ERRATA FOR THE

ROUTINE COMPLIANCE TEST PROCEDURES

FOR DIAGNOSTIC X-RAY SYSTEMS

Diagnostic Devices Branch
Division of Radiological Health
Office of Compliance
Center for Devices and Radiological Health

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PLEASE USE THIS DOCUMENT AS ADDITIONAL RESOURCE INFORMATION.

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ERRATA FOR FIELD TEST PROCEDURES

I. INSTRUCTIONS AND CHANGES TO THE TEST PROCEDURES MANUAL

A. GENERAL INFORMATION (PERTAINS TO MORE THAN ONE PROCEDURE)

1. Number of Each Form Attached (GI Form)

When completing this section of the "General Information" test record, several investigators are using an asterisk "*" to indicate which forms are not included in the test packet. When completing this section, enter the number of each of the specific test records (the AR test procedure results in 3 pages of data but only one field record) attached to the general information test record. All other data items in this section should remain blank.

2. Specific Test Identification

On the General Information Field Test Record in the block entitled "Number of , Each Form Attached," several blanks are provided for specific identification of those test procedures used (AR, UF, etc.) and the number of forms attached. Several of the blanks are not identified with specific test procedures. The following is a guide to identify the blanks with specific procedures:

block 21 = CF
block 24 = HN
block 27 = CT
block 29 = VC

3. Use of the Asterisk

As long as the purpose of the survey and the unique letter designator are recorded correctly on test forms, asterisks in the data fields should be limited to the following situations:

a. When a data item is not applicable and this answer is not provided for by a "X", enter an asterisk in the first available (left justified) column for that data item, and give a very brief explanation in the REMARKS. For ex-ample, if an undertable x-ray source, stationary, fluoroscopic x-ray system does not have a spot-film device, an asterisk must be entered at data item 55 describing the type of spot-film exposure timer.

b. If necessary instrumentation (e.g., photometer, 100 cm^2 chamber, and so forth) either malfunctions or is not available, enter an asterisk in the first available column for the affected data item and give an explanation in the REMARKS. This should be an infrequent occurrence.

c. If the abovetable x-ray source Radiographic system does not provide SID indication beyond the PBL operation range, enter an asterisk in data item 9 on the "Abovetable X-Ray Source Radiographic Systems Field Test Record".

d. Assembler Report Nos.: A report of assembly cannot be verified.

e. Installation Date: A report of assembly relating to the installation of the entire system cannot be verified.

f. System Certification Status : The certification status of one or more certifiable components cannot be ascertained by visual inspection or FD 2579 verification.

g. Control Unique ID: The x-ray control model number is not available in the component listing.

h. Unique ID: On any form (e.g., GI, AR, UF), the component model number cannot be ascertained, or the component model number does not correspond to one on the component listing.

i. Component Certification Information: On any test form (e.g. UF, AR, DR), the certification status of the component in question cannot be ascertained.

j. Indicated Source-Image Distance (item 9, AR form): Means to indicate SID are not present or the indication is in the-PBL range, i.e., 36 to 50 inches, but not at the SID for the initial tests in the Abovetable Radiographic test procedure.

k. PBL X-ray Field/UTIR Size Comparison (items 57 and 65 AR Form): The PBL system operates only at a single SID.

l. Spot Film Reproducibility (item 55 UF Form): The unit does not contain a spot film device.

We would appreciate your input if you encounter other situations where the use of the asterisk is warranted on a routine basis.

4. Conversion of English Sized Cassettes to Metric and Vice Versa

In several instances during compliance testing, the investigator is required to record selected image receptor sizes. These sizes should relate to nominal film sizes and not the actual physical dimensions of the cassette. This data will be audited to be sure it corresponds to common film sizes. The expected nominal film sizes are as follows:

Metric				English			
	40	x	40		14	x	17
	35	x	43		14	x	14
	35	x	35		11	x	14
	30	x	40		10	x	12
	30	x	35		9.5	x	9.5
	24	x	30		8	x	10
	18	x	43		7	x	17
	18	x	24		6.5	x	8.5
	25	x	30		5	x	7

Enter the nominal film size as provided on the cassette, either metric or English, i.e., do not convert these sizes from one measurement system to the other. We would appreciate your input if you encounter any nominal film sizes on a routine basis not identified in the listing above.

5. Spot Film Reproducibility at Less Than 100 Milliseconds

We have received numerous reports that field investigators are unable to acquire exposure times in excess of 100 milliseconds during the spot film reproducibility test of the "Undertable X-Ray Source Fluoroscopic" test procedure.

In an effort to evaluate the extent of this problem, the following procedure must be used for this test until further notice:

Attempt to complete the spot film reproducibility test as prescribed by the field test manual. Should this method fail ....

a. Reduce the kVp (70 kVp or less, if necessary).

b. If available, increase the specified density on the density control of the phototimer.

c. Make another exposure and check the elapsed exposure time. If the exposure time exceeds 100 milliseconds, correct data item 57 (kVp) and complete the test.

d. If after reducing the kVp and increasing the density control, the exposure time is still less than 100 milliseconds, then perform the following tests:

Correct data item 57 (kVp). Complete the test by recording the observed exposure and changing data item 55 (type of spot film exposure timer) to an "S".

NOTE: Under NO circumstances should attenuation material of greater than 0.15 inches of copper or any lead be placed in the beam for this test as this action will only drive the x-ray machine harder and increase the probability of tube overheating failure.

The "S" at data item 55 for this particular instance will be an alert that a problem exists with the reproducibility test for that specific x-ray control model. Thus, a critical audit failure will not occur on that test record for the spot film reproducibility test.

6. Beam Quality Testing for "Automatic Only" Fluoroscopic Systems

The survey procedure for the beam quality test of fluoroscopic x-ray systems requires the test to be performed with the fluoroscopic system in the "manual" mode of operation. Some fluoroscopic systems, however, have only an automatic mode (terms synonymous with automatic are "Automatic Exposure Rate Control, AERC, Automatic Brightness Control, ABC, and Automatic Gain Control, AGC"), and thus, must be tested in this mode instead. However, trying to follow the survey procedural steps explicitly as given In the manual can sometimes introduce an error in the results because of the nature of the operation of automatic fluoroscopic systems. When an exposure is made with such systems, radiation output is usually erratic during the first few seconds as the system is trying to compensate itself to the material being imaged. Once the system does complete the compensation, the radiation output stabilizes and remains constant for the remainder of the exposure provided the imaged material is not changed or the image intensifier carriage moved.

The problem with the survey procedure in surveying such systems for beam quality is that it allows this erratic portion of the radiation output to be integrated with the stabilized portion, and depending on how long the investigator keeps the exposure switch depressed, this erratic portion can represent a larger or smaller percentage of the overall exposure, thus a random variation error is introduced. This, of course, is unacceptable because the beam quality test depends on a change in radiation output due only to penetration through various thicknesses of aluminum with all other factors held constant. Thus, this random error compromises the accuracy of the test and furthermore is unpredictable such that it cannot be mathematically factored into the action levels.

Therefore, when performing the beam quality test of "automatic only" fluoroscopic systems, switch the MDH function selector to the HOLD position prior to making the exposure. Then, depress the fluoroscopic exposure switch and after a few seconds (sufficient time to allow for the system to stabilize) switch the function selector to MEASURE and continue the exposure. Record the exposure and exposure time as before.

7. High Level Control for Manual and Automatic Fluoroscopic Systems

Sometimes, investigators testing fluoroscopic entrance exposure rates are unsure if the system has both a manual and automatic (dual mode system) exposure rate option. This occurs more often with Picker systems since the mode type is not always immediately obvious. This was discussed in a previous memorandum (June 22, 1983). As a reminder, the majority of Picker fluoroscopy systems are dual mode. However, since each type system (dual mode and single mode) has different allowable entrance exposure rate limits the investigator should make every effort to determine which option the system has.

Additionally, a High Level Control (HLC), which is a user option, can be activated when a greater exposure rate is needed. The HLC is also an optional feature, so not all fluoroscopy systems will have it. Some dual mode systems will have the HLC in one mode but not in the other. Thus when testing such systems, the HLC must be tested for each mode that is available.

If the HLC is available, it is usually activated by a "double detent" footswitch. To operate this footswitch properly, minimum pressure activates the normal low level exposure rate, while increased pressure activates the HLC. If the investigator is not cognizant of the two positions, he may inadvertently activate the HLC with excessive pressure. Since high entrance exposure rates occur as a result of activating the HLC (when the HLC is activated, the entrance exposure rate is unlimited) the unsuspecting investigator may site a noncompliance because he is assuming the exposure rates are being made in the normal low level exposure rate mode.

Below is a summary of "Fluoroscopic Entrance Exposure Rate Limits" from 21 CFR 1020.32(d) for manual only, automatic only, and dual mode systems.

Manual Only Systems

Without a High-Level Control (HLC) ..... 5 R/min
With a High-Level Control (HLC) ..... 5 R/min

Automatic Only Systems

Without a High-Level Control (HLC) ..... 10 R/min
With a High-Level Control (HLC) ..... 5 R/min*

Dual (both manual and automatic modes) Systems

Manual Mode Selected:

Without a High-Level Control (HLC)..... 10 R/min
With a High-Level Control (HLC) ..... 5 R/min*

Automatic Mode Selected:

Without a High-Level Control (HLC)..... 10 R/min.
With a High-Level Control (HLC) ..... 5 R/min*

* Except when the HLC is activated, then the exposure rate is unlimited.

8. Pushbutton Time Selector

The Center has received a report of a possible timer problem in units which offer pushbutton timer selection. With these type selectors, it has been noted that switching to a new exposure time does not always automatically result in the cancellation of the first value. Occasionally, a button will stick allowing two buttons to be in the select position simultaneously. This seems to occur only when the buttons are on different rows.

If such a situation is encountered, determine the actual exposure time and report this occurrence to the X-Ray Products Branch. Include in your report the equipment manufacturer, model number, serial number, and Test ID number. A determination would also be made concerning the relationship of the measured exposure time to the selected time.

9. Manual Line Compensation Adjustment

Many systems, radiographic and fluoroscopic, have manual line compensation adjustment which must be correct for the units to be compliant. 'Both before and during testing, be sure that these are properly set. Misadjustment can cause false noncompliances in several areas.

B. ABOVETABLE RADIOGRAPHIC (AR)

1. Test Procedure for Chiropractic or Similar Systems

The X-Ray Products Branch has become aware of problems in the field regarding which procedure to use when surveying CHIROPRACTIC or other similar systems. The problem stems from the fact that the surveyor might not know whether the system requires PBL or

not. Our March 26, 1984, multiple-address letter (Attachment 4) to manufacturers and assemblers, explains under what circumstance PBL would have to be provided. Many Notice of Adverse Findings letters have been sent to assemblers because the systems that they have installed required PBL, but it was not provided. Since this is a significant problem, it is important that the correct field test procedure be used so that our computer data base reflects the actual noncompliance rate for such systems

It is important when testing a system that has or requires PBL that the "Abovetable Radiographic (AR)" procedure be used with the CHIROPRACTIC supplement. The "Vertically Mounted Cassette Holder Radiographic Systems (VC) procedure should be used for systems that neither require nor have PBL.

For those systems which do not have an x-ray table and are limited in use to chest or spinal radiography, the attached flowchart (see Attachment 1) should help you to make a decision on which procedure to use.

2. False SID Accuracy Noncompliances (section 7.0)

On some x-ray tables, the system is designed so that the operator can lower the table to permit patients to get on and off. On these systems the SID indicator is "calibrated' to properly indicate the SID when the table is in the fully raised position, and when the table is lowered the SID indication does not change. At first this appears to be a noncompliance except that most systems of this type lockout the exposure when the table is in the lowered position and do not re-lease the lockout until the table is once again raised to the full up position. If you encounter such a situation, it is important that the system be checked to make sure an exposure is not possible in this lowered configuration before assuming a noncompliant condition exists.

3. SID Indication for Various Stationary General Purpose X-Ray Systems (section 7.0)

a. Section 1020.31(e)1)(i) reads in part "... and to indicate the SID to within 2 percent...". The source-image receptor distance (SID) intended in this paragraph is the distance from the source to the image receptor that is positioned in a fixed holder such as the Bucky tray in the table, or a permanently mounted wall cassette holder. It is not the intention of the regulations, nor is it a Center interpretation, that SID means the distance from the source to the image receptor no matter where it is positioned, e.g., on the tabletop. Thus, a BLD tape measure is not required provided there are other means to indicate the SID.

b. For systems with a fixed or several discrete SID(s), a label or other marking must be provided on the system itself to numerically indicate each SID (see last sentence of third paragraph of the letter included as Attachment 2). If the system provides continuous operation through a range of SIDs, then a graduated scale for numerical indication of all SIDs within the range must be provided.

c. Systems designed to provide PBL operation at only specific SIDs and that provide appropriate numerical indication of these SIDs, are not required to provide numerical indication of other SIDs which can only be used with PBL in the override mode. It should be noted that the override mode of operation is restricted to situations in which the PBL system has failed. It is not intended that the override mode be used

for any radiographic technique employing the permanently mounted Bucky or cassette holder if the PBL system is operational.

4. Focal Spot Location and SID Indication Measurement (section 7.0)

Some tube housing assemblies are manufactured with a tapered endcap (see diagram in Attachment 3) that is significantly smaller than the diameter of the housing, such as the Eimac tube housing assembly models B100, B150, and B160. Since we instruct surveyors to estimate the focal spot location based on a point approximately 1/4 of the distance up the endcap, this would overestimate the SID for housings with tapered endcaps, such as the Eimac models. If you encounter such a housing, please use the following guidance during your testing:

a. If the tube housing has an indication of the location of the focal spot, use this indication during your measurement (provided it looks reasonable, i.e. has not been shifted out of position during repair, maintenance, etc.). You might want to ask the operator if they know that the mark you have found is the actual location of the focal spot.

b. If no indication is present on the tube housing for the focal spot, estimate a point that is 1/4 of the distance from the bottom of the diameter of the widest portion of the tube housing, ignoring the endcap altogether. This is easily accomplished from the center of the tube rather than at the end (see figures 1 and 2 of Attachment 3).

Also attached to this figure is a list of various tube housing assemblies with locations of their respective focal spots (labeled Figure 2 of Attachment 3) that was supplied by one of the manufacturers. You may use this' for guidance when surveying equipment.

5. PBL Sizing (step 8.1)

A problem which may affect the testing of PBL systems has been reported to the Center. PBL systems which operate in both horizontal and vertical mode may react in an unpredictable manner when cassettes are in both holders at the same time. Before testing for PBL sizing, verify that only one cassette is in the system.

6. Testing PBL When Only One Cassette Size is Available (step 8.2)

When completing the PBL sizing test on the AR form, for those rare occasions when only one cassette size is available, you may complete the entire test by rotating the cassette 90 degrees and reinserting for the second film size (e.g. 10" x 12" and 12" x 10'). The objective of the test, as much as possible is to ascertain the alignment and sizing capabilities of the collimator system.

7. PBL Functional Questions (step 8-4)

In some cases, questions 53, 54, and 69 are being incorrectly completed. In the past, CDRH has not interpreted a 'C' response to question 53 on the test record as a noncompliance. If a noncompliance was determined by the surveyor because a system that is required to have PBL did not, then a "No" response to item 54 was entered. As mentioned above, the AR test record is only to be used with a system where PBL is required. A negative response to

question 54 should mean that the PBL is not functioning at all - If this is the case, enter "N" at 54 and skip items 68, 69 and 70 and include an explanation on a "continuation sheet." If additional comment is necessary, provide the information on a "continuation sheet." If the system is functioning, even if it is not functioning correctly, then enter a "Y" at 54 and complete items 68, 69, and 70. If additional comment is necessary, provide the information on a "continuation sheet."

In the future, if a system is found to meet the requirements mentioned in the attached multiple-address letter for PBL, dated March 26, 1984 (see Attachment 4), but the PBL is absent, then a "C" should still be entered in answer to question 53. There has been a revision to the computer which will now show a noncompliance whenever a "C" is entered at item 53 and conditions require a PBL collimator.

If PBL does not function to the UTIR, it is marked inoperable even If it works to the wall stand. Insert "NO" at item 54.

Regarding question 69, be aware that some PBL systems have unique operating characteristics which may make the systems appear to be noncompliant with respect to automatic return to PBL. Two such conditions are: 1) Automatic return to PBL will not occur unless the cassette is completely removed from the tray and then replaced, and 2) Automatic return to PBL will not occur until an exposure is made. If testing for this function by sliding the tray partially out and reinserting it does not" provide automatic return to PBL, try satisfying the conditions in 1) and 2) (i.e., remove the cassette completely and reinserting it, and/or making an exposure and then changing the cassette).

8. PBL Amendment (sections 8.0 & 9.0)

The PBL, Amendments to 1020.31(e)(2), which became effective December 1, 1983, contain three specific compliance topics which should be clearly understood by field testing personnel. In the first case, note should be made that the lower limit of SID at which PBL is required to operate is given as 90 centimeters. This limit applies to PBL systems on which SID indication is given in centimeters. For PBL systems on which SID indication is given in inches, the lower limit of the PBL range will continue to be 36 inches. Test the system in the measurement units used by the manufacturer. In the second case, it is now possible to make a series of exposures with a reduced field size, without the need to cone back down to the field size upon each change of image receptor, as long as the SID and the image receptor size are not changed. The third case requires that, if provided, override of automatic field adjustment for radiographic, spot-film radiographic, or fluoroscopic beam limiting devices must be performed with an override switch bearing the legend "for X-Ray Field Limitation System Failure."

9. PBL Operation and Reducing the X-Ray Field Size (step 9.2)

When 1020.31(e)(2)(iii) was amended (now 1020.31(e)(5)), it was not intended to make any existing PBL design noncompliant with the automatic sizing requirements. Both the previous rule and the new paragraph 1020-31(e)(5) require automatic adjustment of an operator-initiated undersized x-ray field to the size of the Image receptor when the image receptor size is changed. The new paragraph 1020.31(e)(5) now permits PBL systems which allow the operator to reduce the x-ray field size and retain the reduced field size during series of exposures to-the same size image receptors when the SID remains unchanged. It was not,

however, intended that all PBL systems must be designed to provide the series option Just described, but rather that the PBL systems be available which would meet either the automatic sizing requirements of the previous rule, or the series option of the new paragraph 1020-31(e)(5).

Since you will now be encountering both options, it is important that the test for PBL operation be appropriate. Therefore, Step 9.2 of the Abovetable X-Ray source Radiographic Systems test procedure (page AR-8 of the survey manual) should read as follows:

> 9.2 With the x-ray field size adjusted to a size smaller than the image receptor, pull out the cassette tray, change the cassette to one of a different size (or rotate the same one 90º), and then reinsert it. Does the beam-limiting device return to positive beam limitation? Record at item 69.

10. Illuminance (step 11.1)

Change distance of "106 cm" to "108 cm."

C. UNDERTABLE FLUOROSCOPIC (UF)

I. The Surveyor Protection Test (step 4.5)

This test has caused some concern and confusion to investigators on several occasions. This note is provided to help clarify the issue and to initiate a change in the procedure.

First, a problem exists between steps 4.6 and 4.7 since both steps require a response to be entered in data item 6 of the field test record. In step 4.6 a "Yes" answer (example: the system is hazardous) is not a noncompliance with the Federal Performance Standard; but, in step 4.7 a "Yes" answer is a serious noncompliance. Furthermore, it is possible that one answer could be "No" and the other "Yes," creating an impossible situation since only one data item box is available. This causes havoc with our data base since we do not know if the "Yes" answer is a noncompliance or not.

Second, even though the Surveyor Protection Test (steps 4.5 and 4-6) does not evaluate a performance aspect of the system subject to the provisions of 1020.32, it was originally made a part of the compliance test procedure in an attempt to protect the investigator from working with a machine that was emitting excessive radiation. This is still of concern, but it is not always necessary to stop testing the system even if the scattered radiation is excessive, provided that the investigator knows the condition exists. Since in most instances the excessive scatter radiation occurs only when the imaging assembly is raised to its maximum height and the lead drapes no longer reach down to the tabletop leaving an unshielded gap, the system is probably nonhazardous in its usual use configuration. It seems reasonable for the investigator to continue the test, but he/she should be aware that the hazardous situation exists and should take steps to minimize his/her exposure. This can be done be wearing a lead apron, standing behind a portable screen (if available) when making exposures, standing as far away as possible from the table during the survey, and making as few exposures as necessary to obtain the data.

As a result of these problems in the test procedure, step 4.6 is changed to

the following:

4.6 If the GM meter indication is greater than 15 for the model 251 B instrument or 50 for the TMB-1 instrument, make follow-up measurements with the 100-cm^2 ion chamber on the MDH 1015. If these follow-up measurements exceed 50 mR/hr, take precautions such as wearing a lead apron, standing behind a lead screen, standing away from the table, etc. while making exposures. Tell the user what you found including the exposure rate and the conditions under which it was obtained. Explain that this is not a noncompliance with the standard but that the measurement is taken so that the surveyor can take adequate protective measures during the survey depending on the measured scattered radiation. Tell the user you are giving him this information in case he/she was not aware of the scatter radiation levels under the conditions measured so that he/she can consider it as part of their total radiation safety program. Enter in the REMARKS, the observed exposure rate and the conditions under which the excessive radiation rate was obtained, then continue to the next test (step 4-7).

Note that step 4.6 no longer requires a response to be entered in data item 6. Also, step 4.7 remains unchanged which means that if it is answered "yes" (e.g., system is hazardous because the source is not ganged to the image receptor) then testing is to be stopped.

2. Bucky Slot Shield (step 4.8)

The fluoroscopic test procedure requires in the "Surveyor Protection Test that a scan of the primary barrier, leaded curtains, and table scatter shields be performed prior to initiating the test procedure. On some fluoro systems, the functioning of the bucky slot scatter shield is dependent on the positioning of the bucky tray to one end of the table away from the fluoroscopic source. Special attention should be given to surveying the bucky slot area on these types of systems. Follow the instruction in step 4.8 of the fluoroscopic test procedure and scan the area with the GM meter. If excessive exposure is detected in the area of the bucky slot, follow the procedures in step 4.9 using the 100-cm^2 ion chamber. If the followup measurements exceed 50 mR/hr, record at item 9 that the system is hazardous and list the measured values in the comments section.

3. SSD and Entrance Exposure Rate Measurements (section 7-0)

On undertable source fluoroscopic systems with elevating tabletops, the table must be in its lowest position when performing the field test. The intent of the test is to determine the minimum SSD and the maximum entrance exposure rate. Thus, the tabletop should be as near the source as possible. Many surveyors raise the tabletop in order to place the top of the test stand in contact with the image intensifier. This contact is of secondary importance and the calculations can compensate for it. Remember to lower the table to its lowest position.

4. High-Level Control (HLC) Exposure Rate in the Remarks Section (step 7.4)

Steps 7.4 and 8.3 of the UF test procedure instruct the surveyor to determine the entrance exposure rate when the HLC is activated. This value is then recorded in the Remarks section of the field test record. The Center has begun focusing its attention on HLC

exposure rates and thus will be concentrating on the FTR Remarks entries. To collect as precise data as possible, make the following changes to the UF procedure:

7.4 If means to activate a high-level control are provided, make an exposure. Note the exposure rate. While making an exposure, activate the high-level control. Vary the kVp and mA settings to maximize the electrometer reading. Record the high-level exposure rate in the Remarks.

8.3 If means to activate a high-level control are provided, make an exposure. Note the exposure rate. While making an exposure, activate the high-level control. Vary the kVp and mA settings to maximize the electrometer reading. Record the high-level exposure rate in the Remarks.

5. Primary Protective Barrier Transmission (PPBT) (step 9.7)

When testing for PPBT on undertable fluoroscopic systems, the investigator should be cognizant of the fact that the requirement in the performance standard 1020.32(a)(1) applies only to radiation that is transmitted through the barrier and not any radiation that may be scattered around the edges of the barrier. Furthermore, the PPB is defined (1020-30(b)(26)) as "...material placed in the useful beam...". This means that only the image intensifier is the PPB since this is the component that intercepts the useful beam. Even If the system has a spot-film device, the PPB is still only the image intensifier (unless, of course the useful beam is slightly larger than the image intensifier in which case that portion of the spot-film device struck by the useful beam would also be part of the PPB). This has not caused too many problems in the past, even when the investigator scans the entire surface of the spot-film device, since most spot-film device manufacturers shield the device with lead to stop transmission of radiation through any part of it. Without the lead however, it is possible for scattered radiation to actually penetrate through the thinner material of the device. This is not PPB transmission radiation.

The CGR-MC, IBIS 11 fluoroscopic, system is a system which does not have complete lead shielding in the spot-film device but only around the periphery of the image intensifier (see Attachment 5). Scattered radiation actually does penetrate through the spot-film device beyond the edges of the partial lead shield. Since this radiation is not, by definition, primary barrier transmission, the investigator is advised to place lead sheets on top of the spot-film device as shown in the figure to block the scattered radiation when performing the PPB - transmission test on these systems (see also section UF 9.7 of the Routine Compliance Testing Manual).

6. The "Three Penny Technique" for Undertable Source Fluoroscopic Systems. An Alternate Method of Determining Minimum Source to Skin Distance (section 10.0).

Because Image Intensifiers (II) vary in size, sometimes it may be difficult to determine the minimum source-skin distance (SSD) using the focal spot assembly since the maximum visual field is still too small to image both brass strips.

As an alternate test method the -Three Penny Technique" is recommended. Any three coins of equal size (pennies, nickels, dimes, or quarters) can be used in the following manner:

1. Retract any fluoroscopic grids and compression cones on the imaging assembly.

2. Place a 0.10 inch copper sheet on the table beneath the imaging assembly.

3. Lay one coin on top of the copper sheet.

4. Tape two coins (touching edge to edge) to the face of the imaging assembly (Figure I of Attachment 6).

5. While imaging the coins, position the II assembly so that the image of the coin on the table is superimposed on the image of the two coins taped to the image intensifier, then raise or lower the II until the diameter of the single coin image is the same as the diameter of the two coins image as shown in Figure 2 (see Attachment 6). Lock the II in the vertical position.

6. Measure to the nearest millimeter the distance from the coin on the table to the coins taped on the face of the image assembly. This distance is equal to the minimum SSD.

7. Using the measured distance from Step 6 above calculate from the following equation the value for the outside separation of the focal spot strip image and enter this calculated value at data Item 42 of the UF field test record:

$$\text{Outside Separation} = 6.35 \times \frac{(35.95 + \text{Measured Distance})}{(1.61 + \text{Measured Distance})} \text{ centimeters}$$

NOTE: Although this seems to be going backwards in the calculation procedure, this calculation is necessary since data Item 42 is used throughout the computer calculations for a number of test parameters and without it, the calculations would leave many "compliance undetermined" results.

This test method follows the theory of similar triangles. The equation can be found on page 27 of the 'Resource Manual for Compliance Test Parameters of Diagnostic X-Ray Systems.'

7. Spot Film Undersizing

Section 1020.31(g)(1) of the standard precludes the spot film size from automatically opening up unless there is a positive operator action. If the fluoroscopic x-ray field size is smaller than the selected portion of the spot-film image receptor (film), then the beam-limiting device must not open to cover the entire selected portion of the film unless the operator initiates the positive action. However, if the fluoroscopic field is larger than the selected portion, then the beam-limiting device must automatically cone down.

Field testing of UF systems has uncovered problems due to leaving the fluoro in the magnification mode while doing the spot film test. Since the magnification field may be smaller than the selected four-on-one spot film, the system must maintain the smaller. fluoro field when spot-film mode is selected. This results in false spot-film misalignment noncompliances due to undersizing.

D. DENTAL RADIOGRAPHIC (DR)

1. Results Record (page DR-12)

Change result 4 to read:

4. Average Exposure, E_2 = _____ mR

2. Test Record (page DR-14)

Change heading over second diagram from "Reproducibility" to "Field Size and Shape".

E. C-ARM FLUOROSCOPIC (CF)

1. C-Arm Test Procedure for Tilted X-Ray Fields (section 3-0)

The Fluoroscopic X-Ray Field/Image Receptor Alignment Test (section 4.0, page CF-5) of the Compliance Survey Manual presents a problem when used on certain C-arm systems due to the orientation of the x-ray field on the image intensifier. On most C-arm systems with a square x-ray field contained within a round image intensifier, the edges of the x-ray field are either parallel or perpendicular to the plane of the C-arm, support assembly and produces an image of the slide assembly as shown in figure A (see Attachment 7), when the collimator blades are visible on the monitor. If the collimator blades are opened up fully, as in figure B, the grid image extends from edge to edge and the size of the grid image on the monitor and the direct-print paper are the same. However, on the CGR Kalliscop mobile C-arm system, the blades appear on the monitor as in figure C. This is because the collimator blades are angled 45' to the plane of the C-arm assembly. This situation can result in a false noncompliance because the grid lines of the grid image on the direct-print paper and the television monitor are connecting the corners of the image (as shown in figure D), whereas the regulations require the measurement of the visible area along the length and width dimensions of the x-ray field (not the diagonals, as in figure D) which pass through the center of the visible area of the image receptor.

To correct this problem, the following modified test procedure should be used if such a system is being tested:

Test Setup

a. Same except C-arm moved to vertical plane.

b. Mount the test stand on the tripod according to the procedure in Appendix B of the test procedures manual except that the long dimension of the test stand is parallel to the adjustable shaft on the tripod (see Figure 1, Appendix B). Check the test stand with bubble level to assure that the top is parallel to the floor.

c. No change.

d. 9" Image intensifier (II):

Figure E (see Attachment 7) shows the position of the test stand with respect to the diagnostic source assembly and the II. Position the test stand according to the test procedure in the manual (step 3.0 (d)), except that it should be rotated 45' to the plane of the C-arm assembly (see figure F). This can be accomplished by lining up the corners in the square hole in the bottom of the test stand with the C-arm assembly.

6" Image Intensifier (II):

Place several sheets of paper on the input surface of the II to protect the input surface. Place the test stand (no tripod) directly on the if and align it with the C-arm assembly as for the 9" II. If the input surface of the II is rounded or there is another reason that the test stand cannot rest on the II, use the tripod and position the test stand as closely to the input surface as possible.

CAUTION: When the test stand is properly positioned on the tripod and the other equipment is placed in/or on the test stand (copper, slide assembly, etc.) the weight of the additional equipment may cause the test stand to sag or tilt. It may be necessary to place slips of paper between the lower half of the stand and the tripod support to act as shims.

2. Minimum SSD Test for Mobile C-Arm Fluoroscopes (section 3.0)

Section 1020.31(f) requires a means to limit the minimum SSD to no less than 30 centimeters for mobile fluoroscopic systems except for special surgical applications where it can be 20 centimeters. Manufacturers of mobile C-arm fluoroscopes typically provide for the shorter SSD by including a removable spacer such that the 30 cm requirement is met when the spacer is attached to the beam-limiting device.

Our test procedure is designed to test the C-arm system with the spacer attached, and any SSD found to be less than 30 cm is declared noncompliant. This has caused some problems since sometimes the spacer has been removed and cannot be found. Thus, when the test is done without the spacer, the minimum SSD is usually much less than 30 cm. Although it is not a good situation when the spacer is missing, we cannot penalize the manufacturer by declaring the noncompliance since the system is designed to operate in accordance with the standard.

Therefore, if you cannot locate the spacer and have to test for minimum SSD without it, use the letter "x" as the unique letter designator at the end of the field test serial number (e.g., CF12345X). This unique letter designator will instruct the computer to compare the minimum SSD calculation to the 20 centimeter requirement of the standard instead of the 30 centimeter requirement. In addition, you should inform the user of the requirements of the Standard, and inform the State regulatory agency of the undesirable practice of using the system without the spacer.

3. Surveyor Protection Test (section 3-0)

In section C. 1. of this errata there are comments regarding high amounts of scattered radiation being a hazard to the operator, but not a noncompliance. These comments also apply to the CFA procedure, except that for fixed SID C-arm, fluoroscopic systems, the diagnostic source assembly is permanently aimed at the image intensifier so that there are

no current definitions for item 6 on the field test record for hazardous systems. As a result of these problems in the test procedure, step 3.4 is changed to the following:

3 .4 If the GM meter indication is greater than 15 for the Model 251B Survey Meter or 150 for the TBM-1 Ratemeter, make follow-up measurements with the 100-cm ionization chamber. If these follow-up measurements exceed 50 mR/hr, take precautions such as wearing a lead apron, standing behind a lead screen, standing away from the system and the primary x-ray beam, etc. while making exposures. Tell the user what you found including the exposure rate and the conditions under which it was obtained. Explain that this is not a noncompliance with the Standard but that the measurement is taken so that the surveyor can take adequate protective measures during the survey depending on the scattered radiation. Tell the user you are giving him this information in case he/she was not aware of the scatter radiation levels under the conditions measured so that he/she can consider it as part of their total radiation safety program. Enter in the REMARKS, the observed exposure rate and the conditions under which the excessive radiation rate was obtained, then continue to the next test (step 3-5).

4. Fluoroscopic X-Ray Field/Image Receptor Alignment (step 4.11)

Change sentence from "Read to the nearest 0.1 inch" to "Measure to the nearest millimeter."

5. High-Level Control (HLC) Exposure Rate in the Remarks Section

Steps 7.4 and 8.3 of the Undertable Fluoroscopic (UF) test procedure and steps 7.7 and 8.10 of the Abovetable Fluoroscopic (AF) test procedure, instruct the surveyor to determine the entrance exposure rate when the HLC is activated. This value is then recorded in the Remarks section of the field test record. The Center has begun focusing its attention on HLC exposure rates and thus will be concentrating on the FTR Remarks entries. To collect as precise data as possible, make the following changes to the CF procedure:

7.4 If means to activate a high-level control are provided, make an exposure. Note the exposure rate. While making an exposure, activate the high-level control. Is a high-level control present in the manual mode? Record at item 36. Vary the kVp and mA settings to maximize the electrometer reading. Record the high-level exposure rate in the Remarks.

8.1 (last paragraph on page CF-9)

If means to activate a high-level control are provided, make an exposure. Note the exposure rate. While making an exposure, activate the high-level control. Is a high-level control present in the manual mode? Record at item 41. Vary the kVp and mA settings to maximize the electrometer reading. Record the high-level exposure rate in the Remarks.

6. Beam Quality Test (step 10-3)

When performing the beam quality test for C-arm fluoroscopes, if the exposure rate is too low to trigger the MDH 1015 x-ray monitor, and the mA and/or kVp cannot be increased to obtain a sufficient exposure rate, omit steps 10.3 and 10.5 (page CF-11 of the procedures manual) and use the following procedures:

Five exposures are required for the beam quality determination. Set the x-ray monitor mode selector to EXPOSURE. Using a stopwatch to time the exposures, make an exposure for approximately 15 seconds. Record the exposure and stopwatch readings at data items 46 and 47.

Reset the x-ray monitor after the exposure or any situation where an exposure has been terminated because of procedural problems, e.g., start of stopwatch and exposure do not coincide. Continue the procedure as described in steps 10.4 and 10.6.

7. Image Receptor Size (step 11-2)

Note that on many C-arm fluoroscopic systems the selected image receptor dimensions may not be of the same size as the film cassette. The user literature should be checked to ensure that the proper dimensions are recorded on the survey form.

8. X-Ray Field/Spot-Film Size Comparison Test (section 13.0)

Section 1020-31(g)(2) sets forth the allowable misalignment between the K-ray field and the selected portion of the image receptor for spot film devices. For mobile C-arm fluoroscopes with fixed SIDS and only a one-on-one spot-film format, a problem arises in meeting the letter of this requirement because the x-ray field usually cannot be made larger than the image intensifier whereas the spot-film cassette is often quite a bit larger than the image intensifier. When this happens, the calculated results show a negative misalignment exceeding the allowable tolerance of the Standard. We consider this, however, to be an acceptable design format because the selected spot-film format is deemed to be the maximum obtainable x-ray field for the one-on-one condition. Therefore, when testing the spot-film alignment of such systems, if you are making manual calculations and ?L is negative (x-ray field length is less than spot-film image receptor), record 0.00 at Result 63 (page CF-28 of the procedures manual), and similarly, if ?W is negative, record 0.00 at Result 64.

The CDRH computer has been reprogrammed, accordingly, so that negative misalignments will be considered 0.00.

9. Reproducibility (step 12-1)

Change step 12.1 (a) to read:

If both “manual" and "automatic" controls are provided for exposure termination, select the mode of operation most commonly used and complete steps 12.2 and 12.12.

10. C-Arm Fluoroscopy Calculations

A reevaluation of the test stand geometry measurements for the C-arm fluoroscopic survey procedure necessitated an adjustment to one of the dimensions. Please correct the following equations of the C-arm fluoroscopic calculation techniques in part X of the calculation procedures:

A. Source-Image Distance (page CF-17)

1. Change from 227.97 to 224.79

B. Page CF-17, Paragraph A.2.

Change the equation for fluoroscopic SID to:

Fluoroscopic SID = Y + 40.2 + A

All numbers which read 35.9 should be changed to 35.4, in the following sections:

C. Fluoroscopic X-Ray Field/Image Receptor Alignment (page CF-17)

2. Calculate the source-image receptor distance

E. Beam Limitation Requirements (page CF-19)

2. Calculate the width (W')

3. Calculate the length (L')

F. Primary Protective Barrier/X-Ray Field Size Comparison (page CF-20)

2. For X_W^1 and X_L^1

G. Minimum Fluoroscopic Field Size (page CF-20)

I. For L" and W"

See test stand drawing Figure 4 (page CF-24), change the distance between the letter designators S1 and S from 35.9 to 35.4.

Page CF-17, Paragraph C.2

Change the equation for SID' to:

SID' = Y + 35.4 - Item 28 cm.

The current equations for calculating the EER of C-arm fluoroscopic systems (paragraphs D.2 and D.3, page CF-18 of the Routine Compliance Testing Manual) are correct when testing 6" image intensifier machines but incorrect when testing 9" image intensifier machines. Therefore, the equations should be changed to the following in order to be correct for all C-arm systems:

D.2

$$\text{EER} = \text{Item 35} \frac{(\text{Result 1} + 8.9\text{cm})^2}{(\text{Result 1} + 10.2\text{cm})^2}$$

D.3

EER = Item 40 $\frac{(\text{Result 1} + 8.9\text{cm})^2}{(\text{Result 1} + 10.2\text{cm})^2}$

Page CF-19, paragraph E.2.

Change the equation for W' to:

$$W' = W \times \frac{(\text{Result 2})}{(\text{Result 1} + 35.4 - \text{Item 28})}$$

Page CF-20, Paragraph E-3

Change the equation for L' to:

$$L' = L \times \frac{(\text{Result 2})}{(\text{Result 1} + 35.4 - \text{Item 28})}$$

Page CF-20, Paragraph F.2.

Change the equation for X_W^1 to:

$$X_W^1 = \frac{(Y + 40.2)}{(Y + 35.4 - \text{Item 28})} \times X_w$$

Change the equation for X_L^1 to:

$$X_L^1 = \frac{(Y + 40.2)}{(Y + 35.4 - \text{Item 28})} \times X_L$$

Pages CF-20 and CF-21, paragraph G.I.

Change the equation for L" to:

$$L'' = \text{Item 29} \times \frac{(\text{Result 2})}{(\text{Result 1} + 35.4 - \text{Item 28})}$$

$$W'' = \text{Item 30} \times \frac{(\text{Result 2})}{(\text{Result 1} + 35.4 - \text{Item 28})}$$

F. MAM0GRAPHIC SYSTEMS (MA)

I. Beam Quality (section 3.0 test setup)

Change note to read "Note: If a BENT test stand is available, complete steps a), b), and c)."

2. X-Ray Field/Image Receptor Alignment (section 5-0)

Currently, the field test procedure for mammography does not require the surveyor to record the image receptor size that is used or other information pertaining to the test for alignment

of the image receptor with the x-ray field. This makes it difficult to trace the problem of misalignment from field test data to the manufacturer's initial reports and equipment. Therefore, it is requested that the following information be placed in the remarks section on the field test record. An analysis of this information will be conducted to determine if a change should be made in the test procedure:

1. Each cone should be labeled with the image receptor size used at the appropriate SID. Please record this information on the test record.

2. When the SID is determined and recorded in item 3 of the test record, please indicate if this was a measured SID (using the metal tape) from the approximate location of the focal spot on the x-ray tube to the plane of the image receptor or an indicated SID on the unit.

3. Please indicate the size of the image receptor used for the test in whatever units it is designed (inches or centimeters).

If the cone on the unit is designed for an image receptor that is larger than the available cassette size, then switch to the appropriate smaller cone. If the operator uses a cone size that is larger than the image receptor, then this constitutes misuse of the system. If the cone(s) are not labeled properly as to image receptor or SID, then measure the dimensions of the cone on the unit (length and opening at the film side) and record this information in the remarks section before completing the alignment test.

3. Field Test Record (page MA-14)

Change heading in beam quality block from "over 50 kV" to "≥ 50 kV".

G. ABOVETABLE FLUOROSCOPIC (AF)

I. High-Level Control (HLC Exposure Rate in the Remarks Section

Steps 7.7 and 8.10 of the AF test procedure instruct the surveyor to determine the entrance exposure rate when the HLC is activated. This value is then recorded in the Remarks section of the field test record. The Center has begun focusing its attention on HLC exposure rates and thus will be concentrating on the FTR Remarks entries. To collect as precise data as possible, make the following changes to each of the fluoroscopic procedures:

7.7 If means to activate a high-level control are provided, make an exposure. Note the exposure rate. While making an exposure, activate the high-level control. Vary the kVp and mA settings to maximize the electrometer reading. Record the high-level exposure rate in the Remarks.

8.10 If means to activate a high-level control are provided, make an exposure. Note the exposure rate. While making an exposure, activate the high-level control. Vary the kVp and mA settings to maximize the electrometer reading. Record the high-level exposure rate in the Remarks.

2. Results Record (page AF-12)

Change result 19 to read "(2/1 + 4/3)"

II - INSTRUCTIONS AND CHANGES FOR THE TI-59 CALCULATOR INSTRUCTIONS

A. TI-59 PROGRAMMING INSTRUCTIONS

If you are unfamiliar with programming the TI 59, follow these steps:

1. Press the LRN key (the display should show 000 00).

2. Key in the functions or values shown in the third column of any test procedures program listing (note that each time you key in a value, the program step number will increase by one).

3. Press the LRN key (this takes the calculator out of the program mode).

4. Press the GTO key and the number 0.

5. Press the CLR key.

6. Press the number 1, then the 2nd key, then the R/S key (write). Load side one of the card into the calculator.

7. Repeat step (6) for side two of the card except press the number 2, then 2nd and R/S.

This program should now be on your program card. Be sure to check the card to ensure that the program is correct as listed in the test procedures program.

B. UF PROCEDURE CHANGES

For those Investigators using the Texas instruments TI 59 calculator, a change in program steps for the beam quality calculation of undertable source fluoroscopic and spot-film systems (UF) is necessary. This change in the curve-fitting equation will result in a slightly more accurate HVL value when testing at lower kVp's. Use of the TI 59 program as is, yields an HVL value slightly higher (varies in the hundredths place) than it should be, thus in some cases of "borderline" systems, the system may appear just compliant when it is actually noncompliant.

To revise your TI program, change steps 285 through 311 to the following:

285	53	<
286	93	.
287	05	5
288	23	LNX
289	54	>
290	69	OP
291	15	15
292	95	=
293	91	R/S
294	65	X
295	01	1

296	93	.
297	02	2
298	04	4
299	07	7
300	75	-
301	93	.
302	04	4
303	03	3
304	02	2
305	95	=
306	91	R/S
307	00	0
308	00	0
309	00	0
310	00	0
311	00	0

C. CF PROCEDURE CHANGES

Users of the TI 59 programmable calculator should review the attached program listing for the CF procedure to assure that the version they are currently using is the most current. Change the instruction set for paragraphs B, "Fluoroscopic X-Ray Field/Image Receptor Alignment" and D, "Beam Limitation Requirements" on pages 63 and 64 respectively of the TI-59 calculation manual to the following:

D Fluoroscopic X-Ray Field/
Image Receptor Alignment

1. Refer to data items 8 thru 15, and item 28.	Item 8	STO 10	Item 8
	Item 9	STO 11	Item 9
	Item 10	STO 12	Item 10
	Item 11	STO 13	Item 11
	Item 12	STO 14	Item 12
	Item 13	STO 15	Item 13
	Item 14	STO 16	Item 14
	Item 15	STO 17	Item 15
	Item 28	STO 18	Item 28

2. Obtain percent misalignment in two directions and sum of misalignment.		B	%(1/4 + 3/2)
		R/S	%(2/1 + 4/3)
		R/S	%Total .

Second Set of Data

(No change for second set of data)

E Beam Limiting Requirements

I. Refer to items 8 thru 11, and item 28.	Item 8	STO 10	Item 8
	Item 9	STO 11	Item 9

		Item 10	STO12	Item 10
		Item 11	STO13	Item 11
		Item 28	STO14	Item 28
2.	Circular area.		D	
3.	Rectangular area.		D then R/S	

Also, on page 64 of the TI-59 program for C-arm calculations manual, delete storage of "Item 28" into location 11 (paragraphs C-1 and C.3) as this data item is no longer used in the calculations.

III. SPECIFIC MODEL INSTRUCTIONS BY MANUFACTURER

A. PRIMARY PROTECTIVE BARRIER TRANSMISSION ON CGR IBIS TABLE

See section I. C. 5. of this errata.

B. EER PROBLEMS ON CONTINENTAL X-RAY SYSTEMS (CONX)

Analysis of field test results for Continental X-Ray Corporation (CONX) shows what appears to be abnormally high noncompliance problems for the entrance exposure rate (EER) requirement. The problem in fact seems to be the result of surveyor confusion. All CONX controls in question have mA stations "A-E." Positions "A, B, and C provide increasing mA until the 5 R/min limit is approached at "C." Stations "D" and "E" provide HLC by limiting the mA to the value selected by station "C" until the two position footswitch is activated enabling the higher exposure rates.

If you encounter a suspected EER problem, verify that it occurs at "A, B, or C" and that the problem is not related to a malfunctioning or inaudible HLC buzzer.

C. GENERAL ELECTRIC MEDICAL SYSTEMS FLUOROSCOPIC HIGH LEVEL CONTROL (GECO)

Recent review of routine field tests indicated three fluoroscopic units contained an optional high level control. Further investigation revealed that none of these systems contained the optional high level control. However, because Items No. 30 and 35 were recorded as 'Y' (in the UF procedure), the computer calculated results for the tabletop entrance exposure rates between 5 and 10 R/min showed the systems to be noncompliant, which were false indicators.

1. GECO does not provide the optional high level control system as such. Thus, on all GECO systems, Items 30 and 35 should be recorded as 'N'.

2. The GECO systems which provide for video tape recording (TV Record) are not considered by CDRH as the optional high level control mechanism. Thus, Items 30 and 35 on the field test record does not apply to the video tape recording systems.

3. The above comments also apply to Items 28 and 33 on the AF test record and Items 36 and 41 on the CF test record.

D. GENERAL ELECTRIC (GECO) IMAGE INTENSIFIERS

GECO recently submitted updated information to us regarding image intensifier/face plate distances. Therefore, on page CF-25 draw a line through number 2 (GECO Polarix II, 6.15 cm) and replace it with the GECO information below. This should be cut out and taped to the blank portion of page CF-25.

Image Intensifier		Distance "A" in Centimeters
GECO FLUORICON L-300 VASCULAR & C-ARMS (On digital systems remove user-insertable grid.)		
12"	Model 46-233653G1 Housing	
	Thomson 46-216631P1 Insert	3.3
	Varian 46-233654P1 Insert	1.9
9"	Model 46-18408OG1 Housing	
	Thomson 46-174740P1 Insert	2.3
	Varian 46-174055P1 Insert	1.5
GECO 6" POLARIX II/II-E		
Model 46-914507GOI Housing		
	Thomson 46-216076P1 Insert	3.9
	Varian 46-223900P1 Insert	3.5

E. MODEL PBL II AND PBL III MACHLETT (MALA) COLLIMATORS

The PBL override switch is not located on the collimator, but on the logic box near the cable entrance. It may be on the side or bottom of the upright logic box, but is accessible to the user. The logic box is usually located in the x-ray room on the wall as close to the x-ray source as practical.

Before testing for PBL operation, try to locate the override switch, and ensure that it is in the PBL mode. If it is in the override mode, switch it back to the PBL mode and continue with the PBL test.

F. SID MEASUREMENTS FOR PHILIPS MEDICAL SYSTEMS (PHMS)

The Philips system uses a measuring tape for the SID indication. To use this tape the surveyor should pull out the cassette tray and position the source assembly over the tray, then bring the tape into contact with the upper surface of the cassette and record the measurement. The field test data has shown some SID's which appear closer to what the source-table distance is rather than the source-image receptor distance. Please be careful and make these measurements correctly.

G. PICKER (PICO) COLLIMATIC II COLLIMATORS

The Center has received several noncompliant results for actual versus indicated field size for the Collimatic II. These noncompliances seem to be due to a lack of understanding of how to adjust the field size.

The following discussion should clarify the proper setting of the field size indicators and eliminate any possible confusion. The two field size dials are each divided into four scales. These scales are assigned an SID value at which the indicated field size will be correct. The confusion arises over the 36" SID mark. For this purpose, a horizontal line is provided which traverses all four scales. An accurate field size adjustment would then align the selected field size of the appropriate SID scale with the horizontal line. A substantial error can result if

this method is not adhered to. To better understand the above description, see attachment 8 for a drawing of both a correct and incorrect adjustment of a 12" field at 36" SID.

H. EXPOSURE RATE CONTROL FOR PICKER SYSTEMS (PICO)

Some questions have arisen concerning whether or not a fluoroscopic system has a manual or an automatic exposure rate control or both. In particular some Picker models may be confusing when manual adjustment knobs are provided for kVp and mA adjustments. Those systems containing the Universal Fluoroscopic Rate Control (UFRC) are considered automatic exposure rate controls. These systems adjust exposure rate by varying the kVp downward from the maximum selected.

Just as you check a unit to see if there is a high-level control, you should also check to see if there is an automatic exposure rate control by making test exposures with and without the 1/8 inch lead sheet. See procedure steps 7.1 and 8.1 of the UF test procedure for this check.

I. SELECTION OF FILM FORMAT FOR SIEMENS (SIEC)

Siemens has informed the CDRH that some of our inspectors are not using proper film formats when testing some of their above table R-F systems (e.g., Siregraph, Siregraph E, Siregraph 2, Siregraph Multiplanimat, Optiplanimat, Siremat, and Infantoskop). Some of these systems come in metric (centimeter) versions or English (inch) versions and identify only those film formats available for the system. PBL sizing should be checked only for prescribed film formats, however, un-prescribed film formats may be checked for exposure lock out (use data item 70 to answer whether x-ray production is prevented at SIDs not intended) and add a comment to indicate that there is no lock out for an unspecified film size. An attempted exposure may be necessary to ensure lock-out failure.

J. SIEMENS (SIEC) PBL OPERATION

Under some conditions of installation, Siemens PBL systems may not size until the exposure switch is lifted from its cradle. This condition may occur when more than one radiographic tube is controlled from the same console. When the exposure switch is removed from the cradle the other tubes are locked out and power is supplied to the chosen collimator. The sizing then occurs and manual under-sizing may be performed.

K. SIEMENS (SIEC) SIREMOBIL 2U MOBILE C-ARM X-RAY SYSTEM COLLIMATION

The beam-limiting device used on the Siremobil 2U system is not a stepless adjustment collimator. Section 1020.32(b)(2)(iv) of the Standard permits use of beam limitation which adjusts the field size in steps if the system has a fixed SID and a maximum visible area of 300 cm^2 or less. In the case of the Siremobil 2U, available field sizes are 5 cm diameter (to comply with the minimum field size requirement), 7" in diameter (in agreement with the size of the input phosphor of the image intensifier), and 10" x 12" (which is possible only when a film cassette is inserted).

There is a pair of adjustment levers on the operator's console which controls a primary diaphragm for use in fluoroscopy of extremities. This semitransparent slot diaphragm is installed in the tube head. Turning the slot diaphragm permits adjustment of the field to the

direction in which the object (extremity) extends, and the second lever then serves to adjust the field width to the object of interest. The semi-transparent slot diaphragm has a rather low absorption coefficient. Because of the radiation passing through this moderately-absorbing diaphragm, instruments (injection needles, etc.) applied at angles to the beam are visible outside the object under fluoroscopic observation, so that they can be guided into the object. Due to this confinement of the x-ray beam, image contrast is improved.

The use of second beam-limiting means within the field provided by the fluoroscopic BLD (7" diameter) is an additional radiation safety feature of the Siremobil 2U. The semi-transparent slot diaphragm reduces the amount of low-energy radiation exposure to the soft tissue, while permitting visualization of medical instruments. If a "normal' slot diaphragm were used, the instruments would become visible only after they had reached the object inside the collimated field.

The beam limitation provided by the Siremobil 2U meets all requirements of the Federal Standard. Means are indeed provided for reduction of the field to a minimum size of 5x5 centimeters of less. Stepless adjustment is not required because the maximum visible area is less than 300 square centimeters. An x-ray field larger than the input phosphor of the image intensifier is possible only when a 10" x 12" film cassette is inserted into the spot-film device.

L. SIEMENS (SIEC) MOBILE UNITS

The minimum SSD test for mobile x-ray systems (step 4.7, page MR-2 of the test manual) requires the diagnostic source assembly to be lowered until the BLD comes into firm contact with the spacer assembly, or until any spacer bars on the BLD are even with the top of the spacer assembly.

The Siemens model 69-67-830-XO22E mobile system has a BLD with collimator knobs that extend down from the face of the BLD. It is possible to orient the test stand such that the face of the BLD comes into contact with the spacer assembly resulting in the Collimator knobs extending down below the spacer assembly. In this configuration the measured minimum SSD is approximately 25 centimeters which is a class B noncompliance. However, from the design of the collimator knobs, it appears that it would be extremely difficult, if not impossible, to lower the BLD any closer to the patient than to the end of the collimator knobs. Thus, the collimator knobs serve the same purpose as the spacer bar.

Therefore, when determining minimum SSD for this and similar models, lower the BLD such that the end of the collimator knobs are even with the top of the spacer assembly on the test stand.

M. RAYTHEON (RAYM) RME 325 SYSTEMS

The Center has Investigated reports of reproducibility problems associated with Raytheon model RME 325 x-ray controls (model code 006171). The problems manifested themselves at low output techniques, usually associated with radiographs of the extremities.

Whenever an AR field test procedure is performed on a model RME 325 system, the surveyor should perform the beam quality, reproducibility, and linearity portions of the field

test in the normal manner. Before removing the test stand, run additional exposures for reproducibility at the following techniques:

1. 80 kVp, 300 mA, 1/10 second
2. 80 kVp, 300 mA, 1/20 second
3. 55 or 60 kVp, 100 mA, 1/40 second

Record the technique factors, exposure readings, and time measurements on a continuation sheet. Remember to make a full series of ten exposures at each technique if the system appears non-reproducible.

N. XEROX (XERO) MAMMOGRAPHY SYSTEMS

We have learned from LOS-DO that the Xerox 120 Mammography System has some possible problems regarding the position of their labels. They stated that the system label, with a system number 80500G, is located on the bottom right side of the unit, while the label for the control, with a model number of 63625G, is located underneath the control panel. Xerox has indicated that they will contact Fischer Imaging, the manufacturer for the system. In the event that you test one of these units, the label for the control might be difficult to locate, but it should be present.

0. XONICS/TOSHIBA (XONM/TOSE) MODEL 30860-2 X-RAY CONTROL

This control has a "bucky in/bucky out" selector switch which is identified in the operators manual as a 'Technique Selector" switch. The switch is intended to select bucky operation with the cassette in the tray (bucky in) or nonbucky operation with a cassette on the tabletop (bucky out). The Technique Selector" switch is not considered an illegal PBL override.