



Continuous Monitoring

Regulatory Compliance & Quality Assurance

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CM Regulatory Compliance & Quality Assurance Matrix

Mesa Monitoring's continuous monitoring (CM) solutions are designed to safeguard valuable products and vital assets, facilitate regulatory compliance, and enhance overall enterprise quality assurance.

Key regulatory and quality assurance standards, and the recommended CM systems set points, are listed below.

Application / Appliance Type	Standard	Reference Temperature Range	Temperature Range Set in Automated Monitoring System
Food Refrigerator	FDA Food Code 3-501.16-19	2° - 5°C (35° to 41°F)	2° to 5°C 1 st alert 30 min
Food Freezer	Title 22 CCR: Acute Care, Item 25	-18°C (0°F) or below	-30° to -10°C 1 st alert 30 min
Medication Refrigerator	USP Quality Review: Storage Definitions; Title 22, CCR	1° to 8°C (36° to 46°F)	2° to 8°C 1 st alert 30 min
Medication Freezer	USP Quality Review: Storage Definitions; Title 22, CCR	-20° to -10°C (-4° to 14°F) or other freezer temperature range recommended by the drug manufacturer	-30° to -10°C 1 st alert 30 min
Specimen Refrigerator –	College of American Pathologists: 2007 Laboratory Inspection Checklist	1° to 8°C (33° to 46°F)	2° to 8°C 1 st alert 60 min
Breast Milk Refrigerator	Centers for Disease Control http://www.cdc.gov/breastfeeding/recommendations/handling_breastmilk.htm	2° to 8°C (35.6° to 46.4°F)	2° to 8°C 1 st alert 15 min
Breast Milk Freezer	Centers for Disease Control http://www.cdc.gov/breastfeeding/recommendations/handling_breastmilk.htm	-30° to -10 °C (-22.0° to 14°F)	-30° to -10°C 1 st alert 15 min
Tissue Refrigerator	Joint Commission Standard PC.17.10	-17.5° to -15°C (0.4° to 4°F)	Product and usage dependent
Tissue Freezer	Joint Commission Standard PC.17.10	-40°F (-40°C)	Product and usage dependent

Application / Appliance Type	Standard	Reference Temperature Range	Temperature Range Set in Automated Monitoring System
Blanket Warmer	Facility SOP	Not to exceed 43°C (110°F)	38° to 43°C 1st alert 60 min
Fluid Warmer	USP Quality Review: Storage Definitions	30° to 40°C (86° to 104°F); 72 hour limit	30° to 40°C 1st alert 60 min
Contrast Warmer	Manufacturer Package Insert: Omnipaque and Visipaque	15° to 30°C (59° to 86°F)	18° to 27 °C 1st alert 60 min
Vaccine Management	http://www.cdc.gov/vaccines/recs/storage/default.htm	2° to 8 °C (35.6° to 46.4°F)	2° to 8°C for refrigerated vaccines 1st alert 30 min
POCT Test Supplies	Manufacturer's Recommendations	18° to 30°C (64° to 86°F)	18° to 27°C 1st alert 60 min
Blood Bank	FDA and AABB the Standards for Blood Banks and Transfusion Services (27th Edition)	1.5° to 5.5 °C (34.7° to 41.2°F)	1.5° to 5.5°C 1st alert 5 min or less
Platelets	FDA and AABB the Standards for Blood Banks and Transfusion Services (27th Edition)	20.0° to 24.0 °C (68.0° to 75.2°F)	20.0° to 24.0°C 1st alert 15 min or less

For additional information and a consultation with our CM team, please contact us at:



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