CPG Sec. 398.325 Regulatory Actions Against Assemblers Noncompliant Diagnostic X-Ray Equipment

BACKGROUND:

Analysis of Field testing performed on certified medical x-ray systems and components has indicated an unacceptable rate of failure to comply with the Diagnostic X-ray Standard. Most of these noncompliances result from assemblers who have failed to properly follow manufacturers' assembly instructions. Stricter enforcement to assure the proper assembly of diagnostic x-ray equipment is therefore expected to have an overall effect of reducing the rate of noncompliance.

Center for Devices and Radiological Health review and evaluation of field testing records reveals that the most common assembler caused noncompliances are:

1. Collimation problems in radiographic, fluoroscopic, and spot film modes resulting in improper x-ray field sizing
2. Interlock misassemblies resulting in x-ray production when the primary barrier is not in position to intercept the fluoroscopic x-ray beam;
3. Problems with entrance exposure rates that are a result of miscalibration of the fluoroscopic x-ray control allowing selection of tube currents that deliver an exposure rate in excess of that allowed by the standard;
4. Misadjustment of the lamp voltage for collimator light bulbs resulting in inadequate illuminance from the light localizer.

POLICY:

The primary enforcement mechanism for assembler violations of the performance standard will be the assessment of civil penalties. Unless civil penalties against an assembler are proven to be ineffective means to achieve compliance, injunction recommendations will not be routinely approved. If violations continue, a return to court seeking injunction would be appropriate bolstered

by the added weight that civil penalties have been ineffective. Injunction will also be considered where there is evidence of continuing gross negligence by the assembler or willful violation of the performance standard.

REGULATORY ACTION GUIDANCE:

Criteria for recommending civil penalties follow:

1. Test results are obtained as soon as possible after assembly but in no case more than one year after installation of the system or component (to minimize any claims by the assemblers that the noncompliance was due to normal wear and tear, improper maintenance, or improper repair).

   and

2. Field test results are classified as either Class A or Class B noncompliances described in Compliance Program *7386.003, Field Compliance Testing of Diagnostic Medical X-ray Equipment.*

   and

3. Both the assembler and the responsible headquarters official(s) have been advised in writing of past violations and warned of the legal consequences of continuing to commit such prohibited acts. Such a record of prior warning will not be considered necessary where injuries have resulted from the violations or where there is evidence that the assembler was grossly negligent in assembling the x-ray system or willfully violated the performance standard. FDA is required to notify the assembler of all violations pursuant to 21 CFR 1003.11 and 21 U.S.C. *360ll(e).*

   and

4. All notices of adverse finding presented in support of proposed charges related to field testing, must have been issued within 45 days of the date of the field test (60 days for State tests).

   and

5. Field test results on at least two different installations demonstrate noncompliant systems were assembled within one year after the notification and warning provided in criterion "3" and documentation demonstrates that the noncompliances are attributable solely to improper assembly or improper installation of a component into the system or subsystem.

The conditions in criteria 1 and 5 above (i.e., testing within one year of assembly and 2 violative installations after warning) are the absolute minimum criteria. Recommendations will be reviewed on a case-by-case basis.

Material between asterisks is new or revised

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