

Philips Medical Systems 0604 '05 SEP -8 MC '64

September 7, 2005

0509005

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Application for variance from a performance standard for
electronic products

Sirs/Madams:

Pursuant to 21 CFR 1010.4, Philips Medical Systems ("Philips") submits this application for a variance from a performance standard for radiographic systems, specifically parts of the performance standard specified in 21 CFR 1020.31(g)(2)(iii and iv), which require positive beam limitation ("PBL") to function when:

(iii) The x-ray beam axis is within ± 3 degrees of vertical and the SID is 90 centimeters to 130 centimeters inclusive; or the x-ray beam axis is within ± 3 degrees of horizontal and the SID is 90 centimeters to 205 centimeters inclusive; [and]

(iv) The x-ray beam axis is perpendicular to the plane of the image receptor to within ± 3 degrees.

The systems for which Philips is seeking this variance provide PBL, but not throughout the full ± 3 degree range. They otherwise meet the requirements of the standard, and specifically they comply with the requirements of 21 CFR 1020.31(g)(1) as determined by performing the test specified in 21 CFR 1020.31(g)(3).

Philips is submitting in this application information it believes sufficient to conclude that either:

1. The products subject to this requested variance utilize an alternate means for providing radiation safety or protection equal to or greater than that provided by products meeting all requirements of the applicable standard (21 CFR 1010.4(a)(2)(i));
or
2. The requirements in the performance standard specifying the angles of the x-ray beam from vertical, horizontal or perpendicular to the image receptor plane at which PBL must function are not appropriate given the design and features of Philips diagnostic x-ray systems, which do provide suitable, but



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JAL 7

different means for assuring radiation safety or protection (21 CFR 1010.4(a)(2)(iii)).

The information in this application below is numbered with reference to 21 CFR 1010.4(b)(1):

(i) **Description of the product and its intended use**

The products for which the variance is sought ("Subject Systems") are all Philips Medical Systems Radiographic X-ray Systems with the PBL option (Bucky Diagnost, Digital Diagnost, EasyDiagnost Eleva, OmniDiagnost Eleva, Multi Diagnost Eleva). Their intended use is general radiographic and tomographic examination of patients in supine, seated, or standing positions.

(ii) **Explanation of how compliance would be restrictive /inappropriate**

Philips Medical Systems believes that compliance with the ± 3 degree PBL requirement would be inappropriate and unnecessary given the design of the Subject Systems. It is Philips' understanding that the intent of this requirement was to ensure that PBL is active during clinical examinations for which a perpendicular beam is desired, and 3 degrees was an estimate of how far off-perpendicular a user might inadvertently position the beam. By contrast, clinical applications requiring an off-perpendicular beam involve angles far greater than 3 degrees.

When the standard was developed, many X-ray systems were equipped with collimation systems that employed mercury switches to detect X-ray beam angle and did not include a reliable way to assure that PBL was active whenever a perpendicular X-ray beam was intended.

The Subject Systems, however, are designed to ensure a perpendicular alignment, minimizing the probability that the user will inadvertently position the beam at an angle. With this feature, the requirement that PBL extend fully 3 degrees off-perpendicular provides little, if any, added safety benefit.

The PBL selection for the Subject Systems is integrated with the positioning mechanism of the X-ray tube ceiling suspension (not the collimator). Using a positive detent, this mechanism facilitates "finding" zero degrees with a "snap-in-place" operation, which concurrently activates PBL. The x-ray system also provides a clear visual indication when this position has been achieved. See the section entitled "Detailed description of integrated positioning/PBL mechanism" below for more information.

The positioning mechanism achieves a precise alignment that is significantly better than that required by 21 CFR 1020.31(g)(1). In a factory test of a sample of an EasyDiagnost Eleva system (a representative Subject System) with an overtable tube set at 100 cm SID, a 24.2x29.3 cm cassette (nominal 24x30cm), and a ± 2.43 degree tube angulation, the measured x-ray/image misalignment was +0.1 cm (length) and +0.1 cm (width) - 0.1% against the 3% limit under 21 CFR 1020.31(g)(1)(i), and 0.2% against the 4% limit under (g)(1)(ii). A copy of the test report is attached as Exhibit A.

The combination of an integrated positioning/PBL mechanism and the collimator display makes it difficult to inadvertently position the

beam off-perpendicular, while achieving an alignment that is significantly improved to that specified in 21 CFR 1020.31(g)(1). Philips Medical Systems believes that this approach is consistent with the intent of the performance standard and achieves a degree of radiation safety equivalent if not greater than would be achieved by a system that minimally satisfied all of the individual elements of the PBL standard. Moreover, it would be inappropriate to reduce the precision of the integrated positioning/PBL mechanism by adding unnecessary "play" to the detent to achieve the full ± 3 degree PBL functionality.

(iii) ***Proposed deviation from the requirements of the standard***

Philips Medical Systems requests a variance from the requirement that PBL function when the x-ray beam is within ± 3 degrees of vertical, horizontal or perpendicular to the plane of the image receptor, respectively (21 CFR 1020.31(g)(2)(iii) and (iv)). Instead, Philips requests that under the Variance, if a PBL x-ray system includes (a) a positive mechanical or electromechanical detent indicating a perpendicular beam and (b) a visual display on the collimator indicating Automatic or PBL mode, then PBL is only required to function when that detent is engaged. However, in all cases, PBL shall function within ± 0.5 degrees.

(iv) ***Description of advantages of proposed deviation; and***

(v) ***Explanation of how alternate or suitable protection is provided***
Included in (ii) above.

(vi) ***Period of time for variance to be in effect***

Philips Medical systems ask that this Variance extend for a period of a minimum of 3 years from the date of the grant of the Variance. Philips believes that this period of time may be necessary for the promulgation of a corresponding amendment to the performance standard.

Detailed description of integrated positioning/PBL mechanism

In the integrated positioning/PBL mechanism of Philips x-ray systems, the detent locks the collimation system at 0 degrees by use of an electromagnetic brake. Locking at 0 degrees is indicated by an SID reading and the collimator displays an "A" indicating automatic mode (PBL) with 0 degree detent. Release of the electromagnetic brake is required to move the collimator out of the detent into manual mode, and thereby out of 0 degrees or a position non-perpendicular to the image receptor. In order for the operator to achieve a 3 degree setting the operator must release the brakes and rotate the collimator out of the detent, which is a non-clinical position. If you tilt the collimator even less than ± 3 degrees, the collimation display changes noticeably, indicating you are no longer perpendicular to the tabletop (0 degrees). Specifically, the collimator displays an "M" for manual mode and "???" or no SID, all indicating manual/non-PBL mode to the operator. Only after the operator pulls down the SID tape to measure distance to the tabletop will the system collimator indicate the SID value while in this manual mode. As with any non-PBL operation, once non-perpendicular, the operator must then adjust the collimator to optimize alignment of the image receptor to the x-ray field. The attached

excerpt from the instructions for use for the EasyDiagnost Eleva, a representative Subject System, is attached to this application and explains this operation in even greater detail (Exhibit B).

Summary

For the reasons discussed above, Philips Medical Systems believes that by combining precise alignment and positive detents, its PBL x-ray systems provide an alternative means of achieving radiation safety or protection equal to or greater than that provided by products meeting all requirements of the applicable performance standard.

Lastly, Philips Medical Systems also requests to be exempted from the requirement to modify the tag, label, or other certification under 21 CFR 1010.4(d).

Thank you for consideration of this application for a variance. Please contact me if you have any further questions or comments on this application.

Respectfully submitted,



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Enclosures: Exhibit A: Field Size Measurement
Exhibit B: Selected Instructions for Use from the
EasyDiagnost Eleva System