PART I

GENERAL INFORMATION

FORM FDA 3071

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ROUTINE COMPLIANCE TESTING

GENERAL INFORMATION

(Test Procedure GI - Use Form FDA 3071)

The general information test record has been devised to consolidate all of the administrative information relating to the field compliance testing of a single x-ray system. The form consists of blocks for data relative to the facility at which the field test is conducted, the surveyor and his agency, the specific x-ray system and its assembly, system maintenance, instrumentation used in the field test, and the specific test procedures used in the survey. The general information test record will have, at the end of the field testing, attached specific test records for each test procedure followed in the testing of the system.

The following guidance is supplied for the completion of the general information test record:

GI TEST SERIAL NUMBER: This identifying number is found preprinted on each general information test record. No significance is placed on the number itself; it serves simply to identify the field test record and all accompanying test records. The field test serial number is made up of the first two letters of the test protocol form, the numeric digits of the GI test serial number, and a unique letter designator for each tube source tested. The special letters S, T, and U are used for special tests that vary from the test protocol. The special letters X and Y are reserved for testing units with SSD spacer attachments removed.

IMPORTANT!

The field test serial number must be shown on each page of any accompanying test records.

REGIONAL REVIEW: This block is to be completed by the individual within the FDA Regional or District Office who is charged with the responsibility for reviewing the field test data for completeness and accuracy. The reviewer, by affixing his signature in this block, indicates that he has reviewed the test record.

FACILITY IDENTIFICATION

NAME: Use the name of the physician, dentist, and so forth, if the x-ray system is located in a private office. Otherwise, enter the name of the hospital, medical group, or corporation at which the x-ray system is located.

STREET ADDRESS: Enter the street address or rural route number of the facility. Do not use post office box numbers, even though they may appear on the assembler report form (FD2579).

CITY: The name of the city or town in which the facility is located.

STATE CODE: Select the appropriate two letter code from the "Table of Federal and State Agency Codes." (see Appendix A)

ZIP CODE: Enter the correct five-digit zip code for the facility.

ROOM NUMBER: This is the room number or other location at which the x-ray system master control is located. For mobile systems not limited to a specific room, specify the floor number, wing, department, or other area as applicable (e.g., 3rd floor, O.R.).

PERSON INTERVIEWED: Write the initials, last name, and title abbreviation of the person who provided the information regarding system maintenance (e.g., S.H. Rogers, DMD).

TELEPHONE NUMBER: Enter the area code and seven-digit commercial telephone number of the facility. Should the x-ray department have a direct line, use that number instead of the general facility number.

SURVEYOR INFORMATION

NAME: The name of the person completing the test record is to be entered as indicated; last name, first name, and middle initial.

ACCOMPLISHING AGENCY: Select the appropriate two digit code from the "Table of Federal and State Agency Codes." (see Appendix A).

ACCOMPLISHING DISTRICT: Enter the letter digit code for the FDA District in which the facility is located. If unknown, leave blank.

SIGNATURE: Please sign in this block.

FDA REGION: Enter the two-digit code for the FDA Region in which the field test is conducted. If unknown, leave blank. (see Appendix A).

DATE: Enter the date the x-ray system was tested. Use the format of month, day, year using two numerical digits for each. For example, June 16, 1972, would have been coded 06 16 72. Although the test form is printed with two digit year dates, the data entry form in XRAYAPS is Y2K compliant and 4 digit year dates should be entered.

SURVEY INFORMATION

PURPOSE OF SURVEY: Enter here the reason for the current survey of the x-ray system choosing from one of the following:

I-Initial Survey:	This is the code for any first survey of this system (provided that the survey is not part of an HIA, audit, or other compliance activity).
R-Resurvey:	A resurvey indicates that the system had been previously tested without finding a noncompliance but is being retested anyway.
C-Compliance F/U:	This code represents a reinspection that is initiated to determine if a

previously reported noncompliant unit has been brought into compliance.

A-Audit: This code is to be used by x-ray auditors when conducting followup or joint surveys to audit radiation survey personnel methodology in following the test protocol.

H-HIA: This code covers any field test that is conducted under a direct request by the Center for Devices and Radiological Health; either as part of a Recall Effectiveness Check or a special assignment.

ASSEMBLER REPORT NUMBERS: Space has been provided for the entering of up to three Assembler Report Numbers. Enter the seven-digit accession number of each form in the appropriate spaces. Should there be more than three assembler report forms for the system, enter first the forms reporting the installation of the system; i.e., major components such as controls, generators, tables, and BLD's. Following this, enter next the most recent components installed, so as to indicate what is presently in the x-ray system. List the other assembler report numbers on the "Continuation Sheet."

INSTALLATION DATE: Enter the date of installation for the system using a month, day, year format.

PREVIOUS FTR'S: Enter the identifying Field Test Serial number for up to two of the most recent tests of the x-ray system. Should there be more than two previous field tests of the system, enter additional test numbers on the "Continuation Sheet."

SYSTEM INFORMATION

CERTIFICATION STATUS: Check each of the certifiable components in the system to determine its certification status. Indicate whether the system is composed of : fully certified without variances (C), fully certified with variances (V), mixed certified/noncertified (M), or fully noncertified (N).

CONTROL MANUFACTURER: From the system master x-ray control (the control that contains the main power switch for the system) copy the name of the manufacturer.

SERIAL NUMBER: Copy the serial number for the master x-ray control as it appears on the identification label.

DATE OF MFR: Enter the date of manufacture for the master x-ray control using a month, year format.

CONTROL MODEL NUMBER: Copy the model code (sometimes designated as "type") as it appears on the identification label on the master x-ray control.

MFR CODE: The regional reviewer will enter the four-digit code for the control manufacturer listed in the previous block.

UNIQUE ID: The Regional Reviewer will enter the six-digit Unique ID assigned to the model code listed in the previous block.

SYSTEM MAINTENANCE

Is a schedule of maintenance, designed to ensure compliance with the DHHS standard, being followed? Ask this question of the chief x-ray technician, the head of Radiology, or other knowledgeable individuals present at the facility. Pursue the question until you get an answer. Only as a last resort are you to enter an "X" for "Unknown."

If the answer to the previous question is yes, ask to review the maintenance schedule. You do not actually have to evaluate the maintenance schedule; just make sure one is available. Is the maintenance schedule available for review?

Who does the compliance maintenance? Determine if the facility has the maintenance performed by a manufacturer's representative, in some cases the assembler (M); a private firm that is not affiliated with the manufacturer (P), their own in house maintenance personnel (I), does not do any compliance maintenance (N), or the information is not known (X).

INSTRUMENTATION

Enter the serial number of the appropriate instrumentation used in the survey. These serial numbers will be used to obtain specific correction factors for these instruments.

FORMS ATTACHED

In the space provided, enter the number of each of the specific test forms that are attached to the general information test record. All other data items in this section should remain blank. The forms are referenced by two letter codes associated with the test procedure. Refer to page GI-6 section 06 for an image of the form. The following is a guide to identify the blocks with specific procedures:

block 19	(AR) Abovetable Radiographic Test Record
block 20	(DR) Dental Radiographic Test Record
block 21	(CF) C-Arm Fluoroscopes Test Record
block 22	(AF) Abovetable Source Fluoroscopes Test Record
block 23	(MA) Mammographic Systems Field Test Record
block 24	(HN) Head and Neck Radiographic Systems
block 25	(UF) Undertable Source Fluoroscopic Test Record
block 26	(KV) Peak Kilovoltage Test Record
block 27	(CT) Computed Tomography X-ray Systems
block 28	(MR) Mobile Radiographic Test Record
block 29	(VC) Vertically Mounted Cassette Holder Test Record

ASSEMBLER DATA

Enter the name and address of the x-ray assembler responsible for the system. The home district and assembler code will be entered by the regional reviewer. For equipment installed by more than one assembler, enter the assembler names and addresses on the "Continuation Sheet" and the regional reviewer will enter the name and address of the most responsible assembler in this block. The most responsible assembler will be the one who most recently installed or altered a component that fails a compliance test.