

CPG Sec. 398.425 Override of Positive Beam Limitation - 21 CFR 1020.31(g)(5)

BACKGROUND:

On November 21, 1973, the Center for Devices and Radiological Health (CDRH) issued an advisory opinion which stated that Positive Beam Limitation (PBL) can be overridden only at Source to Image Receptor Distances (SID's) for which PBL is provided, and operation of the override switch must still prevent x-ray production at any SID where PBL is not provided. However, questions have been raised as to whether this policy should apply when an override switch is provided only for system failure. Because PBL system failures often involve the SID sensing mechanism, it is reasonable for an override switch for PBL system failure to totally disconnect the PBL logic system, providing totally manual collimator operation at all SID's, including those where PBL does not exist. This opinion is contrary to the CDRH's advisory opinion of November 21, 1973. In addition, after studying the designs of numerous PBL system manufacturers, the CDRH has discovered that service switches are sometimes provided to override the PBL function during repair of the PBL system. However, not all of these service switches have been captured key switches as described in *Section 1020.31(g)(5)*.

POLICY:

The CDRH believes that in the event of PBL system failure, it is important to keep the x-ray system operational until it can be repaired. Therefore, it is consistent with the intent of the Regulations for any override switch provided only for use by the serviceman or for any override key provided for PBL system failure, to allow totally manual collimator operation at all SID's including those where PBL is not provided. Any service switch which has a capability of overriding the PBL and which is readily available to the operator, must be a captured key switch as described in *Section 1020.31(g)(5)*. Any service switch that is normally inaccessible to the operator does not require a key.

The Regulations also provide for an additional override capability to perform special procedures. If such an override capability is provided, it shall only override the PBL function at those SID's where PBL is provided. A captured key switch is required for all override switches that are readily accessible to the operator.

Material between asterisks is new or revised

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