(NOTIFICATION LETTER)
(TO ASSEMBLERS FOR CORRECTION OR COMPLETION OF SUBMITTED FDA 2579's)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear (Addressee) :

On (date) your firm was inspected/contacted by (investigator) from our (Location) District office. At that time, he (she or they) explained to you (or name & title of agent) your firm's responsibility as an assembler to submit complete and accurate Reports of Assembly of a Diagnostic X-ray System, Form FDA 2579, for each diagnostic x-ray component (system) installed by your firm.

Accurate and complete Reports of Assembly of a Diagnostic X-ray System, Form FDA 2579, are required to be submitted to FDA within 15 days following the completion of assembly pursuant to 2l CFR l020.30 (copy enclosed).

We are requesting that you provide us with a corrected Report of Assembly of a Diagnostic X-ray System, Form FDA 2579, within 30 working days of the receipt of this letter for (FDA 2579 number), which is for equipment assembled at (location). A copy of the report you previously submitted is enclosed.

Along with a corrected FDA 2579, you should notify this office in writing, within 30 working days of receipt of this letter, of the specific steps you have taken to prevent the recurrence of similar violations. Your response should be sent to (name), Compliance Officer, Food and Drug Administration, (street address), (city), (state & zip code). If you have any questions, (name) can be contacted at (telephone #).

Sincerely,

(NOTIFICATION LETTER)
(TO ASSEMBLERS FOR STANDARDS VIOLATIONS FOUND DURING REVIEW OF FDA 2579's OR RECORDS REVIEW AT THE ASSEMBLER)

CERTIFIED MAIL RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear (addressee) :

During an inspection of your firm located in (address), conducted on (date), our Investigator(s) determined that your firm is an assembler of diagnostic x-ray equipment. At that time, he (she or they) specifically discussed your assembly of a general purpose radiographic unit at (location) and explained to you that your installation of a beam limiting device which does not provide variable beam limitation on such a unit was in violation of 21 CFR 1020.31(d)(1).

At that time you agreed to replace the beam limiting device with the type called for by the standard, i.e., variable x-ray field limitation, and submit a corrected Report of Assembly of a Diagnostic X-ray System, Form FDA 2579 to the Food and Drug Administration, the State Radiation Control Program, and the purchaser by (date). Please use the enclosed forms for this purpose. We have enclosed an envelope for your use in returning the original (white) copy directly to this office.

Subsequent to (date agreed upon), a representative of the Food and Drug Administration may investigate your assembly at (location) to verify your correction.

Failure to correct a defect or noncompliance or failure to file a Report of Assembly of a Diagnostic X-ray System, Form FDA 2579, is a violation of the Federal Food, Drug, and Cosmetic Act (the Act), section 538 of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of l968).

Accurate and complete Reports of Assembly of a Diagnostic X-ray System, Form FDA 2579, are required to be submitted to FDA within 15 days following the completion of assembly pursuant to 2l CFR l020.30.

Along with a revised FDA 2579, you should notify this office in writing, within 30 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation(s), including an explanation

of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time within which the corrections will be completed. Your response should be sent to (name), Compliance Officer, Food and Drug Administration, (street address), (city), (state & zip code). If you have any questions, (name) can be contacted at (telephone #).

Sincerely,

Enclosures

(NOTIFICATION LETTER)
(TO ASSEMBLERS -FAILURE TO FILE FDA 2579 REPORTS OF ASSEMBLY)

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear (addressee) :

During an inspection of your firm located in (address), conducted on (date), our Investigator(s) determined that your firm is an assembler of diagnostic x-ray equipment. At that time, he (she or they) explained to you (or to your agent) your responsibility to file a Report of Assembly of a Diagnostic X-ray System, Form FDA 2579, for each certified diagnostic x-ray component (system) you assemble (see attached copy of applicable regulations). We have identified the following facility(s) for which your assembly was not reported to FDA in accordance with 21 CFR 1020.30:

l. (name and location)

2. (name and location)

etc.

Accurate and complete Reports of Assembly of a Diagnostic X-ray System, Form FDA 2579, are required to be submitted to FDA, the appropriate State Radiation Control Program, and the purchaser within 15 days following the completion of assembly pursuant to 2l CFR l020.30.

Failure to file a Report of Assembly of a Diagnostic X-ray System, Form FDA 2579, is a violation of the Federal Food, Drug, and Cosmetic Act (the Act), section 538 of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of l968).

Along with a FDA 2579 for each of the above listed installations, you should notify this office in writing, within 30 working days of receipt of this letter, of the specific steps you have taken to prevent the recurrence of similar violations. Your response should be sent to (name), Compliance Officer, Food and Drug Administration, (street address), (city), (state & zip code).
If you have any questions, (name) can be contacted at (telephone #).

Sincerely yours,

Enclosures

(NOTIFICATION LETTER)
(NOTIFICATION OF DEFECT/NONCOMPLIANCE AS THE RESULT OF FIELD TESTING)

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear _____:

On (date), FDA performed a field test of a certified diagnostic x-ray system which your firm assembled on (date), according to Report of Assembly of a Diagnostic X-ray System, Form FDA 2579, (number). We tested this system to determine its compliance with portions of the Performance Standard for Diagnostic X-ray Equipment (Title 21, Code of Federal Regulations (CFR), sections 1020.30-32). Diagnostic x-ray equipment are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). This field test, Test ID # ____, was performed at:

Name of Facility
Address
City, State, Zip Code
X-ray Control Manufacturer
X-ray Control Model # _____, Serial #
Room Number

WHEN YOU HAVE A CLASS A VIOLATION INSERT THE FOLLOWING:

This letter confirms our telephone notification of (date) to Mr./Ms. (name) of your firm regarding a serious noncompliance with the performance standard and our request that you immediately correct this violation.

(Note: When there is a Class A violation, the letter will be titled "WARNING LETTER" and time frames will be 15 working days instead of 30 working days. There will be appropriate warning letter tracking and follow up. The signature block should be for the District Director for WARNING letters).

Example of a Class A Violation

We measured the entrance exposure rate of the fluoroscopic system to be 27 Roentgens per minute at the point where the center of the useful beam enters the patient. This condition is a serious radiation health hazard and warrants your immediate attention.

21 CFR 1020.32(d)(1) limits the entrance exposure rate to 10 Roentgens per minute for systems with automatic exposure rate control.

WHEN YOU DECLARE A CLASS B VIOLATION, INSERT THE FOLLOWING:

Our analysis of the field test data indicates that the system does not comply with the following items of the performance standard:

Example of a Class B Violation

We measured the illuminance of the light localizer to be 126 Lux at 100 centimeters. 21 CFR 1020.31(d)(2)(ii) requires that the average illuminance be 160 Lux or more at 100 centimeters or the maximum SID, whichever is less.

WHEN YOU DECLARE A DEFECT, INSERT THE FOLLOWING:

While conducting our field test, we determined that the system was defective in the following manner:

Example of a Defect

The x-ray system would initiate x-ray exposure without activation of the exposure button.

WHEN YOU HAVE A CLASS C VIOLATION AND YOU ARE DECLARING CLASS A AND/OR B VIOLATIONS OR A DEFECT, ADD THE FOLLOWING:

In addition to the above problems, we consider the compliance status on the following item(s) to be suspect. Please verify the compliance status of this item (these items) when you correct the previously cited problems.

Example of a Class C Violation

We measured the difference between the x-ray field size and the image receptor size, in the plane of the undertable image receptor to be 3.8 percent of the SID for the across table dimension. The cassette size was 8" x 10" and SID was 40 inches. 21 CFR 1020.31(g)(1)(i) requires that the x-ray field and image receptor length or width difference in the plane of the image receptor be no greater than 3 percent of the SID.

We request that you, as the responsible assembler, immediately investigate the deviation(s) from the performance standard cited above in accordance with 21 CFR 1003 and 1004 as follows:

1. If you determine that the deviations and/or defect(s) is (are) caused by improper assembly or installation, you must correct them and/or the defect(s) at no charge to the user by either repairing the system, replacing it, or refunding the cost.

2. If you determine that the deviations and/or defect(s) is (are) caused by the factory-based manufacturer, you must notify him of the noncompliance(s) and/or defect(s) and send documentation of such notification to this office.

3. If you can establish that the system is compliant, that the alleged deviation or defect does not exist or does not relate to the safety of the product, or is directly attributable to user abuse or lack of maintenance, you may submit such evidence in accordance with 21 CFR 1003.30 within 30 working days of receipt of this letter.

You must report the results of your investigation and follow-up actions to this office within 30 working days of receipt of this letter. Your response should include the date that the corrective action was completed and copies of service records and/or other supportive documents. If you do not respond within 30 working days, the FDA may consider you to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), sections 538(a)(2) and 538(a)(4) of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of l968).

Please note that improper installation, including failure to follow installation instructions which cause the system to be noncompliant with the Performance Standard may cause the system to be adulterated. Under 501(c) of the Act the system would not be of a quality represented by the labeling (including the certification statement).

Failure to promptly correct this violation(s) can result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include seizure and/or injunction and/or the imposition of civil penalties as provided for in section 539 of the Act. Persons violating section 538 of the Act are subject to civil penalties of up to $1,000 per violation and up to a maximum of $300,000.

You should notify this office in writing, within 30 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation(s), including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time within which the corrections will be completed. Your response should be sent to (name), Compliance Officer, Food and Drug Administration, (street address), (City, State & zip code).

If you have any questions, (name) can be contacted at (telephone #).

Sincerely yours,