This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer 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. This guidance will be updated in the next revision to include the standard elements of GGP's.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date OCT 13 1993

From Acting Chief, Diagnostic Devices Team, DOE I, OC
CDRH (HFZ-300)

Subject PBL and Other Changes to the Performance Standard; Small Target Angle X-Ray Tubes; Maximum EER and Large Image Intensifiers

To Diagnostic X-Ray Compliance Testing Personnel and Selected Interested Federal and State Personnel

Positive-Beam Limitation (PBL) Requirements

Background

On May 3, 1993, the FDA published a final rule in the Federal Register to amend the Performance Standard for Diagnostic X-Ray Systems and Their Major Components (Performance Standard). This change allows assemblers to install manual beam-limiting devices (BLD) in stationary, general-purpose radiographic x-ray (GP) systems. The requirement that GP systems be equipped with PBL has been eliminated. For those systems equipped with PBL, this proposal still contains the requirements that apply to PBL. This change was effective June 2, 1993. In our previous memorandum, dated April 15, 1993, we provided interim guidance to field surveyors on the testing of certain radiographic systems.

Policy

This memorandum supersedes the April 15 memorandum. All of the requirements for PBL still apply for assembled PBL systems. The following represents testing guidance for GP systems:

1. Routine testing of GP systems equipped with an x-ray table should continue, using the Abovetable X-Ray Source Radiographic Systems (AR) test procedure, including the testing of the PBL. Any PBL problems, such as failure of the PBL system to operate properly, will be valid noncompliances. These violations include, but are not limited to, failure to prevent exposure until proper collimation has been accomplished, PBL size comparison, and failure to prevent exposures at source-image receptor distances (SID) at which the PBL is not designed to operate. If a GP system is equipped with a manual BLD, then the answer to item 53 on the field test record would be "C" as before. This question will not generate a noncompliance. The system testing should continue as

before, with an "*" placed in data item 54. Skip the rest of section 8 and all of section 9 of the instructions in the AR test procedure.

2. For those GP systems without a table which are equipped with a manual BLD, the Vertical Cassette Radiographic Systems (VC) test procedure should be used. Failure to install PBL on these systems will not be cited as a violation.

3. If a GP system without a table is equipped with PBL, then the Chiropractic Supplement to the AR procedure (ARB) would apply.

4. When a system is tested involving a PBL collimator, you should determine whether the PBL mode of operation actually functions. If not, then you should determine whether the PBL functioned at the time of installation. We allow the owner, under 21 CFR 1020.30(q)(2), to modify a system under the following conditions:

> The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may modify the system, provided the modification does not result in the failure of the system or component to comply with the applicable requirements of this section or of § 1020.31, § 1020.32, or § 1020.33. The owner who causes such modification need not submit the reports required by Subpart B of Part 1002 of this chapter, provided the owner records the date and the details of the modification, and provided the modification of the x-ray system does not result in a failure to comply with § 1020.31, § 1020.32, or § 1020.33.

If the user decided to disable his own PBL system for manual operation, this would not constitute a noncompliance. If the user has modified the system in such a manner that the PBL mode is no longer operational, but all other aspects of the system appear compliant, record a "C" at item 53 on the field test record and add the following statement in the remarks section of the field test record:

> PBL mode disabled by user on [insert date of modification here].

We do not expect that many users will have their PBL systems disabled, since they can usually use the system in the override condition without a modification of the

hardware. If, however, the user states that the PBL mode has not functioned since the date of installation, then this would still be a valid noncompliance. Record an "A" or "B" for the type of PBL at item 53 on the field test record and a "N" at item 54. This will generate a noncompliance for fully certified systems.

We have also attached a copy of a letter to manufacturers and assemblers, providing additional guidance as to how the new amendments will be enforced with respect to PBL.

Change in Performance Standard (CFR) References

As you should already be aware, the Performance Standard for Diagnostic X-Ray Systems and Their Major Components (Performance Standard) was amended on May 3, 1993 (*Federal Register*, Volume 58, Number 83, page 26386) to change various requirements, the most notable are those pertaining to positive beam limitation (PBL) and reassembly of components. With these changes in the Performance Standard, the references used have changed in certain circumstances. To use the correct reference for the Performance Standard, please refer to the *Federal Register* publication. This is especially important for FDA district offices when issuing diagnostic x-ray field test noncompliance letters.

Reaching Maximum Entrance Exposure Rate (EER)

With the advent of larger field image intensifiers, there may be difficulties making sure that the maximum EER is measured when the automatic exposure rate control (AERC) mode is tested. Since AERC modes operate by monitoring the light level from the output phosphor of the image intensifier, the beam must be completely blocked by lead to drive the system to the maximum value of EER. If the lead sheet included with the test kit is used (1/8 x 10 x 10"), it may not be large enough to completely cover a large field image intensifier. When the x-ray field extends beyond the edge of the lead sheet and produces light on the output phosphor, the system will not reach the maximum EER (see Figure 1 - the table and test stand are not shown in this diagram). To avoid this problem, the lead sheet may be moved closer to the x-ray tube and away from the image intensifier. However, it might be easier to observe the following instructions:

1. For undertable-source fluoroscopic systems (UF), the x-ray field may be adjusted so that it is just larger than the MDH chamber. The position of the chamber should be determined by viewing the monitor without the lead sheet in the beam. Reduce the size of the field

and position the chamber in the center. Insert the lead before the final EER measurement.

2. For C-arm fluoroscopic systems (CF), the beam-defining assembly should be in slot 1 of the test stand. With the lead sheet out of the beam, reduce the size of the x-ray field to slightly larger than the aperture (see Figure 2). Only the aperture, with the MDH chamber in the center, will be visible on the monitor (see Figure 3). Insert the lead sheet before the final EER measurement.

Small Target Angle X-Ray Tubes

Recently, we received a copy of a diagnostic x-ray field test noncompliance letter where a General Electric assembler was notified that a system did not comply with the PBL sizing requirements in 21 CFR 1020.31(g)(1)(i). The testing was conducted with a 14" by 17" film cassette at a source-image receptor distance (SID) of 36". After the letter was sent to General Electric, they stated that the system tested uses an 11° target angle x-ray tube insert. They responded by indicating that the test was conducted at an SID where full film coverage was limited to certain film sizes. They provided a copy of a page from the user's information, which states these limits as follows:

Target Angle (40" SID)	Field Coverage
11°	14" x 14"
12.5°	16" x 16"
15°	17" x 17"

While the PBL sizing requirements state that such a system must align the x-ray field with the image receptor at this SID, we believe that use of these film sizes under the above conditions does not constitute a public health concern. We believe that the possibility of this type of undersizing becoming a problem in a real clinical situation in unlikely (see attached diagram for graphical representation of this scenario).

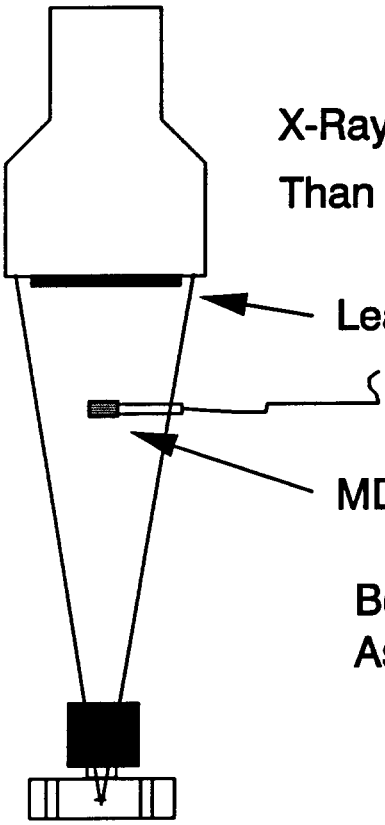
If you have any questions, please contact Michael P. Divine of the Diagnostic Devices Branch at 301-594-4591.

Thomas M. Jakub

Entrance Exposure Rate

Large Field Image Intensifiers

Figure 1



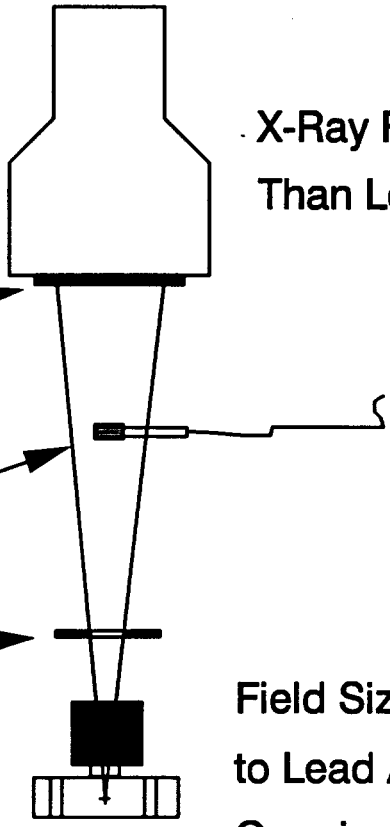
X-Ray Field Larger
Than Lead Sheet

Lead Sheet

MDH Chamber

Beam Defining
Assembly

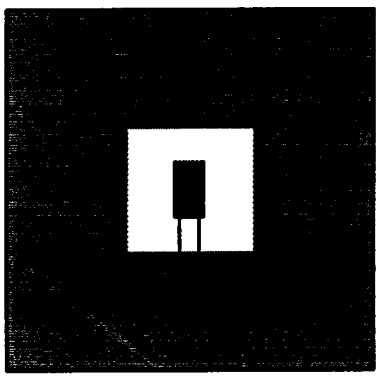
Figure 2



X-Ray Field Smaller
Than Lead Sheet

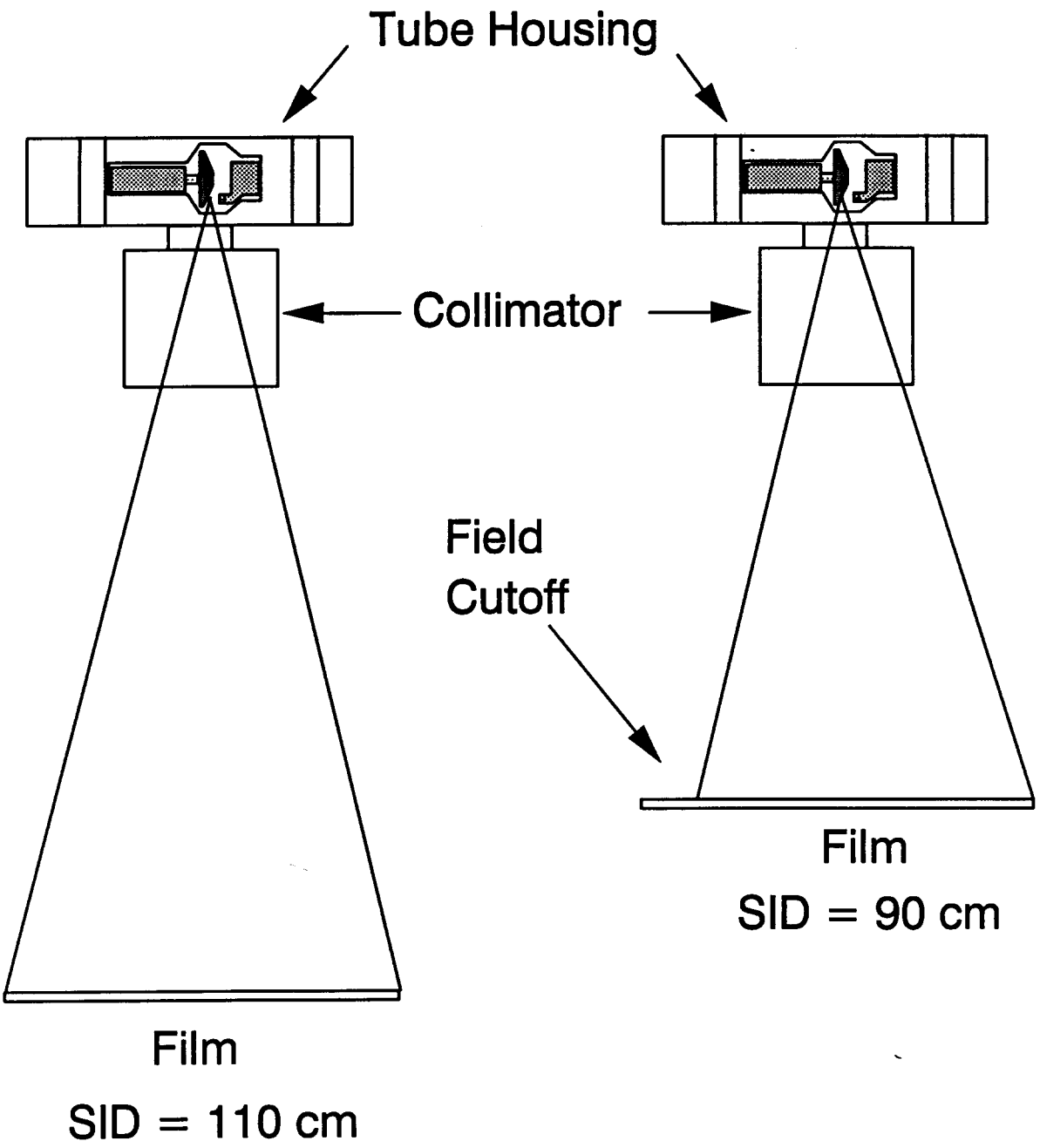
Field Size Reduced
to Lead Aperture
Opening

Figure 3



Entire chamber should
be visible on monitor
when viewed without lead

Small Target Angle
X-Ray Tubes



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

OCT 13 1993

TO: Manufacturers and Assemblers of Diagnostic X-Ray Systems

SUBJECT: Enforcement Policy for Positive-Beam Limitation (PBL) Requirements in 21 CFR 1020.31(g)

On May 3, 1993, the FDA published a final rule in the Federal Register to amend the Performance Standard for Diagnostic X-Ray Systems and Their Major Components (Performance Standard). This change allows assemblers to install manual beam-limiting devices (BLD) in stationary, general-purpose radiographic x-ray (GP) systems. The requirement that GP systems must be equipped with PBL was eliminated. For those systems equipped with PBL, this rule still contains the requirements that apply to PBL. This change was effective June 2, 1993.

Recently, we have received questions from several different sources requesting clarification as to the requirements that apply to GP systems. We hope this policy letter helps clarify our position with respect to the new amendments. We have chosen a question and answer format to address some of the questions we have already received and others that we anticipate might be asked.

If you have any questions on this policy, please contact Michael P. Divine of the X-Ray Products Branch at 301-~~427-1165~~. 594 4591

for Ronald M. Johnson
Director
Division of Compliance
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Enclosure