocona General Hospital
100 Park Road
Nocona, Texas 76255

Paige Veigl, ARRT ,(R)(M)
Director of Radiology
Nocona General Hospital
100 Park Road
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(940) 825-3235

Mr. Lyle Jaffe
Food & Drug Administration
Fax (301) 827-6870

6/12/02

Dear Mr. Jaffe,

Thank you for your phone call this morning. As per your request, I am attaching an environmental impact statement for inclusion in our recent petition to the FDA.

I am unable to access Title 21, Chapter 1, Part 25, Section 25.24, which I understand would delineate the proper form in which the environmental impact statement should be configured. Therefore, I am hoping that this simple form will suffice. If not, please contact me again at the above listed phone number with further instructions.

Thank you again.

Sincerely,

Paige Veigl
Director of Radiology

In reference to the Code of Federal Regulations, Title 21, Volume 1, Cite 21CFR25.30, the recent petition from Nocona General Hospital to the FDA wishes to include the following statement:

Part 25-Environmental Impact Considerations
Subpart C-Categorical Exclusions
Sec. 25-30 General
(a) Routine administrative and management activities, including ***inspections***, and issuance of field compliance programs, program circulars, or field investigative assignments.

We believe that our petition request will not produce any adverse reaction to the environment. Further, it appears that in accordance with the above cited regulatory statutes, an environmental impact statement will not required, as our petition request deals exclusively with our response letter to a mammography ***inspection.***

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

MQSA Facility Inspection Report
Inspection ID: 1715950005
CFN: 164
Inspection Date: 10/08/1999
Print Date: 10/08/1999

Facility:
Nocona General Hospital
Radiology Department
100 Park Street
Nocona, TX 76255

Facility Accreditation Contact:
William G. Kernek, M.D.

Facility Inspection Contact:
Paige Veigl
Director of Radiology
Phone: (940) 825-3235

Compliance Contact:
William G. Kernek, M.D.
Radiation Safety Officer
Phone: (940) 825-3235

Lead Interpreting Physician: WILLIAM KERNEK

[Equipment Test Results]

Unit Number:	**1**
Room name or number:	MAMMO
X-Ray unit still in use:	YES
Manufacturer:	Lorad Medical Systems Inc.
Medical Physicist's survey date:	10/05/1999
Image receptor type:	Film-Screen

X-Ray Tests:

Calculated dose (phantom) =	214 mRad
Reproducibility coefficient of variation (3 cassettes) =	0.013
Beam quality: HVL (@ 25 kVp) =	0.317 mmAl

Phantom Image 1

Number of fibers =	5
Number of speck groups =	3
Number of masses =	5

[Processor STEP Test:]

Processor number: 0000000001 **Processing Speed = 94 Normal**

Manufacturer: Kodak
Model: X-OMAT M35 or M35A-M

Site: Nocona General Hospital
Room: MAMM0

[Darkroom Fog Test:]

Room: MAMMO **Fog OD = 0**
Site: Nocona General Hospital

[List of Observations]

Noncompliance Level: 1

The system to communicate results is not adequate for site Nocona General Hospital because:
- There is no system in place to provide timely lay summaries
- There is no system in place to communicate serious or highly suggestive cases ASAP

Noncompliance Level: 2

The time period between the previous and current surveys for x-ray unit 1, Lorad Medical Systems Inc., MII exceeds 14 months

The radiologic technologist did not meet the continuing education requirement of having completed a min. of 15 CEUs in mammography in a 36 month period: VIVIAN PAIGE VEIGLE (13.5 CEU's in 36 months)

1 of 6 random reports reviewed did not contain an assessment category for site Nocona General Hospital

Noncompliance Level: 3

The screen-film contact QC is not adequate for site Nocona General Hospital because:
- QC was not done at the required frequency

This Post Inspection report was generated based on incomplete inspection data.

Inspection conducted by: JUDY KOCH (I2014)

Name of State or District Office: Texas

Address: _____

_____

_____

Telephone: _____

Signature of Inspector: Judy K Koch

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
SOUTHWEST REGION

Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982
TELEPHONE: 214-655-8100
FACSIMILE: 214-655-8130

WARNING LETTER

October 15, 1999

Certified Mail
Return Receipt Requested

00-SWR-WL-01/7

William G. Kernek, M.D.
Nocona General Hospital
Radiology Department
100 Park Street
Nocona, TX 76255

RE: Inspection ID - 1715950005

Dear William G. Kernek, M.D.,

We are writing to you because on 10/08/1999, your facility was inspected by a representative of the State of TX, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 and level 2 findings at your facility:

Level 1: The system to communicate results is not adequate for site because:
- There is no system in place to provide timely lay summaries.
- There is no system in place to communicate serious or highly suggestive cases ASAP.

Level 2: The radiologic technologist did not meet the continuing education requirement of having completed a minimum of 15 CEUs in mammography in a 36 month period: VIVIAN PAIGE VEIGLE (13.5 CEU's in 36 months).

Level 2: 1 of 6 random reports reviewed did not contain an assessment category.

Level 2: The time period between the previous and current surveys for x-ray unit 1, Lorad Medical Systems Inc., MII exceeds 14 months.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:
Deborah M. McGee
Food and Drug Administration
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Deborah M. McGee at (214) 655-8100 ext. 138 or fax (214) 655-8130.

Sincerely yours,

Edward R. Esparza
Regional Food and Drug Director

PAIGE VEIGL, ARRT (R)(M)
RADIOLOGY DEPARTMENT HEAD
NOCONA GENERAL HOSPITAL
100 PARK ROAD
NOCONA, TEXAS 76255
(940) 825-3235

DEBORAH M. MCGEE
FOOD AND DRUG ADMINISTRATION
7920 ELMBROOK DRIVE, SUITE 102
DALLAS, TEXAS 75247

OCTOBER 22, 1999

RE: INSPECTION ID- 1715950005

Ms. McGee,

Please review the following response to our recent mammography inspection. Please note that your inspector's software did not allow for variances to be made regarding violations, leaving the inspector no choice but to issue a complete " violation" when merely an elaboration of written procedure was needed.

LEVEL 1:

" -There is no system in place to provide timely lay summaries."
Response: In fact, we do have such a system in place; however, the inspector felt that our written procedure was not specific enough in regards to exactly how the system operates.

This has now been modified; for example, our procedure now states that lay summaries are mailed to patients within 7 days of exam, that category 4 and 5 lay summaries are sent by certified mail within 7 days.

"-There is no system in place to communicate serious or highly suggestive cases ASAP."
Response: Here again, we do in fact have such a system in place, but have expanded upon it in our written procedure manual. Our procedure manual now states that category 4 or 5 lay summaries are sent via certified mail to patients, and that reports are mailed to out of town referring physicians via certified mail. Category 4 or 5 reports are hand-delivered to staff physicians as soon as they are dictated and typed and are signed by physician at that time documenting that they have seen report.

Additionally, if physicians are available at time of interpretation, the radiologist verbally communicates report to them.

LEVEL 2:

"-Insufficient CEU hours for technologist."
Response: This has already been corrected; please note enclosed copy of CEU certificate.

"- 1 of six random reports reviewed did not contain an assessment category."
Response: Radiologist will review all reports before signing to verify that both category assignment and descriptor are listed.

"-The time period between the previous and current surveys for x-ray unit 1, Lorad Medical Systems Inc., MII exceeds 14 months."
Response: As explained to Ms. Koch, our physicist's survey exceeded 14 months due to the fact that we were not performing mammography at the time inspection would have normally been due. Since we were not performing mammography due to manufacturer's backlog of C-arm motion prevention devices, and would be required to perform physicist survey after motion prevention device was installed, the physicist's survey was postponed until that time.

The number of months during which we performed mammography did not exceed 14 months. Our 1998 inspection was in June; our 1999 inspection was in October. We did not perform mammography during May, June or most of July 1999. Therefore, we do not feel that we have violated this requirement.

Please notify me if any further action is required. Thank you.

PAIGE VEIGL, ARRT(R)(M)
RADIOLOGY DEPARTMENT HEAD

CERTIFIED MAIL

7099 3220 0002 3322 9519

FROM:

SERV: CE

TRK#: 709932200002332295

06/11/02
11:40

TO: HFA-305/ RM 1061

FDA

OF PCS: 1

8162024205904

RM: HFA-305/ RM 1061