



# Arkansas Department of Health

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4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000

Governor Sarah Huckabee Sanders

Renee Mallory, RN, BSN, Secretary of Health

Jennifer Dillaha, MD, Director

## PUBLIC COMMENT REPORT

### Proposed Standards Pertaining to Human Breast Milk Bank

#### PUBLIC COMMENTS:

Public comment period expired February 28, 2024.

The Department received the following public comment regarding laboratory testing and calibration requirements, and the related laboratory accreditation standards:

Randall Query, Director Government Relations  
American Association for Laboratory Accreditation (A2LA)

*We appreciate the opportunity to provide comments directed at the proposed rule “Standards Pertaining to Human Breast Milk Banks.” Specifically, we write regarding laboratory testing and calibration requirements and the related laboratory accreditation standards. By way of background, A2LA is a non-profit, accreditation body with over 4200 actively accredited certificates representing all 50 states and international, and 30 organizations accredited in Arkansas including the Arkansas Public Health Laboratory. We have been granting accreditation to laboratories in various industries since 1979.*

*The criteria forming the basis for our testing and calibration laboratory accreditation programs is ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories. We also provide accreditation to clinical laboratories to ISO 15189 Medical laboratories – Requirements for quality and competence; and achieved and maintain Centers for Medicare and Medicaid Services (CMS) Deem Status as an accreditation organization to accredit clinical laboratories to the Clinical Laboratory Improvement Amendments (CLIA) requirements. We ourselves, as an accreditation body, have been evaluated against rigorous standards in providing these accreditation services and we are the only accreditation body in the world that is recognized globally as an International Laboratory Accreditation Cooperation (ILAC)-recognized accreditation body and CMS deemed status accreditation organization.*

*We offer the following comments for your consideration. Our recommended language is inserted in bold: In section 4.4.3, the requirements specify “A **CLIA certified high complexity clinical laboratory, or an ISO 17025 accredited clinical laboratory** does the tests...” Please note that an additional ISO standard exists that is based on ISO/IEC 17025 and ISO 9001 but specifies requirements for quality and competence that are*



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*particular to medical laboratories. This ISO standard is ISO 15189 and has been in use for close to twenty years. We recommend that 4.4.3 be revised to “A CLIA certified high complexity ~~clinical~~ laboratory or an ISO/IEC*

*17025 or ISO 15189 accredited clinical laboratory, **which achieved accreditation from an International Laboratory Accreditation Cooperation recognized accreditation body, does the tests...**”*

*In section 8.1, consider revising certified laboratory to the following: “A certified **or accredited** laboratory is to conduct screening blood tests... Section 10.1 provides requirements for the breast milk bank to have disaster plans. We support this requirement; however, we advise that a provision be included to require periodic testing of the disaster plans to ensure that they are effective. We recommend that Section 10.1 be amended by adding a third, final sentence “**The disaster plan shall be testing at periodic intervals to determine effectiveness.**”*

*In section 15.3.2, the requirements specify, “Thermometers may be certified calibrated by National Institute of Standards and Technology(NIST) (or similar agency) or calibrated quarterly by the milk bank using an NIST certified reference thermometer. The milk bank must keep records of calibration.” It is industry practice to rely on NIST calibration or rely on an ISO/IEC 17025 accredited calibration laboratory that is accredited by an ILAC recognized accreditation body for calibration of the reference thermometers. Then the milk bank may verify working thermometers against the reference thermometers. This can be more cost effective to the milk bank than as currently written in the proposed rule. We recommend the following revision to section 15.3.2: “**Thermometers may be calibrated by a national metrology institute (NMI) such as the National Institute of Standards and Technology (NIST) or an ISO/IEC 17025 accredited calibration laboratory that is accredited by an ILAC recognized accreditation body, for the calibration of the reference thermometers. The milk bank shall verify working thermometers against the calibrated reference thermometers at least quarterly. The milk bank must keep records of the calibration and verification records.**”*

*In Section 14.1, second sentence, we recommend the following addition: Two distinct and appropriately calibrated (**see section 15.3.2**) thermometers – whether electronic, or indwelling, or mercury—monitor freezers. Also note that the EPA has launched an effort to reduce the use of mercury-filled non-ferrous thermometers. As referenced on the EPA website: EPA has launched an effort (<https://www.epa.gov/mercury/mercury-thermometers>) to reduce the use of mercury-filled non-ferrous thermometers used in industrial settings where suitable alternatives exist. As part of a partnership EPA developed with the National Institute of Standards and Technology (NIST), NIST no*



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*longer provides calibration services for mercury thermometers. You can read more about the impact the decision will have in NIST's February 2011 press release announcing the change. Section 26.1.3 appears to be inconsistent with section 4.4.2, where language was struck out concerning the baby. Section 26.1.3 still includes a requirement for the infant. This may need to be reviewed further to consider striking the infant requirement.*

*Section 27.5, requirements are in place to initiate a root cause analysis. We respectfully recommend that this language be improved upon. We recommend a fourth and final sentence added to 27.5 that states "**Following implementation of a corrective action, (e.g. three months), audit the correction to determine its effectiveness.**"*

The Department has revised the Standards in response to the public comments.

AGENCY RESPONSE:

Proceed to adoption.