



B&R Compliance Associates LLC
Regulatory Update Bulletin

**Bulletin
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**Medical Gas Product Integrity Protection
in Case of Natural Disaster**

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Issue

In response to frequent questioning on the above subject, this bulletin is being issued to describe the procedures for maintaining site security and integrity of Medical Gas products (Drugs) during a natural disaster.

By Definition

Natural Disaster	Disturbances impacting the facility such as tornado's, floods, and hurricanes.
Medical Gas Products	Gases which are labeled as either USP or NF or Medical Devices.
Emergency Plan	A documented plan which includes procedures by which the security of Drug and Medical Device Gases will be assured, and that un-approved drug or device gases will not be released to customers during a Natural Disaster.

Procedure/Guideline

1. Each Program Member Company should include as part of their "Facility Emergency Plan" procedures to ensure the continued security of Medical Gas products during a natural disaster.
2. Each Program Member Company shall review local and state requirements when developing this facility emergency plan as requirements vary considerably between locales, however, all plans shall include at a minimum:
 - Provisions for ensuring that medical gases designated as controlled substances are kept secure during times of natural disasters and that medical gases are not unintentionally contaminated as a result of floods or other natural disaster events
 - Provisions for ensuring the integrity and availability of production records that indicate which medical products have been approved and released for distribution and which medical products are still in process and have not been approved and released for distribution. Provisions for ensuring the integrity and availability of distribution records of medical products that would facilitate any potential recall of medical gas products.
 - Considerations for reviewing fill system integrity and cleanliness prior to production re-starting after a natural disaster.
 - Considerations for reviewing and ensuring purity, strength, and identity of product used to fill medical gas containers on return to production.
 - Considerations for reviewing and ensuring the suitability of containers and components used to manufacture medical gases prior to introducing product into them following a natural disaster.

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.