Appropriate Processing procedures and records to include mass balance

Disqualify vendor and/or materials

Revise or write necessary SOPs and forms/audit schedule

Temperature mapping and freezing profile

Disqualify vendor and/or materials

Perform temperature mapping and establish freezing

Temperature monitoring

Disqualify vendor and/or materials

Institute temperature monitoring

Documented test results

Disqualify vendor and/or materials

Institute procedures and/or use samples to generate results

Proceed to thawing