



Stability Storage: Buy or Rent?

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When a company is evaluating whether to buy a stability storage room or chamber – or lease space – there are several factors to consider.

Operating on-site stability storage includes expenses other than the purchase of a room or chamber. Additional expenses include:

- Cost of validation for the conditions required.
- Yearly calibration of temperature and humidity sensors.
- Back-up space in the event the main chamber goes out of specification or breaks down.
- Back-up generator to supply electricity to the stability area in the event of a power disruption.
- Initial extension and ongoing service costs of required utilities – water, drain, and power.
- Personnel to help monitor chamber and conduct performance maintenance.

Several factors should be considered when deciding whether to rent shelf space for stability storage or to purchase an on-site chamber or room. These factors include:

- Amount of product requiring storage.
- Length of time storage is required.
- Condition (temperature and RH) required according to ICH.
- Back-up contingencies.

The study's duration, the amount of space required and necessary environmental conditions can be related. For example, a company may have several chambers operating at 25/60 that could accommodate a small study for a specific length of time. But if the study requires uncommon conditions – such as 25/40 or 30/75 – the company may not have chambers operating at these conditions, so tapping existing excess space is not an option. At that point, the company needs to compare the total expense of purchasing an additional chamber versus the cost of renting space.

Renting stability storage space may not be as convenient as owning when it comes to pulling and testing samples. Companies renting stability storage should establish appropriate ship dates for samples taken from specific lots when signing a contract.

Some companies choose to store larger quantities of product off site and keep only the quantities required for scheduled pulls on site. This keeps on-site storage at a manageable level while providing the convenience of readily available samples.

A main benefit of renting stability storage is the fact that expenses can be spread across the duration of the study as compared to buying stability storage, which requires an upfront capital investment. Attached is a chart highlighting savings realized using off-site stability storage.



Precision Stability Storage Advantage

Case Study 1			
Size:	10 Cubic Foot		
Conditions:	25° C at 60%		
Duration:	24 months		
Expenses	Owning Chamber	Parameter Space	Savings
Stability Chamber with 3 shelves	\$ 17,000	Space Provided	
Utility installation	\$ 1,500	Included	
Validation	\$ 8,500	Included	
12 month recalibration	\$ 700	Included	
Monitoring (probe, cable, integration)	\$ 1,400	Included	
Leased Space (3 x 3 area at \$15 per sq.)	\$ 3,240	Included	
Utilities	\$ 4,000	Included	
Maintaince	\$ 1,200	Included	
Cost	\$ 37,540	\$ 4,800	\$ 32,740
Per Month (24 month period)	\$ 1,564	\$ 200	\$ 1,364
Extra Insurance			
Back up Space	\$ 33,540	Included	
Back up Electrical Generator	\$ 8,000	Included	
	\$ 41,540	\$ -	\$ 41,540
Total Cost	\$ 79,080	\$ 4,800	\$ 74,280
Per Month (24 month period)	\$ 3,295	\$ 200	\$ 3,095

Case Study 2			
Size:	200 Cubic Foot		
Conditions:	25° C at 60%		
Duration:	24 months		
Expenses	Owning Chamber	Parameter Space	Savings
Stability Room (installed and with shelving)	\$ 45,000	Included	
Utility installation	\$ 2,000	Included	
Validation	\$ 8,500	Included	
12 month recalibration	\$ 1,400	Included	
Personell -- study managment (excluding pulls)	\$ 10,000	Included	
Monitoring (probe, cable, integration)	\$ 1,400	Included	
Leased Space (10 x 10 area = \$1200 per month)	\$ 28,800	Included	
Utilities	\$ 4,800	Included	
Back-up Generator	\$ 8,000	Included	
Back-up Chamber (room, 10 x 10, validation, cal.)	\$ 85,700	Included	
Maintaince	\$ 1,200	Included	
Total 24-month Cost	\$ 196,800	\$ 96,000	\$ 100,800
Per Month (24 month period)	\$ 8,200	\$ 4,000	\$ 4,200

Expense of owning a chamber requires most of the investment at the beginning. Using Precision Stability Storage allows the expense to be spread across the duration of the study.

Precision Stability Storage provides off-site stability storage space for products that require ICH specified environmental conditions. We offer the highest-quality equipment and facilities available for environmental and humidity control. All of our rooms meet or exceed ICH guidelines and have been mapped and validated for FDA mandated long and short-term shelf life studies under various temperature and humidity requirements. Our strategic alliance partnership with Parameter Generation & Control allows us to offer Precision Stability Storage clients the highest-quality equipment and facilities available for environmental and humidity control. Learn more about us at <http://precisionstabilitystorage.com/>.