

CPG Sec. 398.350 Regulatory Actions Against Assemblers of X-ray Equipment that Fail to File Reports of Assembly

BACKGROUND:

21 CFR 1020.30(d) requires that assemblers of diagnostic x-ray systems file reports of assembly (FD 2579). Completed reports must be submitted to the Director, Center for Devices and Radiological Health (CDRH) as well as to the purchaser, and, where applicable, to the State, within 15 days following completion of the assembly. The reports are date stamped at CDRH and sent to the field for review and filing.

POLICY:

When an assembler of diagnostic x-ray equipment fails to submit a report(s) of assembly, the District may initiate and issue a Notice of *Noncompliance Letter or a Warning* Letter. If the assembler does not correct the violation(s) in a timely manner *and continues to fail to comply,* the District should submit a request for civil penalties and/or injunction to the CDRH.

Thirty (30) days is sufficient time for completing a report, mail time and completion of other administrative activities. Reports of assembly received more than 30 days after assembly is completed will be considered late.

REGULATORY ACTION GUIDANCE:

The following represents criteria for direct reference issuance of *Warning* Letters to the assembler* by district offices:

1. The District must establish clear proof that the form FD-2579 was either never filed or was filed late. This can be obtained by records inspection at the firm, review of records at the FDA District Office, review of CDRH computer files, interview of purchaser, and review of State records.

and

2. The District shall have sent at least one Notice of *Noncompliance Letter* addressing late filing or failure to file. This must be confirmed by a return receipt or other evidence of receipt.

Criteria for requesting civil penalties and/or injunction:

The District should establish a clear record of continuing violation and of warning; e.g., the assembler has failed to report or has reported late at least twice and the assembler has been warned in writing at least twice within a twelve month period. *The assembler has received a Warning Letter and failed to respond, correct or comply with provisions of the Warning Letter.* Civil penalty will ordinarily be the action of choice.

Material between asterisks is new or revised

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