



B&R Compliance Associates LLC
Regulatory Update Bulletin

**Bulletin
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Nitrogen Open Top Dewar Filling for Medical Use

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Issue

In response to frequent questioning on the above subject, this bulletin is being issued to provide some guidance on the topic.

Terminology

Open Top Dewar – means an open mouthed, non-pressurized, vacuum jacketed vessel used to hold cryogenic liquid, which has a cap to prevent spilling. The contents are typically dispensed out of the container by either dipping it out with a ladle or by pouring it out.

Medical vs. Industrial Applications

Shrinking metal, sperm/tissue storage, branding animals, and academic applications typically fall under the industrial classification and medical nitrogen should not be used.

Medical nitrogen use from small open dewars includes, but is not limited to, the following:
(*Cryogenic Surgery in Dermatologist's Office*)

Consideration Points

1. All locations filling open-top dewars with NF Nitrogen must register with the FDA as a manufacturer.
2. When trans-filling nitrogen intended for medical use, the source or bulk supply must be MEDICAL.
3. Open Top Dewars lack a means by which one can withdraw the product for analysis and therefore do not require analysis subsequent to filling.
4. cGMP requirements which apply to open top dewar trans-filling include but are not limited to:
 - a. Written SOP's covering the filling process
 - b. Training of personnel performing the filling
 - c. Labeling
 - d. Lot Numbering
 - e. Use of "Fill Record" to document filling
 - f. Maintaining Distribution Records

For more information on this subject, or any other medical gases compliance issue please contact Ron Ball at (317) 297-8518, or ron.ball@brcompliance.com.