Universal Pharmaceutical Waste Regulations + USP <797> Recent Highlights

Florida Healthcare Engineering Association

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GOBBELL HAYS PARTNERS, INC.
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- GHP established in 1977
- Performed Services in Healthcare since the mid-1980's
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Pharmaceutical Waste Regulations

Review of Guidelines and Regulations Pertaining to Pharmaceutical Waste Handling

Objectives of Waste Management Program

- Comply with State and Federal Regulations
- Avoid Penalties by complying
    - State Fines = $50,000/day/violation
- Cost Savings
- Protect the Environment and Human Health
- Public Image

Pharmacy Waste Management – The Steps

The Steps to Managing Pharmacy Waste

1. Establish a Pharmacy Management Program
2. Identify your Hazardous and Non- Hazardous Waste
3. Implement Best Management Practices
4. Determine your Waste Generator Status
5. Comply with Guidelines for Transportation and Disposal

Pharmacy Waste Management – The Steps

The Steps to Managing Pharmacy Waste

STEP 1 - Establish a Pharmacy Waste Management Program

- Evaluate Current Program
- Commitment to Reducing Waste
- Facilitate and Encourage Training

Pharmacy Waste Management – The Steps

General Pharmaceutical Management

- Expired Pharmaceutical Audits (check for outdated drugs)
- Samples are included
- Verify drugs for reverse distribution
- If Discarded by Facility, Facility must make determination if material is non-haz or haz

Pharmacy Waste Management – The Steps

General Pharmaceutical Management (cont'd)

- Discourage "sewering" (disposal to drain) of any material
- Don't mix or dilute wastes
- Train staff

Pharmacy Waste Management – The Steps

Options for Handling Outdated Pharmaceuticals:

Option 1: Process all returns and wastes internally

- Segregate by manufacturer and their policy
- Use Manufacturer's return policy
- Policy should include; storage, labeling, shipping, and record keeping.
- Ship only returnable drugs to Reverse Distributor
- Non-returnable waste taken by waste handler

Pharmacy Waste Management – The Steps

Options for Handling Outdated Pharmaceuticals:

Option 2: Ship Drugs to Reverse Distributor for Handling

- Create written policy following RD's procedures
- Policy should include; storage, labeling, shipping, and record keeping
- http://ww2.doh.state.fl.us/irm00praes/praslist.asp
  Search the drop down list for Restricted Rx Drug Distributors-Reverse Distributors

Pharmacy Waste Management – The Steps

Options for Handling Outdated Pharmaceuticals:

Option 3: Reverse Distributor comes to site and Inventories Drugs and ships to their facility

- All Pharmaceuticals are shipped by Reverse Distributor
- Reverse Distributor sorts at their facility
- Reverse Distributor becomes the generator

Pharmacy Waste Management – The Steps

The Steps to Managing Pharmacy Waste

STEP 2 – ID Your Haz and Non-Haz Waste

- Per EPA, pharmaceuticals can be shipped as non-haz if shipping to RD and or manufacturer
- P, U and D listed wastes

Pharmacy Waste Management – The Steps

The Steps to Managing Pharmacy Waste

STEP 2 – ID Your Haz and Non-Haz Waste (cont'd)

- Universal Waste Rule (UWR) – allows LQG and SQG handlers of universal pharmaceutical waste to reduce their haz waste generator status by managing certain haz waste pharmaceutical as universal waste.

Pharmacy Waste Management – The Steps

Universal Waste Rule *applies* to:

- Pharmaceuticals that are non-viable and are discarded.
- Non-Viable means; Product can not be returned for credit.

Pharmacy Waste Management – The Steps

Universal Waste Rule *does not apply* to:

- Pharmaceutical returned for credit
- Spill residues, cleanup material, etc.

Note: Haz waste pharmaceutical not managed as universal waste shall be managed in accordance with Chapter 62-730, F.A.C. and shall be disposed of at a permitted haz waste TSD facility.

Pharmacy Waste Management – The Steps

STEP 2 – ID Your Haz and Non-Haz Waste

- Determine Your Handler Status
- Large Quantity Handler of Universal Waste, at any time;

- Accumulates 5,000 kilograms or more total of universal waste (batteries, pesticides, thermostats, lamps, or pharmaceuticals, calculated collectively).
- Accumulates universal pharmaceutical waste consisting of more than one kilogram total of pharmaceuticals listed in 40 CFR 261.33(e) as acutely hazardous waste (P-listed wastes). The designation as a large quantity handler of universal waste is retained through the end of the calendar year in which the universal waste is accumulated.

Pharmacy Waste Management – The Steps

STEP 2 – ID Your Haz and Non-Haz Waste

- Determine Your Handler Status
- Small Quantity Handler of Universal Waste is a Universal Waste handler that does ***not:***

A small quantity handler of universal waste is a universal waste handler that does ***not***:

- Accumulate 5,000 kilograms or more total of universal waste (batteries, pesticides, thermostats, lamps or pharmaceuticals, calculated collectively); or
- Accumulate universal pharmaceutical waste consisting of more than one kilogram total of pharmaceuticals listed in 40 CFR 261.33(e) as acutely hazardous waste (P-listed wastes).

Pharmacy Waste Management – The Steps

STEP 2 – ID Your Haz and Non-Haz Waste

Small Quantity Handler of universal waste may accumulate universal pharmaceutical waste for no longer than ***one year***

Large Quantity Handler of universal waste may accumulate universal pharmaceutical waste for no longer than ***six months***

Pharmacy Waste Management – The Steps

STEP 2 – ID Your Haz and Non-Haz Waste

What is Hazardous Waste?

- P, U and D listed wastes
- Acutely Hazardous Waste (P Listed)

  2.2 pounds (1 kilo)/Month = full hazardous waste regulations

Pharmacy Waste Management – The Steps

STEP 2 – ID Your Haz and Non-Haz Waste

P-listed Pharmaceutical Wastes–
These wastes are known as **acutely hazardous for toxicity.**

NAME	HW#
Nicotine	P075
Physostigmine	P204
Physostigmine salicylate	P188
Sodium Azide	P105
Strychnine	P108
Warfarin >0.3%	P001

U-listed Pharmaceutical Wastes – These wastes are hazardous for toxicity.

NAME	HW#
Acetone	U002
Chlorambucil	U035
Chloroform	U044
Cyclophosphamide	U058
Daunomycin	U059
Dichlorodifluoromethane	U075
Diethylstilbesterol	U089

Pharmacy Waste Management – The Steps

STEP 3 – Implement Best Management Practices

- Recordkeeping
- Spills
- Segregation
- Tracking Quantities
- No disposal to drain or diluting

Pharmacy Waste Management

Hazardous Pharmaceutical Waste Storage Accumulation

Pharmacy Waste Management – The Steps

STEP 4 – Determine Your Haz Waste Generator Status

CESQG = < 220 pounds of haz waste and < 2.2 pounds of acutely hazardous waste

SQG = 220 to 2,200 pounds of haz waste and < 2.2 pounds of acutely hazardous waste

LQG = > 2,200 pounds of haz waste and > 2.2 pounds of acutely hazardous waste

Remember this is for the entire facility!

Pharmacy Waste Management – The Steps

STEP 5 – Transportation and Disposal

- Use permitted transporter
- DOT Labeling
- Use permitted TSD
- Maintain manifests for all hazardous waste

Pharmacy Waste Management – The Steps

Key Summary Points

- Revisit your Pharmacy Waste Management Plan
- Evaluate your facility's compliance
- Reverse Distribution Options
- Evaluation your handler/generator status (Universal and Hazardous)
- Be sure to properly identify and segregate waste

http://www.dep.state.fl.us/waste/quick_topics/publications/shw/hazardous/HazardousWasteManagementforPharmacies.pdf

USP <797> Recent Highlights

Review of Florida Statute for Standards of Practice for Compounding Sterile Preparations (CSPs)

Florida Statute – 64B16-27.797

- Promulgated into Florida State Law on June 18, 2008
- Amended January 7, 2010
- Purpose to Provide Standards for:

1. Pharmaceutical Care
2. Preparation, Labeling and Distribution of Sterile Pharmaceuticals
3. Maintain Product Quality

Florida Statute – 64B16-27.797

Definitions:

- Anteroom – Area for hand hygiene and gowning; staging of components, CSP labeling, and distribution of sterile pharmaceuticals
- Biological Safety Cabinet (BSC) – Containment unit suitable for preparation of Low, Medium, and High risk agents where protection of product, personnel, and environment is needed.
- Buffer Area (AKA Cleanroom) – Area where activities of CSPs take place. Shall not contain sinks or drains – ISO Class 7 environment

Florida Statute – 64B16-27.797

Definitions: (cont'd)

- Class 100 Environment – Atmospheric environment that contains no more than 100 particles 0.5 microns in diameter or larger per cubic foot of air – Equivalent to ISO Class 5 environment

- Compounding Aseptic Isolator (CAI) – Form of Barrier Isolation specifically designed for CSP manipulation. It maintains an aseptic compounding environment throughout the CSP process. Any air exchange is HEPA filtered.

- High Risk Level CSPs – Products compounded where they are either non-sterile or at high risk of becoming non-sterile with infectious microorganisms (Note: All High Risk CSPs must be rendered sterile)

Florida Statute – 64B16-27.797

Definitions: (cont'd)

- ISO Class 5 Environment – Particulate contamination of not more than 3,520 particles 0.5 microns or larger per cubic meter of air, i.e., Laminar Airflow Workbench (LAFW), Bio-safety Cabinet (BSC), or Compounding Aseptic Isolator (CAI)

- ISO Class 7 Environment – Particulate contamination of not more than 352,000 particles 0.5 microns or larger per cubic meter of air

- ISO Class 8 Environment – Particulate contamination of not more than 3,520,000 particles 0.5 microns or larger per cubic meter of air

Florida Statute – 64B16-27.797

Definitions: (cont'd)

- Low Risk Level CSPs – Products compounded entirely within ISO Class 5 (Class 100) environment – Manipulations limited to no more than three sterile ingredients, products, components, or devices

- Medium Risk Level CSPs – Products compounded aseptically under Low-Risk Conditions – CSPs with more than 3 sterile drug products and requiring complex manipulations

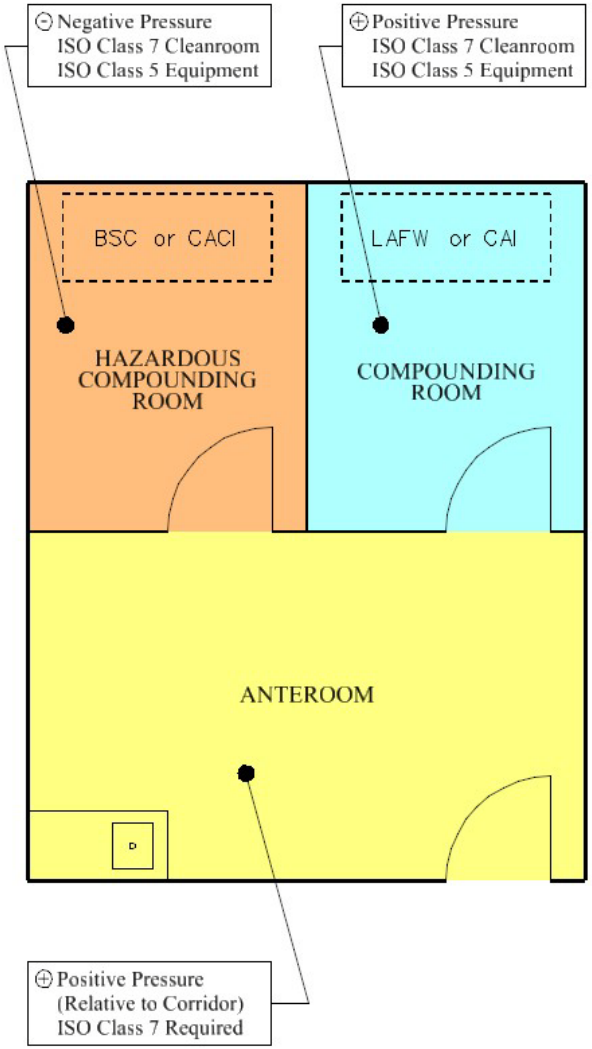
Determining Compliance

Required Room Option:

- Standardized Room Option A – Required if High Risk Level CSPs are performed and if Chemotherapy Preparations are performed along with Medium and Low Risk CSPs

- Standardized Room Option B – Required if Medium Risk Level CSPs are the highest risk level CSP's that are performed

- Standardized Room Option C – Required for only Low Risk Level CSPs or if utilizing a CAI, or glove box for higher risk preparations



Standardized Room – Option A

General Requirements:

Floors: Medical sheet vinyl with heat-welded seams and integral cove base.

Walls: Epoxy-painted gypsum board or other approved impervious material.

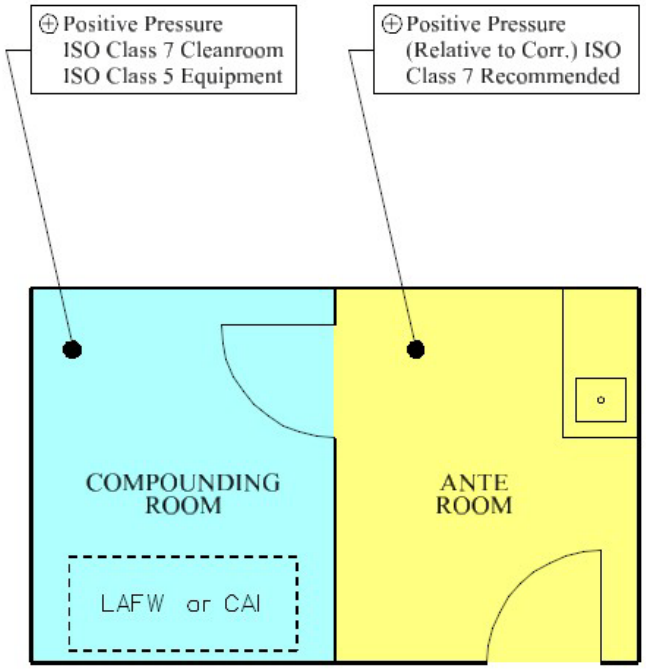
Ceilings: Epoxy-painted gypsum board or Mylar-coated medical-grade ceiling tiles with perimeter of tiles fully-sealed to ceiling grid.

Storage: Bulk inventory shall be stored in a separate location outside the compounding and anterooms.

Sinks: At least (1) sink should be provided in Anteroom. Sinks and floor drains are prohibited inside compounding rooms.

Hazards: All hazardous compounding, such as chemotherapy product manipulations, shall be performed in the designated hazardous compounding location.

Standardized Room – Option B



General Requirements:

Floors: Medical sheet vinyl with heat-welded seams and integral cove base.

Walls: Epoxy-painted gypsum board or other approved impervious material.

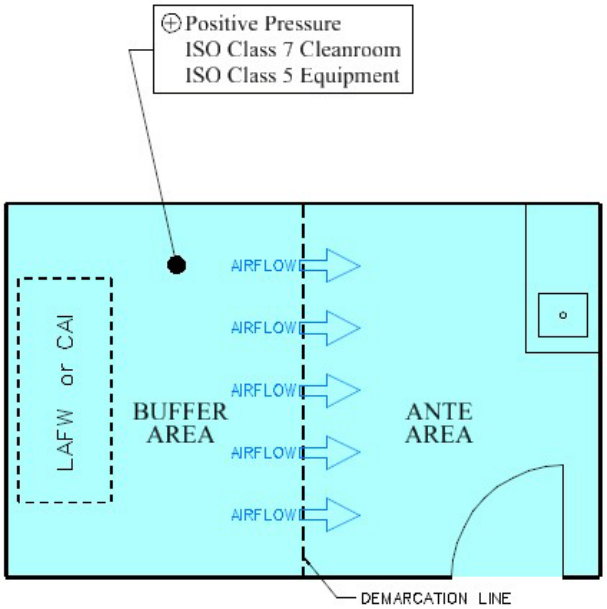
Ceilings: Epoxy-painted gypsum board or Mylar-coated medical-grade ceiling tiles with perimeter of tiles fully-sealed to ceiling grid.

Storage: Bulk inventory shall be stored in a separate location outside the compounding and anterooms.

Sinks: At least (1) sink should be provided in anterooms. Sinks and floor drains are prohibited inside compounding rooms.

Hazards: All hazardous compounding, such as chemotherapy product manipulations, are performed in separate locations outside this suite.

Standardized Room – Option C



General Requirements:

Floors: Medical sheet vinyl with heat-welded seams and integral cove base.

Walls: Epoxy-painted gypsum board or other approved impervious material.

Ceilings: Epoxy-painted gypsum board or Mylar-coated medical-grade ceiling tiles with perimeter of tiles fully-sealed to ceiling grid.

Storage: Bulk inventory shall be stored in a separate location outside the compounding and anterooms.

Sinks: At least (1) sink should be provided in Anteroom. Sinks and floor drains are prohibited inside compounding rooms.

Hazards: All hazardous compounding, such as chemotherapy product manipulations, are performed in separate locations outside this suite.

Determining Compliance

Standard Information to Obtain:

- What volume of High Risk Level CSPs and/or Chemotherapy Preparations are prepared on a regular basis along with Medium and Low Risk CSPs?
- If Medium Risk Level CSP's are the highest risk performed, what volume are prepared on a regular basis?
- If Low Risk Level CSPs are the highest risk performed, what volume are prepared on a regular basis?

Determining Compliance

Standard Information to Obtain:

- Are Chemotherapy Preparations made in a BSC or CAI barrier isolators?
- Are High, Medium , or Low Risk CSPs manipulations performed within an ISO Class 5 Environment, such as a LAFW or a room designed to meet that requirement?
- Are the IV or Chemotherapy Preparation spaces separated from the rest of the General Pharmacy by an Anteroom?

Determining Compliance

Standard Information to Obtain:

- Is the Buffer Area surrounding any ISO Class 5 Equipment designed and tested to an ISO Class 7 Environment?
- Have the spaces or LAFW and BSC equipment been certified within the past year?
- Regardless of Risk Level is there a handsink located adjacent to or in the immediate vicinity of any ISO Class 5 Equipment

Determining Compliance

Standard Level of Room Finish:

- Are the floor finishes seamless and easy to clean?
- Are walls and ceilings finished with an easily cleanable material or coating? (Typically, ceilings in IV and Chemo Prep spaces are a hard inaccessible type)
- Are casework, countertops, shelving units, and work tables constructed of homogenous materials that contain no fibrous material, such as wood or paper products? Ideal materials are metal with baked paint finish or stainless steel and solid surface countertops are typical.

Determining Compliance

Standard MEP Measures:

- Are light fixtures sealed and gasketed?
- Is the supply air cleaned by HEPA filtration? If a BSC is utilized, is it exhausted directly to the outside air with a hazardous exhaust type vent stack?
- Are pressure gauges located outside each individual space providing constant pressure readings between the different spaces?
- Are AHUs and other electrical items served by the Critical Emergency Power Branch Circuits?

Maintaining Compliance

Standard Documentation Requirements:

- Policy and Procedure Manual – Prepared and maintained for the compounding, dispensing, and delivery of sterile preparations. This manual shall be available for inspection by the Board of Pharmacy and shall include:

  - Use of single and multiple dose containers….
  - Verification of compounding accuracy and sterility
  - Personnel training and evaluation in aseptic manipulation skills
  - Environmental Quality and Control Information (See information below)
  - Personnel monitoring and validations
  - Finished Products checks and tests
  - Etc.

Maintaining Compliance

Standard Documentation Requirements:

- Policy and Procedure Manual (Cont'd.)
  - Environmental Quality and Control Information shall include the following:
    - Air particulate monitoring for the hoods, clean room, and buffer area
    - Unidirectional airflow – pressure differential monitoring
    - Cleaning and disinfecting the sterile compounding areas
    - Personnel cleansing and gowning
    - Environmental monitoring – air and surfaces

Florida Statute – 64B16-27.797

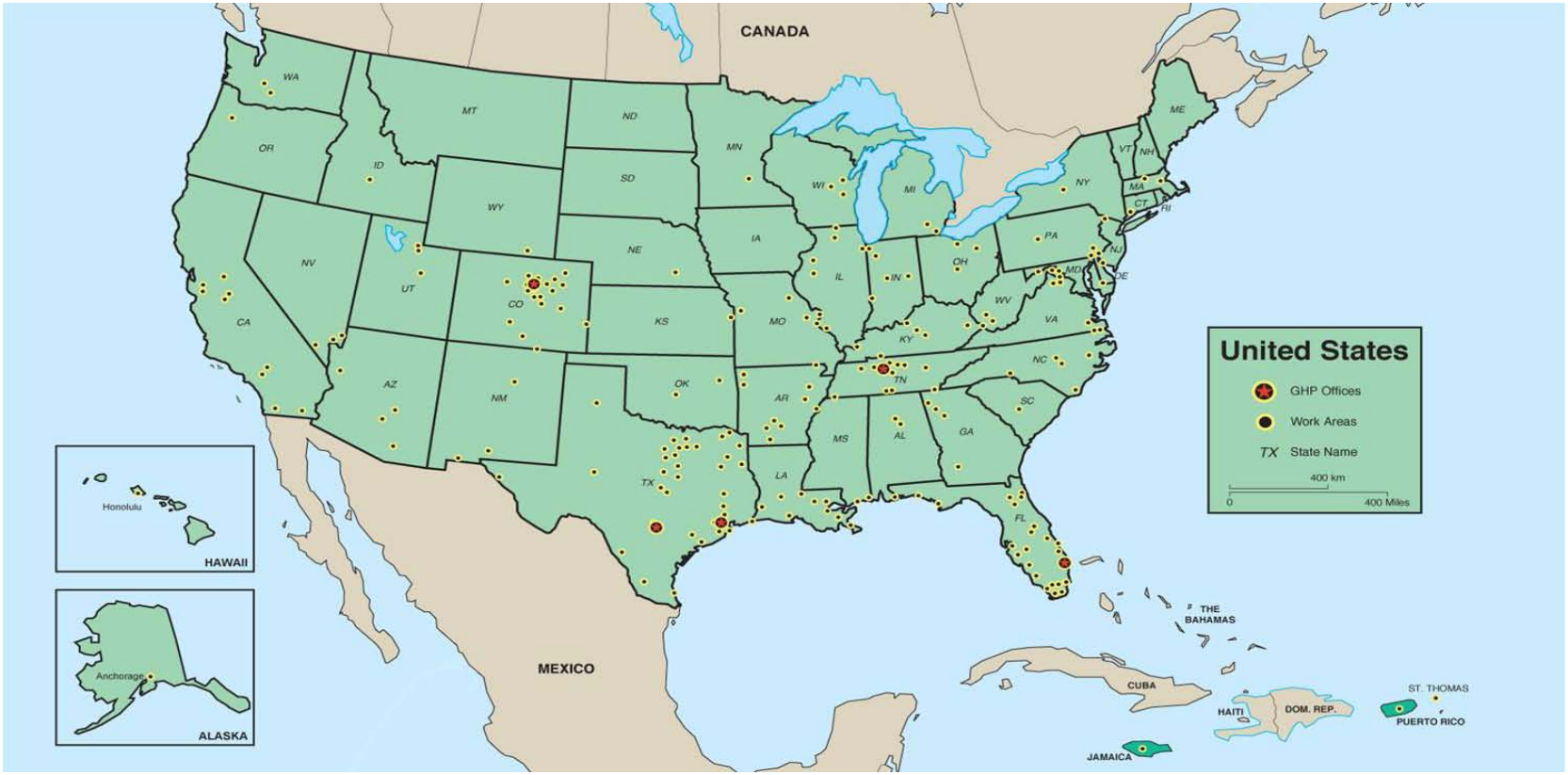
Main Difference between June 18, 2008 version and version Amended January 7, 2010

- Addition of Radiopharmaceuticals as CSPs:
  - Upon release of a PET radiopharmaceutical as a finished drug product requiring further manipulation, handling, or use will be considered to be compounding complying with these rules
  - As long as they are contained, they may be Low Risk
  - Manipulation of blood products shall be in conducted in an environment similar to Standardized Room Option B at minimum.

Thank You!

Questions or Comments?

Gobbell Hays Partners, Inc.



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