



**CALIBRATION LABORATORIES**

**NVLAP LAB CODE 105018-0**

**SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005**

<p><b>CDRH X-Ray Calibration Laboratory</b>          Food and Drug Administration          10903 New Hampshire Avenue W062-4103          Silver Spring, MD 20993-0002          Ms. Mary Walker          Phone: 301-796-2558 Fax: 301-796-9795          E-mail: <a href="mailto:mary.walker@fda.hhs.gov">mary.walker@fda.hhs.gov</a></p>	<p><b>Parameter(s) of Accreditation</b>          Ionizing Radiation</p>
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**CALIBRATION AND MEASUREMENT CAPABILITIES (CMC) <sup>Notes 1,2</sup>**

Measured Parameter or Device Calibrated	Radiation Type or Beam Code	Exposure Rate Range	Uncertainty ( $k=2$ ) <sup>Note 3</sup>	Remarks
<b>IONIZING RADIATION</b>				
<p><b>NVLAP Code: 20/I01 DOSIMETRY of X-RAYS, GAMMA RAYS, and ELECTRONS</b>            Survey Instruments</p>	<p>H50</p>	<p>0.5 mR/h to 200 mR/s</p>	<p>5 %</p>	
<p>Instruments for Diagnostic Levels            X-ray Beam Codes</p>	<p>L80, L100, M20, M30, M50, M80, M100, and M120</p>	<p>2 mR/s to 100 mR/s</p>	<p>3 %</p>	
<p>Mammography Entrance</p>	<p>Mo/Mo 25, Mo/Mo 28, Mo/Mo 30, Mo/Mo 35, Mo/Rh 28, Mo/Rh 32, Rh/Rh 30, and Rh/Rh 35</p>	<p>5 mR/s to 200 mR/s</p>	<p>3 %</p>	
<p>Mammography Exit</p>	<p>Mo/Mo 25X, Mo/Mo 28X, Mo/Mo 30X, Mo/Mo 35X, Rh/Rh 30X, and Rh/Rh 35X</p>	<p>2 mR/s to 17 mR/s</p>	<p>3 %</p>	

2012-01-01 through 2012-12-31  
*Effective dates*

*David E. Alderson*  
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 For the National Institute of Standards and Technology



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**CALIBRATION AND MEASUREMENT CAPABILITIES (CMC) <sup>Notes 1,2</sup>**

<b>Measured Parameter or Device Calibrated</b>	<b>Radiation Type or Beam Code</b>	<b>Exposure Rate Range</b>	<b>Uncertainty (k=2) <sup>Note 3</sup></b>	<b>Remarks</b>
Instruments for Reference Class X-ray Beam Codes	L80, L100, M20, M30, M50, M80, M100, and M120	2 mR/s to 100 mR/s	3 %	
Mammography Entrance	Mo/Mo 25, Mo/Mo 28, Mo/Mo 30, Mo/Mo 35, Mo/Rh 28, Mo/Rh 32, Rh/Rh 30, and Rh/Rh 35	5 mR/s to 200 mR/s	3 %	
Mammography Exit	Mo/Mo 25X, Mo/Mo 28X, Mo/Mo 30X, Mo/Mo 35X, Rh/Rh 30X, and Rh/Rh 35X	2 mR/s to 17 mR/s	3 %	
<b>END</b>				

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Notes

**Note 1:** A Calibration and Measurement Capability (CMC) is a description of the best result of a calibration or measurement (result with the smallest uncertainty of measurement) that is available to the laboratory's customers under normal conditions, when performing more or less routine calibrations of nearly ideal measurement standards or instruments. The CMC is described in the laboratory's scope of accreditation by: the measurement parameter/device being calibrated, the measurement range, the uncertainty associated with that range (see note 3), and remarks on additional parameters, if applicable.

**Note 2:** Calibration and Measurement Capabilities are traceable to the national measurement standards of the U.S. or to the national measurement standards of other countries and are thus traceable to the internationally accepted representation of the appropriate SI (Système International) unit.

**Note 3:** The uncertainty associated with a measurement in a CMC is an expanded uncertainty using a coverage factor,  $k = 2$ , with a level of confidence of approximately 95 %. Units for the measurand and its uncertainty are to match. Exceptions to this occur when marketplace practice employs mixed units, such as when the artifact to be measured is labeled in non-SI units and the uncertainty is given in SI units (Example: 5 lb weight with uncertainty given in mg).

**Note 3a:** The uncertainty of a specific calibration by the laboratory may be greater than the uncertainty in the CMC due to the condition and behavior of the customer's device and specific circumstances of the calibration. The uncertainties quoted do not include possible effects on the calibrated device of transportation, long term stability, or intended use.

**Note 3b:** As the CMC represents the best measurement results achievable under normal conditions, the accredited calibration laboratory shall not report smaller uncertainty of measurement than that given in a CMC for calibrations or measurements covered by that CMC.

**Note 3c:** As described in Note 1, CMCs cover calibrations and measurements that are available to the laboratory's customers under *normal conditions*. However, the laboratory may have the capability to offer special tests, employing special conditions, which yield calibration or measurement results with lower uncertainties. Such special tests are not covered by the CMCs and are outside the laboratory's scope of accreditation. In this case, NVLAP requirements for the labeling, on calibration reports, of results outside the laboratory's scope of accreditation apply. These requirements are set out in Annex A.1.h. of NIST Handbook 150, Procedures and General Requirements.

**Note 4:** Uncertainties associated with field service calibration may be greater as they incorporate on-site environmental contributions, transportation effects, or other factors that affect the measurements. (This note applies only if marked in the body of the scope.)

**Note 5:** Values listed with percent (%) are percent of reading or generated value unless otherwise noted.

**Note 6:** NVLAP accreditation is the formal recognition of specific calibration capabilities. Neither NVLAP nor NIST guarantee the accuracy of individual calibrations made by accredited laboratories.

**Note 7:** See [NIST Handbook 150](#) for further explanation of these notes.

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