

POSITION STATEMENT

REGISTRATION OF FACILITIES FILLING OPEN TOPPED MEDICAL LIQUID NITROGEN DEWARS FOR DEVICE USE IN THE UNITED STATES

Question

Do facilities filling open topped medical liquid nitrogen dewars need to register with the U.S. Food and Drug Administration (FDA) as a device manufacturing facility?

Answer

No. Per a letter from Dr. Larry Spears, Center for Devices and Radiological Health (CDRH), received July 30, 2007, "Firms filling small dewars from large cryogenic containers are not required to register as device establishments, list their devices and comply with the Quality System regulation (21 CFR Part 820), if they utilize and document the use of the large cryogenic containers. The large containers must be filled and labeled according to relevant drug regulations [1]."

NOTE—At this time, FDA Center for Drug Evaluation and Research (CDER) has not responded to CGA's input regarding the filling of open topped medical liquid nitrogen dewars. For that reason, this position statement does not address facility drug registration and licensure requirements.

Question

Are there other procedures that a filler of open topped medical liquid nitrogen dewars should follow?

Answer

1. The firm shall have a detailed written standard operating procedure (SOP) and associated documentation for the personnel training, receipt of the supply, and filling these vessels;
2. The firm shall ensure that open topped medical liquid nitrogen dewars are filled with nitrogen NF source product;
3. The firm shall ensure that each dewar has been inspected in accordance with the firm's SOP prior to fill;
4. Persons handling and filling open topped medical liquid nitrogen dewars shall have documented training on the firm's SOP; and
5. Open topped medical liquid nitrogen dewars do not require medical labels or lot numbers but shall have a product identification label. Traceability of the liquid nitrogen NF filled in to the vessel may be maintained by means other than by lot number.

References

Unless otherwise specified, the latest edition shall apply.

[1] *Code of Federal Regulations*, Title 21 (Food and Drugs), U.S. Government Printing Office. www.gpo.gov

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Work Item 19-058
Medical Gases Committee

NOTE—Technical changes from the previous edition are underlined.

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