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

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear (addressee) :

On (date) , a field test was performed on the (name of mfr.) diagnostic x-ray system, control model number _____, located in room ___ of your facility. 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).

Analysis of the data obtained from the field test shows the system fails to comply with the following requirements of the Federal performance standard for diagnostic x-ray systems:

**(Describe Each Item of Noncompliance)**

Our investigation indicates that neither the manufacturer nor the assembler is likely to be responsible for these noncompliances under the regulations. The use of a noncompliant x-ray system may result in unnecessary radiation exposure to the patient or operator. Therefore, we encourage you to arrange for correction of the noncompliance.

**(If Class A Conditions are Involved, Substitute the Following)**

Our investigation indicates that neither the manufacturer nor the assembler is likely to be responsible for the noncompliances under the regulations. These problems may pose a serious health hazard to the patient or operator. We strongly encourage you to discontinue use of the system and arrange for its repair immediately.

You are hereby requested to 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 noncompliance. 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,

Note: Indicate at the bottom of the original letter that the state radiation control program has received a copy of this letter.

# RESPONSIBILITY FOR DEFECTS AND NONCOMPLIANCES

The Diagnostic X-ray Performance Standard specifies certain limits of responsibility for manufacturers and assemblers of x-ray equipment. Assemblers are responsible only for noncompliances that are "attributed solely to improper assembly or installation..." caused by improperly following the instructions provided by the manufacturer. Manufacturers are responsible for noncompliances caused by improper assembly only if adequate instructions were not provided to the assembler (1020.30(c)). The performance standard does not specifically address the limits of responsibility regarding equipment age or user responsibility.

Manufacturers are required by the performance standard to provide purchasers with a schedule of maintenance necessary to keep the x-ray equipment in compliance with the performance standard. The regulations require manufacturers to provide a maintenance schedule because it is unreasonable to expect x-ray equipment to meet certain performance requirements if proper maintenance is not performed. After the first maintenance is performed or after the time it should have been performed, the assembler may no longer be responsible for requirements affected by proper adherence to the maintenance schedule. Some assemblers of older certified equipment will correct the noncompliance and bill the owner rather than attempting to refute responsibility for the noncompliance. This practice frequently upsets the x-ray system owner since he believes this work should have been performed free of charge.

Evidence that would exempt manufacturers/assemblers from responsibility includes:

1. Failure by the user to follow the manufacturer's prescribed maintenance schedule for those items requiring periodic adjustment.

2. Photographs or other documentation (written description) of physical damage to the x-ray system which was due to abuse.

The manufacturer/assembler may be held responsible if the user has failed to follow the maintenance schedule but the facility has documented continued compliance problems with the system beginning in the warranty period.

Items that may require periodic adjustment under a manufacturer's maintenance schedule include:

a) linearity
b) x-ray field/light field alignment
c) PBL sizing
d) illuminance
e) entrance exposure rate
f) fluoroscopic alignment
g) spot film alignment

h) indication of technique factors
i) signal and warning lights

Some items require adjustment on a time basis while others require adjustment at time of a tube reloading or bulb change in the collimator lamp. The individual maintenance schedule must be checked to determine the applicable situation and time interval.

# LIST OF QUALIFIED X-RAY AUDITORS

| | | PHONE NUMBER/FAX NUMBER |
|---|---|---|
| New England District | Michael J. Leal | 508-793-0422 |
| | | 508-793-0456 |
| New York District | Vacant | 516-921-2035 |
| | | 516-921-3025 |
| Baltimore District | Elizabeth Laudig | 410-962-3591x159 |
| | | 410-962-2219 |
| Cincinnati District | Terry R. Bolen* | 513-679-2700x138 |
| | | 513-679-2772 |
| New Jersey District | Tonietta K. Williams | 973-526-6018 |
| Philadelphia District | Rita Larocca | 251-362-0740 |
| | Robert E. Davis | 412-644-3394x13 |
| | | 412-644-5496 |
| Atlanta District | Thomas D. Clarida* | |
| Florida District | Janneth Caycedo* | 561-338-5236x23 |
| | | 407-367-8685 |
| New Orleans District | Karen Smallwood | 615-781-5380x144 |
| | Abraham Maekele | 901-544-0345x20 |
| | | 615-781-5391 |
| New Orleans District | Francis Guidry* | 337-262-6603 |
| | | 337-262-6678 |
| San Juan District | Jorge Martinez* | |
| Chicago District | Dennis E. Swartz* | 313-226-6260x155 |
| Detroit District | Dennis E. Swartz | 313-226-6260x155 |
| | Leonard Pesetsky | 313-226-6260 |
| | | 313-226-3717 |
| Minneapolis District | Thomas W. Garvin | 414-771-7167x12 |
| | | 414-771-7512 |
| Dallas District | John D. Mays | 214-655-8100x125 |
| | Deborah McGee | 214-655-8100x138 |
| | Scotty L. Hargrave | 214-655-8100x139 |
| | Angela T. Moak | 214-655-8100x135 |
| | | 214-655-8130 |
| Kansas City District | Reggie Cope | 913-752-2403 |
| St. Louis District | Reggie Cope* | 913-752-2403 |
| | | 913-752-2413 |
| Denver District | Robert G. Antonsen | 303-236-3025 |
| | | 303-236-3551 |
| Los Angeles District | Ron Alexander | 949-798-7703 |
| San Francisco District | Minh Phan | 949-798-7711 |
| | | 949-798-7794 |
| Seattle District | John Hall | 425-483-4932 |
| | | 425-483-4915 |

*Providing auditor functions for district

WARNING LETTER
(SAMPLE DISTRICT ORDERED ASSEMBLER RECALL LETTER TO
X-RAY ASSEMBLERS)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear (Addressee) :

Field compliance testing of fully certified diagnostic x-ray systems assembled by (firm name) since (date) has shown that (number, i.e.: 43) percent of the x-ray systems tested failed to comply with the Performance Standard for Diagnostic X-ray Systems and Their Major Components (Performance Standard). Diagnostic x-ray equipment are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The Food and Drug Administration (FDA) has issued (number, i.e.: 12) letters to you addressing your firm's noncompliant assemblies, yet you continue to install diagnostic x-ray systems which fail to comply with the Performance Standard. Based on this high rate of noncompliance with the Performance Standard and your inability to provide assurance that x-ray systems which you assemble will comply with the Performance Standard, the FDA has determined that you fail to comply with Title 21, Code of Federal Regulations (21 CFR), section 1020.30(d). The FDA, hereby declares your assemblies since (date) as noncompliant. As noted below you are hereby required to provide user notification and corrective action plan (CAP) for the recall of your assemblies.

You are advised that it is a prohibited act under the Federal Food, Drug, and Cosmetic Act, section 538 of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of l968), to fail to correct electronic products that do not comply with an applicable standard, or that have a defect which relates to the safe use of such products. Additionally, under the Act, it is a prohibited act to adulterate a medical device after receipt in interstate commerce. Your installations are in violation of 21 U.S.C. 351(c) because they fail to have the quality that they purport or are represented to possess in that they do not comply with the Performance Standard for Diagnostic X-ray Systems and Their Major Components, 21 CFR 1020.30.

You must respond in writing within 15 working days of receipt of this letter and provide the number of x-ray assemblies you have completed since (date). In responding, you have the following options:

A. Refutation - You may submit your views and evidence to establish that the alleged noncompliances do not exist.

NOTE: Should your refutation not be accepted, you may request a Regulatory Hearing to state your views in accordance with 21 CFR 1003.11(a)(3).

B. Exemption Request - You may request an exemption from user notification and from the obligation to correct the violative assemblies. Your request must include the grounds upon which you base the exemption request (see 21 CFR 1003.30 and 1003.31).

C. Purchaser Notification and Corrective Action - If you neither refute the noncompliances nor request an exemption, you must; (1) notify purchasers of the violative products as specified in 21 CFR 1003.10(b), and (2) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.

1. Notification Letters - Requirements for preparing notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter to be sent to purchasers should also be sent to this office for review before it is sent to purchasers.

2. Corrective Action Plan - Requirements for preparing a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4. Note: the cost of any service or correction of violations by FDA directive is not to be passed on to the owner or user.

If you require additional time to prepare your refutation, notification, CAP, or evidence to support an exemption request, you must submit within 15 working days of the receipt of this letter a written request to this office which outlines the reasons for any delays and a reasonable target date for submission of your response. If your response is not received within 15 working days, the FDA may consider you to be in violation of section 538(a)(2) of the Act for failure to submit required reports.

Please be advised that if your refutation or exemption request is not accepted by the FDA, you must submit a CAP for all certified diagnostic x-ray systems you have assembled since (date). An acceptable CAP submission must include:

1. An agreement to test all assemblies of certified components installed since (date), to ensure that all assemblies comply fully with the Performance Standard.

2. A statement of the testing to be performed, and a copy of the test method.

3. An agreement to correct any items of noncompliance detected by the above testing, at no cost to the user. If you can document that the noncompliance is directly attributed to user abuse or attributable to servicing by another party, you may submit this evidence in lieu of correcting the noncompliance.

4. A listing of all equipment to be used in the testing and calibration of diagnostic x-ray systems.

5. An agreement that all equipment that will be used in testing and calibration will be within current calibration.

6. The number of certified systems assembled since (date).

7. A timetable for the correction of all affected systems.

8. An agreement to submit copies of all test data for FDA review.

9. A copy of the notification letter to be sent to affected purchasers or a draft of said letter.

10. Provisions to ensure that all future assemblies of certified diagnostic x-ray systems comply with all aspects of the Performance Standard.

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 15 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 15 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,

District Director

Enclosures

(GUIDANCE FOR EVALUATING AN ASSEMBLER RESPONSE TO A DISTRICT ORDERED ASSEMBLER RECALL)

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) affords manufacturers the opportunity to respond to a declaration of defect or noncompliance in one of three ways:

1. Submit evidence to refute the alleged defect or noncompliance.

2. Submit an exemption request.

3. Submit a corrective action plan (CAP).

Generally, noncompliance declarations are prepared in the expectation that the manufacturer will willingly submit a CAP. In reality, some manufacturers appear to have in place a strategy of first attempting to refute the cited noncompliance, then seeking an exemption, and if not successful, submitting a CAP. While such strategy may seem like stonewalling or foot dragging by the manufacturer, this is perfectly legal under the Act.

Evaluating Refutations

If an assembler can demonstrate that more than one individual noncompliant system was not attributable to improper assembly or calibration, he may have a valid refutation for the declaration of noncompliance. The statistics involved in identifying assemblers for coverage in this program are such that a shift of one or two violations greatly affects the decision to pursue a District Ordered Assembler Recall (DOAR). Because of this, we do not include any field tests which are reported to be of manufacturer origin, or are reported as being in dispute.

The refutation must, of course, have a sound basis. The assembler should submit copies of test data and the test method to demonstrate the system fully complied with the Performance Standard at the time of assembly. Unless such evidence is presented, there is no valid basis for the assembler certification of the respective system.

If you would like assistance in evaluating a refutation, please contact the Diagnostic Devices Branch (HFZ-322) at (301) 594-4591.

Exemption Requests

Exemption requests are permitted by FDA regulations, 21 CFR 1003.30. The regulations require the manufacturer to submit his exemption request in writing, within 15 working days of receiving a declaration of defect or noncompliance. In the case where refutation has been denied, the exemption request must be submitted within 15 working days of receiving written denial of the refutation.

Exemption requests may be granted only if the manufacturer submits evidence to demonstrate the failure to comply with the Performance Standard does not create a significant risk of injury, including genetic injury, to any person. Since the capability to evaluate such submission does not exist in most FDA District offices, all exemption requests should be forwarded to the Diagnostic Devices Branch (HFZ-322) for evaluation. The Diagnostic Devices Branch will provide the district with their evaluation and a determination as to the acceptability of the exemption request.

Please note that a manufacturer who has his exemption request denied may contest the denial in a hearing by the Secretary. It is essential therefore, that all exemption requests be submitted to HFZ-322 for proper evaluation.

If an exemption is granted, no further action is required. Since granting an exemption implies no significant hazard to the user, the violative systems cited may not be used for future legal action (civil penalty or injunction) for the same specific violation.

Please note that the Center does not expect to approve many exemption requests, due to the implied health hazard presented by violative field test results.

When the Center's evaluation of the exemption request is received in the district, it will contain either a draft denial letter, or draft approval letter. If the exemption request is denied, the manufacturer is required to submit a CAP within 15 working days of receiving the denial letter. The return receipt should be maintained as evidence of receipt by the manufacturer.

Corrective Action Plan

Corrective action plans (CAPs) must include one of the following options:

1. Repair the noncompliant products.
2. Refund the purchase price of noncompliant product.
3. Replace the noncompliant products with compliant products.

Of the three options, most manufacturers elect to repair the noncompliant components. Since the other two options do not require explanation, only the repair option will be discussed further.

The underlying philosophy of declaring as noncompliant all diagnostic x-ray systems installed over certain time period presupposes that combined FDA/State testing has not tested all systems installed by a particular assembler. This implies that there exist other assemblies (not tested by FDA or the State) of diagnostic x-ray equipment which also fail to comply. The purpose of the noncompliance declaration is to obtain a CAP which will require the testing (and correction) of previously untested system.

An acceptable CAP will contain the following elements:

1. The assembler's proposed method of re-testing all assemblies of certified components installed within specified time period. (CDRH will help the district with the time frame to be cited in the noncompliance declaration.)

2. A statement of the testing to be performed and a copy of the test method.

3. A listing of all equipment to be used in the testing.

4. Documentation that all equipment used in the testing will be properly calibrated.

5. The number of certified systems assembled during the period covered by the noncompliance declaration.

6. A timetable for the correction of all affected systems.

7. Provisions to submit copies of all test data for FDA view.

8. A draft notification letter to affected purchasers or a copy of the letter that was sent.

Assemblers certainly will not submit such detailed information in their initial response to the district. Once a CAP is received, the district should perform a review, and if further guidance is required, contact the Diagnostic Devices Branch (HFZ-322) at (301) 594-4591. Since submission of a CAP represents a commitment to correct the violative products, an establishment inspection should be scheduled to collect the recall information required by the R & R.

During this inspection the investigator may obtain the above commitments regarding the CAP. If an inspection cannot be conducted in a timely manner, a letter to the assembler requesting the required information may be sent in lieu of an establishment inspection.

An establishment inspection at this point may check that all items enumerated above can be provided. The investigator should confirm the following:

- The assembler has the test equipment to perform the required testing.

- Measurement equipment is properly calibrated.

- The adequacy of any test method to be used in compliance testing.

- The assembler has maintained records for tracing assemblies of diagnostic x-ray systems.

- The assembler has adequate personnel to perform the testing.

- The assembler is capable of meeting specified timetables for correction of all systems.

You should consider granting a 30-day grace period for submitting the above information. Assemblers may require this much time to prepare an adequate CAP. If additional time is required, advise the assembler in writing that he must provide the user notification to affected purchasers within 15 working days of receiving this letter or he will be in violation of The Federal Food, Drug, and Cosmetic Act (the Act), section 538(a)(2) of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of l968).

Please note: Exemptions usually only apply to products already introduced into commerce, not to future or ongoing installations. A variance may be requested and granted for a manufacturer to continue the introduction of products into commerce which do not comply with a part of the Performance Standard in accordance with 21 CFR 1010.4.

**(SAMPLE USER NOTIFICATION LETTER FOR DISTRICT ORDERED ASSEMBLER RECALL AND CAPS)**

CERTIFIED MAIL RETURN RECEIPT REQUESTED

DOCTOR'S NAME
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear (Addressee) :

(Firm name i.e.: ABC X-ray Company) has been advised by the Food and Drug Administration (FDA) that diagnostic x-ray systems assembled by ABC X-ray Company since January 1, 1985, may fail to comply with the Performance Standard for Diagnostic X-ray Systems and Their Major Components (Performance Standard). The FDA advised that (number, i.e.: 43) percent of the (number, i.e.: 27) systems they tested failed to comply with the Performance Standard for Diagnostic X-ray Systems and Their Major Components, Title 21, Code of Federal Regulations, Section 1020.30.

We are working with the FDA to develop a plan for testing all diagnostic x-ray systems we have installed since (date, i.e.: June 1, 1985). Any system we test which fails to comply with the Performance Standard will be adjusted and re-calibrated as necessary to correct the noncompliance. This will be done at no cost to you, the purchaser/ user.

Correction of noncompliant diagnostic x-ray systems is a requirement of the Federal Food, Drug, and Cosmetic Act, section 538 of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of l968).

We shall contact you shortly to test your diagnostic x-ray system, and make the necessary adjustments.

Sincerely,

John Doe
ABC X-ray Company

**(SAMPLE CAP APPROVAL LETTER TO X-RAY ASSEMBLERS)**

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear (Addressee) :

On (date) , the FDA sent you a letter advising that between (mo./day/yr.) and (mo./day/yr.) , (number, i.e. 43) percent of your assemblies of certified diagnostic x-ray systems which were tested for compliance with the Performance Standard for Diagnostic X-ray Systems and Their Major Components (Performance Standard) failed to comply. Of the three options outlined in our letter, you elected to submit a corrective action plan (CAP). A partial CAP was submitted in our letter of (mo./day/yr.) .

On (date) , FDA Investigator(s) from this office visited your firm to obtain further information concerning the details of your proposed CAP. On (date) , you submitted additional information which resulted in your CAP submission being complete.

We understand that you intend to conduct your CAP as follows:

1. You will identify all installations of fully certified diagnostic x-ray systems which you assembled between (mo./day/yr.) and (mo./day/yr.) .

2. You will notify all affected purchasers (via certified mail) concerning your CAP.

3. You will retest all assemblies of fully certified diagnostic x-ray systems (which have not previously been tested by FDA) reported in 1. to determine if each system is in full compliance with the Performance Standard.

4. You will correct all items of noncompliance which you encounter during your retests. You will also notify this FDA office of each of the noncompliances you encounter.

5. _____.

6. _____.

We are approving your CAP contingent upon the following:

1. You will submit monthly status reports which include: (1) the number of systems to be corrected, (2) the number of purchaser notification letters sent, (3) the number of letters returned as undeliverable, (4) the number of systems tested, (5) the number of systems which were noncompliant, and (6) the number of noncompliant systems which were corrected, including details of each noncompliance

   Purchaser notification will be made in accordance with all requirements of 21 CFR 1003.21. This office is to be included in the notification process as if it were a purchaser.
2. _____.

You may commence implementation of your CAP upon receipt of this letter.

Please note that the ABC X-ray Company is responsible for the correction of all certified x-ray systems which you have assembled between (mo./day/yr.) and (mo./day/yr.). Should your CAP prove ineffective, we reserve the right to require you to take more stringent measures.

The Food and Drug Administration classifies corrective action plans for diagnostic x-ray products as recalls. We shall shortly notify you of the classification of this recall and the FDA recall number. When making monthly reports or in any future correspondence relating to this CAP, please reference the recall number. Monthly status reports should be sent to:

(Name)
Recall and Emergency Coordinator, HFR-
Food and Drug Administration
(Street address)
(City, State and zip code)

Please be advised that it is FDA policy to report facts surrounding all noncompliances with the Performance Standard in the FDA Enforcement Report. This publication is available to the public.

If you have any questions concerning this matter, please contact (name) at (address), (telephone number).

Sincerely yours,

District Director