

FDA REQUIREMENTS FOR HOME RESPIRATORY COMPANIES

The following is a brief summary of pertinent FDA requirements, revised February 1989. For more recent information it is best to contact:

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COMPRESSED MEDICAL GASES GUIDELINE

- For liquefied gas put into cryogenic home units at the plant for delivery to users, each home unit is tested for identity and strength.
- Home units that are retained by customers and are serviced in place periodically by refilling from vehicle mounted vessels need not be directly tested after filling if the filling firm has available suitable records of analysis covering the identity and strength testing performed on a sample taken from its vehicle mounted vessel, or has satisfied the conditions below.
- For HRC (Home Respiratory Company) firms dispensing liquid oxygen from vehicle mounted vessels, acceptable mean of compliance with the identity and strength testing requirements are as follows:
 - If the HRC obtains bulk liquid oxygen from a bulk supplier, the identity and strength test is performed by the bulk supplier and witnessed by the HRC. Documentation of this testing is maintained by the HRC.
 - If the HRC obtains bulk liquid oxygen from a bulk supplier who supplies a certificate of analysis but the test is not witnessed by the HRC, the HRC must perform an identity test on each lot received and establishes the reliability of the supplier's analyses at appropriate intervals.
 - If the HRC neither witnesses the identity and strength test nor receives a certificate of analysis, the HRC must test each vehicle mounted vessel filled by the bulk supplier for identity and strength.
- If the HRC owns or leases a stand tank (stationary holding tank), the HRC must perform a test for identity and strength taken directly from the stand tank after each oxygen delivery before any vehicle mounted vessel is filled. Vehicle mounted vessels filled from this stand tank need not be tested if the HRC can demonstrate compliance with all of the following conditions:
 - No other stand tanks are located at the facility.
 - The vehicle mounted vessels filled from the stand tank are dedicated to the delivery of oxygen by the HRC for home care use only; and
 - The vehicle mounted vessels filled from the stand tank have not been completely emptied or have not been out of service.

TESTING OF THE INCOMING LIQUID OXYGEN

- If the home respiratory company dispenses liquid oxygen from vehicle mounted cryogenic vessels (VMV):
 - No testing is required, if the HRC witnesses the testing, receives a valid CA (Certificate of analysis), and documents that the testing has been witnessed.
 - If testing is not witnessed, the HRC can rely on a valid CA for the strength determination, however, it must perform an identity test and periodically verify the reliability of the supplier's analysis.
 - Full USP testing would be required if the HRC neither witnesses the testing nor receives a valid CA.
- If the HRC owns or leases a stand tank, then an identity and strength test taken directly from the stand tank after each oxygen delivery must be performed before any VMVs are filled. VMVs filled from this stand tank need not be tested if:
 - There are no other stand tanks.
 - The VMVs are dedicated to the delivery of oxygen.
 - The VMVs filled from the stand tank have not been completely emptied or out of service.

TEST RESULTS MUST BE DOCUMENTED

TESTING OF CRYOGENIC HOME UNITS

- No testing is required as long as the following three criteria are met:
 - Liquid oxygen is the only liquid being transfilled.
 - Incoming liquid oxygen is adequately tested for identity and strength, according to one of the above methods. This requirement is important, in fact, the testing of the incoming oxygen in this scenario is considered finished product testing. What you have is liquid oxygen being repackaged into another cryogenic unit.
 - Cryogenic home units are retained by the home respiratory company.

(Note: If cryogenic home units are set out for repair/maintenance, then each home unit returned must be re-tested for identification, at the least, prior to redistribution. This is in accordance with Section 211.87 of the regulations.)

- If any other liquid is being transfilled, the ALL cryogenic home units returned to the facility for filling must be tested for identity and strength. This would include any home units that are returned, exchanged, out of service, or empty.