

**HEALTH FACILITIES ADVISORY COMMITTEE (HFAC)**  
**MEETING MINUTES**

**February 29, 2008, 12:00 P.M. (Eastern Time)**

**Roll Call:**

Chairman: Mr. Tommy Bowman X

Vice-Chairman: CAPT Keith Shortall X

Members: CAPT Jose Cuzme X CAPT Dale Mossefin ( )  
Mr. Jim Biasco X CDR Brian Hroch X  
Mr. Ken Harper X LCDR Mat Martinson X

Alternates: CAPT Michael Weaver, Mr. Kevin D'Amanda, Mr. Howard  
Wellspring

Guests: CAPT Gary Gefroh

**Approval of the previous meeting minutes:** Jim motioned to approve meeting minutes of Jan 30, 2008, as is. Brian seconded motion. **Motion passed without objection.**

**Old Business:**

- Approval of new Chapter – USP 797 Pharmacy Room.
  - Brian confirmed he had contacted other organization regarding their intention of using USP 797. Jerry Gervais, The Joint Commission (TJC) informed Brian TJC is not using USP 797. CMS representative stated she was unaware of using USP 797 but stated they may use it and were currently relying upon “best management practice”. Brian sent draft technical handbook chapter to a group of IHS Pharmacists, including CAPT Dan Diggins and CAPT Ray Cope. They commented on the threshold for low use of hazardous drug. They felt that less than 5 drugs per month is a fair threshold. Michael stated Rocky Mountain Lab informed him they had nothing. Jose contacted RADM Robert Pittman, Pharmacist at NIH, who stated they had no application for USP 797. Jose said he needed to check with *Stone Reagan*. But the group decided it was not necessary to delay action on this technical handbook chapter.
  - Brian, Gary, Paul Ninomura, Keith Cook, and Mark Strauss discussed required number of air changes prior to this HFAC conference call. They concurred to recommend 15 ACH. Mat questioned if CDC had

**PART XX - DESIGN CRITERIA AND STANDARDS**

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been consulted because they the “guru” for hazardous substance standards. He stated a hazardous drug room differed from a clean room. Brian responded that he had reviewed NIOSH and IHS Circular regarding occupancy exposure and concluded that only 12 ACH was required. But the USP 797 workgroup recommended 15 ACH of total air exchanges based upon 2 ACH of outdoor air for Protective Environment room and liability and compliance concerns. Gary added that the biological safety cabinets required 20-30 ACH and that would overpower the room.

- Brian agreed with Paul’s memorandum that HEPA filters were overkill and that 90% efficiency filters (MERV 14) were adequate. Paul’s memorandum equated the air quality/cleanliness of an operating room to be sufficiently clean environment for a pharmacy clean room. The *FGI Guidelines for Design and Construction of Health Care Facilities* required 90% efficiency filters.
- Brian stated the 40 fpm air movement was too difficult to measure and to design for; therefore, this requirement was dropped from the proposed technical handbook chapter.
- Brian explained the temperature requirement. Rather than adopt a temperature requirement less than 68 degrees (Fahrenheit), he stated the temperature range for an operating room (68 deg to 73 deg) was reasonable for pharmacist wearing personal protective equipment (PPE).
- Reference Decision Matrix on page 9 of 12, Brian emphasized that the statement, “No HD room/equipment is needed” meant that low usage rates would be accomplished by out-source contract rather than no room or equipment was required.
- Reference Decision Matrix on page 8 of 12, Keith asked if the \$60k capital cost was adequate. Ken responded that it was based upon costs for Health Center at Annette Island, Alaska in 2007 dollars and that this amount was adequate.
- Reference page 5 of 12, Note 2, Jose asked if the Note required 30 ACH. Brian responded no.
- Jose requested that all acronyms be spelled out initially (ISO, USG).
- Reference page 2 of 12, definition for “Compounded Sterile Preparations (CSP)”, Keith stated his pharmacist, Randy Haigh, commented that the definition appeared contradictory. Brian explained he used the text from [www.pharmacyisolators.com](http://www.pharmacyisolators.com). Keith stated he wasn’t too concerned because IHS didn’t do it anyway.

- Jose made motion to approve this proposed technical handbook chapter for pharmacy's design criteria and standards, as is. Brian seconded motion. **Motion passed without objections.**
- Brian asked what the next step is. Ken replied to send a clean copy of this chapter to Tommy, who will forward it to Lee Robinson. Jim added to include header, "Draft Approved by HFAC" to clearly identify to Lee that this version had been approved by the HFAC. Keith asked if the chapter could be put on the fast-track because he had a need to use it now. Ken replied yes.
- Approval of Technical Handbook Chapter 21-15 Security Level Selection FOR USE IN THE DESIGN OF NEW FEDERAL FACILITIES.
  - Michael stated the proposed edits by Sid Caesar were extensive. He suggested tabling approval and invite Sid to participate in the next HFAC conference call in April.
  - Ken commented that the proposed edits mixes operation with construction requirements.
  - Jim suggested HFAC members submit their comments to Michael a couple of weeks before the next HFAC conference call and for Michael to compile comments and send to Sid. Tommy pinned down the date for submitting comments to Michael on March 19, 2008.
  - Michael asked what training was being offered by Sid in an e-mail sent to Tom Gaulke and if that training affected any building parameters.
  - Ken suggested that this technical handbook should state the building parameters rather than create an approval process by the Sid and his security staff.
  - Jim disagreed and stated the Security staff needs to approve or at least review the building design to ensure updated security requirements or overlooked requirements are incorporated into the design of new buildings.
  - Keith asked Ken if the security requirements would apply only to federally own and operated facilities and not include 638 projects. Ken and Tommy responded that the security requirements should be presented to the tribe as a benefit – not as a “have to do” and to negotiate this requirement into the 638 contract **for Tribally owned and/or operated facility.** [Inserted revision]

- Jim reiterated his position that the security requirement should be defined by the security staff and not by HFAC.

**New Business:**

- Review of updates to Technical Handbook Chapters.
  - Michael updated members on the status of Technical Handbooks. He stated the member names on the webpage has been updated except the spelling of Brian's last name and naming an alternate for Mat.
  - Technical Handbook Chapter 21-5 Electrical Guide has been approved and sent to Lee for review.
  - The International Property Management Code has been sent to the Code Committee for review and comment.
  - Michael described the inconsistency between the Technical Handbook Chapter 24-2 Applicability of Codes and the A/E Guide regarding the International Building Code. The proposal to correct this inconsistency was to delete reference to the Uniform Plumbing, Uniform Mechanical, and Uniform Electrical code listed under the International Building Code in the technical handbook but still keep the International Building Code. Tommy asked the HFAC if a new vote to approve this minor clarification was necessary. Jim agreed it was not necessary; no one else voiced an objection. The previous approved Technical Handbook Chapter 24-2 with the above proposed edit was accepted.

**Action Items:**

- Brian to send clean Technical Handbook Chapter on USP 797 to Tommy.
- HFAC members to submit comments regarding Technical Handbook Chapter 21-15 Security Level, to Michael no later than March 19, 2008.
- Jose to notify Sid Caesar to expect receipt of these comments and invite him to participate on the next HFAC conference call.

**Next Meeting:** April 17, 2008 at 12:00 p.m. (Eastern Time).

**Adjournment:** Mat motioned to adjourned. Brian seconded motion. All were in favor. Motion passed.

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OFFICE OF ENVIRONMENTAL HEALTH AND ENGINEERING TECHNICAL HANDBOOK  
INDIAN HEALTH SERVICE  
VOLUME III - HEALTH CARE FACILITIES DESIGN AND CONSTRUCTION  
**PART XX - DESIGN CRITERIA AND STANDARDS**

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Attachments:

- ATTACHMENT 1 Agenda Conference Call
- ATTACHMENT 2 Link to HFAC Meeting Minutes for January 30, 2008
- ATTACHMENT 3 Draft Tech Handbook - Pharmacy
- ATTACHMENT 4 DRAFT Tech Handbook Security Level Selection
- ATTACHMENT 5 Memo Mechanical Engineer DES-Seattle to Director DES-Dallas

ATTACHMENT 1 Agenda Conference Call

**Conference Call: # 888-455-3614**  
**Pass Code: 26537**

**Roll Call:**

Chairman: Mr. Tommy Bowman ( )  
Vice-Chairman: CAPT Keith Shortall ( )  
Members: CAPT Jose Cuzme ( ) CAPT Dale Mossefin ( )  
Mr. Jim Biasco ( ) CDR Brian Hroch ( )  
Mr. Ken Harper ( ) LCDR Matt Martinson ( )

**Approval of the previous meeting minutes** (Jan 30, 2008)

**Old Business:**

- Approval of new Chapter – USP 797 Pharmacy Room
- Approval of Technical Handbook Chapter 21-15 Security Level Selection FOR USE IN THE DESIGN OF NEW FEDERAL FACILITIES

**New Business:**

- Review of updates to Technical Handbook Chapters

**Next Meeting:** April 16, 2008 at 12:00 p.m. (Eastern Time)

Attachments:

**Attached were the Technical Handbook Pharmacy Chapter  
and the 21-15 Security Level Selection 12-8-05**

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ATTACHMENT 2 Link to [HFAC Meeting Minutes for January 30, 2008](#)

**ATTACHMENT 3 Draft Tech Handbook - Pharmacy**

**CHAPTER XX-X PHARMACY ENVIRONMENTAL RECOMMENDATIONS**

XX-X.1 INTRODUCTION .....1  
XX-X.2 GUIDELINES .....2  
XX-X.3 Table 1 (Construction Guidelines) .....3  
XX-X.4 Table 2 (Critical Work Environments) .....6  
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XX-X.6 CSP/HD Decision Matrix-Flow Sheet .....9  
XX-X.7 Diagram 1 Clean Room: Low & Medium Risk CSP's .....11  
XX-X.8 Diagram 2 CSP & Hazardous Drug Prep Rooms .....12

**XX-X.1 INTRODUCTION**

- A. PURPOSE - This chapter provides minimum design guidance for Indian Health Service (IHS) pharmacies to provide an environment conducive to providing the safest and contamination-free compounded sterile preparations and hazardous drugs.
- B. SCOPE - The scope of Chapter XX-X includes all new construction and renovation for IHS and Tribal health care facilities.
- C. BACKGROUND - In 2002, the Center's for Disease Control and Prevention published a Morbidity and Mortality Weekly Report, which advised that "clinicians should consider the possibility of improperly compounded medications as a source of infection in patients". This was the beginning of an increased focus to provide controlled environments and practices when compounding sterile preparations.

This design guidance seeks to address only the aspects of compounding sterile preparations and hazardous drugs that are related to the built environment (architectural, mechanical, and electrical).

D. DEFINITIONS

- (1) Ante Area/Room - An ISO 8 or better area/room where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate generating procedures are performed (text from USP-797-2008).
- (2) Biological Safety Cabinet (BSC) - A ventilated cabinet for protection of Compounded Sterile Preparations, personnel, product and/or the environment, which has an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. (text from USP-797-2008)

- (3) Buffer Area/Zone - An ISO 7 or better area/zone where the primary engineering control (PEC) is physically located. (text from USP-797-2008)
- (4) Compounding aseptic containment isolator (CACI) - An environmental isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. (text from USP-797-2008)
- (5) Compounded Sterile Preparations (CSP)- A biologic, diagnostic, drug, nutrient, or pharmaceutical which is prepared according to the manufacturer's labeled instructions, contains non-sterile ingredients or uses non-sterile components/devices that need to be sterilized before use. (text from [www.pharmacyisolators.com](http://www.pharmacyisolators.com))
- (6) Primary Engineering Control (PEC) - A device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSPs. Examples include BSCs, CACIs and LAFWs. (text from USP-797-2008)
- (7) Laminar Air Flow Workbench (LAFW) - A controlled environment created by a high efficiency particulate air (HEPA) filter to retain airborne particles and microorganisms. (text from Compounding Sterile Preparations, 2<sup>nd</sup> ed., Buchanan, Schneider)

## **XX-X.2 GUIDELINES**

### **A. GENERAL DESIGN CRITERIA**

- (1) When practical, locate air handling unit outside of pharmacy area to avoid dust/debris generation, within pharmacy area, during maintenance activities, e.g., filter replacement, etc..
- (2) For facilities that perform "Low" and/or "Medium" risk procedures, as defined in USP 797-2008, an ante area or ante room shall be provided adjacent to the buffer room. Please see "Diagram 1 - Clean Room: Low & Medium Risk CSP's"
- (3) For facilities that perform "High" risk procedures, as defined in USP 797-2008, the buffer room shall be physically separated and adjacent to the ante room.

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- (4) For CSP and hazardous drug buffer rooms/areas, the square footage should be as small as functionally necessary, to limit the storage of unnecessary materials. For facilities that anticipate compounding small volumes of hazardous drugs, these facilities should store their hazardous drugs, outside of their cardboard containers, in the buffer zone, which would be under negative pressure.
- (5) For facilities that perform hazardous drug procedures, as defined in USP 797-2008, the hazardous drug prep room should be located immediately adjacent to the CSP buffer zone or area. Please see "Diagram 2 - CSP & Hazardous Drug Prep Rooms".
- (6) Hazardous drugs are a group of drugs that are associated with or suspected of causing adverse health effects. A current list of drugs commonly classified as "hazardous drugs" may be found at [www.cdc.gov/niosh](http://www.cdc.gov/niosh). Additional "hazardous drug" information and IHS requirements may be found at The Indian Health Manual (IHM) Part 3 - Professional Services, Chapter 27-Controlling Occupational Exposure to Hazardous Drugs.
- (7) For guidance in selecting the most appropriate means of providing CSPs and Hazardous Drugs, please refer to the "CSPs/HDs Questionnaire" and the "CSP/HD Decision Matrix - Flow Sheet".

B. SPECIFIC DESIGN CRITERIA - The rooms used for compounding sterile preparations shall comply with the design recommendations listed below in Table 1 and Table 2. For additional information, please refer to "Diagram 1 - Clean Room: Low & Medium Risk CSP's" and "Diagram 2 - CSP & Hazardous Drug Prep Rooms".

Table 1 Construction Guidelines for Pharmacy Compounding Sterile Preparation Rooms New Construction and Major Renovation			
	COMPOUND STERILE PREPARATION	HAZARDOUS DRUG PREPARATION	ANTE AREA
Air Quality (Note 1)	ISO Class 7 in buffer area/zone.	ISO Class 7 in buffer area/zone	ISO C1
Air filtration	Air supply shall be filtered with filters rated as 90% efficient filter (MERV <span style="border: 1px solid black; padding: 2px;">Comment [BEH1]: Is there a MERV rating associated with this type of filter?</span> )		
Minimum total Air	15 ACH	15 ACH	15 ACH

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Table 1 Construction Guidelines for Pharmacy Compounding Sterile Preparation Rooms New Construction and Major Renovation			
	COMPOUND STERILE PREPARATION	HAZARDOUS DRUG PREPARATION	ANTE AREA
Changes per Hour (ACH) (Notes 2 & 3)		For hazardous drug storage areas, 12 ACH	<b>Comment [BEH2]:</b> Other option is to provide this as a note.
Minimum outdoor Air Changes per Hour (ACH) (Note 4)	2 ACH	2 ACH	2 ACH
Air Movement relationship to adjacent areas For additional information, please refer to Diagrams 1 & 2	Out	In (from Compound Sterile Preparation area)	In (from Comp Preparation area) Out (to all other areas).
Pressure Differential Monitoring (Note 5)	In locations with a physical barrier and a doorway or other penetration is present permanently installed visual mechanism to constantly monitor the relative pressure be installed. In these locations with physical barriers, a relative pressure difference 0.01" water gauge (2.5 Pa)		
	Locations with a line of demarcation, (buffer area and ante-area) shall be designed air will move/flow from "clean" to "less clean" areas, as displayed in Diagrams 1 a		
Humidity (Note 4)	30 – 60% RH	30 – 60% RH	30 – 60% RH
Temperature °C / °F (note 6)	20-23°C (68-73°F)	20-23°C (68-73°F)	20-23°C <b>Comment [BEH3]:</b> The current chapter calls for 20°C (68°C) or less to maintain comfortable conditions for compounding personnel when attired. It would seem reasonable to leave this as is.
Floor drains and sinks	No floor drains or sinks in buffer area/zone	No floor drains or sinks in buffer area/zone	Provide in ante area/room should be designed hands-free, such sensitive or focus

**Table 1**  
**Construction Guidelines for Pharmacy Compounding Sterile Preparation Rooms**  
**New Construction and Major Renovation**

	COMPOUND STERILE PREPARATION	HAZARDOUS DRUG PREPARATION	ANTE AREA
Ceilings (Note 7)	Smooth, impervious, free from cracks and crevices, non shedding and resistant to agents. For example: <ul style="list-style-type: none"> <li>• finish drywall with epoxy-painted finish</li> <li>• coated ceiling tiles in anodized aluminum T-bar grid (lock down clips required; tiles should be sealed to the grid and perimeter of grid should be caulked).</li> <li>• Interior Acoustical Tile Panel Model 3270-15096, 5/8 inch thick; rated "G".</li> </ul>		
Floor (Note 7)	Smooth, impervious, free from cracks and crevices, non shedding and resistant to agents. Typically: <ul style="list-style-type: none"> <li>• sheet vinyl with joint sealing technique of grooved, melted, welded, vinyl floor impervious waterproof seal. Provide seamless sheet vinyl base integral with flooring, using the same joint sealing technique.</li> </ul>		
Wall finish (Note 7)	Smooth, impervious, free from cracks and crevices, non shedding and resistant to agents. For example: <ul style="list-style-type: none"> <li>• finish drywall with epoxy-painted finish or FRP sheets</li> </ul>		
Doors	Epoxy-painted door/frame with no ledges (flush with walls).		
Windows	Anodized aluminum frames with no ledges with tempered safety glass.		
Light fixtures	Recessed "clean room" fixture sealed to grid or fixture frame. Acrylic lens with buff finish.		
Shelving & Fixtures	Stainless Steel Wire racks/shelving, washable counters, and minimal horizontal surfaces		

Note 1: Reference USP 797, 2008 revision.

Note 2: These 15 ACH are to be provided exclusively by the room, with an additional 15 ACH to be provided by the Primary Engineering Control (PEC).

Note 3: In order to maintain the specified relative pressure relationships, the PEC's rate of exhausted air must be considered. More than 15 ACH (Supply) may be required to overcome the PEC's exhaust rate.

Note 4: Humidity range from AIA Guidelines for Design and Construction of Hospitals and Health Care Facilities (2006)

Note 5: AIA Guidelines for Design and Construction of Hospitals and Health Care Facilities (2006) Table 2.1-2 Foot Notes 2 and 11.

Note 6: AIA Guidelines for Design and Construction of Hospitals and Health Care Facilities (2006) Table 2.1-2. 20-23°C (68-73°F) is the design temperature for rooms where additional protective clothing and Personal Protective Equipment

are also worn to reduce contamination and ultimately microbial growth and infection.

Note 7: Avoid condensation /trapping warm moist air on cold, impervious surfaces resulting in moisture accumulating on gypsum wall board.

Note 8: (Source: Specifications for Health Center at Annette Island, AK)

Table 2 Guidelines for Pharmacy Compounding Sterile Preparation Critical Work Environments (see Note 9) New Construction and Major Renovations		
	COMPOUND STERILE PREPARATION	HAZARDOUS DRUG PREPARATION
Critical work environment	Laminar Airflow Workbench (LAFW) (See Note 10)	Biological Safety Cabinet; Class II Type B1, Class II Type B2, or Class III. LAFW's are not to be used for hazardous drug preparations. Compounding Aseptic Containment Isolators should not be used (Note 10)
Air Quality	ISO Class 5	ISO Class 5

Note 9: The "critical work environment" is the site where drugs are exposed to air in the physical environment and where active manipulation occurs. For CSPs, this will be the workbench of the LAFW or inside the BSC. For hazardous drugs, this will be the inside of the BSC.

Note 10: At the time of this issuance, compounding aseptic containment isolators (CACI's) are not currently recommended, except for unique applications. There is a general consensus that instead of using CACI's, it is more practical and efficient to use either: 1) laminar air flow workbenches (LAFW's) for compounding sterile preparations (CSP's) or 2) biological safety cabinets (BSC's) for CSP's and/or hazardous drugs.

file name: *technical handbook pharmacy chapter (feb 13 2008) merged draft.doc*

## CSP/HD Questionnaire

The following questionnaire is intended to assist in determining the appropriate equipment, construction, and/or method of providing Compounded Sterile Preparations (CSP)/Hazardous Drug (HD) services in compliance with United States Pharmacopeia (USP) guidelines. The following questions and decision matrix need to be considered as part of the determination process. This process should involve pharmacy and possibly facilities staff depending on the matrix factors that are involved.

### **1. Clinical Need for HD's (# of HD's Prepared/month)**

<b>a. Current Need (1-5 year)</b>		<b>b. Projected Need (5-10 year)</b>	
None		None	
Low	< 5/mth	Low	< 5/mth
Medium	5-20/mth	Medium	5-20/mth
High	> 20/mth	High	> 20/mth

### **2. Clinical Need for CSP's (# CSP's Prepared/month)**

<b>a. Current Need (1-5 year)</b>		<b>b. Projected Need (5-10 year)</b>	
None		None	
Low	< 5/mth	Low	< 5/mth
Medium	5-20/mth	Medium	5-20/mth
High	> 20/mth	High	> 20/mth

### **3. Availability of HD Services**

**Are HD services reasonably available from other sources (IHS or Contract)?**

Shipping, travel, transportation, timely, reliability, cost, etc.

<b>a. HD Services available (1-5 year)</b>	<b>b. HD Future availability (5-10 year)</b>
Yes	Yes
No	No

### **4. Availability of CSP Services**

**Are CSP services reasonably available from other sources (IHS or Contract)?**

Shipping, travel, transportation, timely, reliability, cost, etc.

<b>a. CSP Services available (1-5 year)</b>	<b>b. CSP Future availability (5-10 year)</b>
Yes	Yes
No	No

### **5. Availability of Pharmacy staff to prepare CSP's/HD's In-house**

(Includes permanent, temporary, and/or contract staff/service)

<b>a. CSP staff available (1-5 year)</b>	<b>b. CSP future staff available (5-10 year)</b>
Yes	Yes
No	No

**6. Technical Expertise – Clinical Staff (Nursing, Physicians, etc.)**

(Includes permanent, temporary, and/or contract staff/service)

Staffing available to prescribe, administer, and manage HD's/CSP's?

- |  |   |
|--|---|
| <p><b>a. Current staffing (1-5 years)</b></p> <p style="padding-left: 20px;">Yes</p> <p style="padding-left: 20px;">No</p> | <p><b>b. Future staffing (5-10 year)</b></p> <p style="padding-left: 20px;">Yes</p> <p style="padding-left: 20px;">No</p> |
|--|---|

**7. Technical Expertise – Support Programs (Maintenance, Biomed, Certifiers, etc.)**

(Includes permanent, temporary, and/or contract staff/service)

Staffing available to operate/maintain rooms (Heating, Ventilation, and Air Conditioning (HVAC), High Efficiency Particulate Air (HEPA) filters, etc.) and equipment (Laminar Air Flow Workbench (LAFW), Biological Safety Cabinet (BSC), and/or Compounding Aseptic Containment Isolator (CAICACI)).

- |  |   |
|--|---|
| <p><b>a. Current staffing (1-5 years)</b></p> <p style="padding-left: 20px;">Yes</p> <p style="padding-left: 20px;">No</p> | <p><b>b. Future staffing (5-10 year)</b></p> <p style="padding-left: 20px;">Yes</p> <p style="padding-left: 20px;">No</p> |
|--|---|

**8. Room/Equipment Operational Costs (PMs, Certification, Testing/Sampling)**

Room PM costs (HEPA filters, belts, etc.)	\$ 300.00/Year
(Particle & Biological sampling)	\$ 200.00/Year
LAFW PM costs (Filters, Testing/etc.)	\$ 200.00/Year
(6 month certification x 2/year)	\$ 400.00/Year
BSC PM (Filters, Testing/etc.)	\$ 200.00/Year
(6 month certification x 2/year)	\$ 400.00/Year
CAICACI PM costs (Filters, Testing/Certifications)	\$ 200.00/Year
(6 month certification x 2/year)	\$ 400.00/Year

**9. Capital Costs (Room, HVAC, & Equipment)**

CSP room with HD room (300 square feet)	\$ 60,000.00
LAFW with installation & initial certification	\$ 4,800.00
BSC with installation & initial certification	\$ 7,500.00
CAICACI & initial certification	\$ 17,000.00

**Note 1:** USP-797 allows a BSC to be placed into the CSP room/area if less than 5 HD preparations/week. This would reduce the capital costs of construction, increase the administrative procedures (staff protection), and would reduce maintenance PM costs.

**Comment [BEH4]:** Question for Pharmacists. What would be a reasonable weekly number to consider as "rare" for hazardous drugs preparations. of Hazardous Comment by Keith Cook "We might consider another threshold instead of five for "low." It might be a facility that does not plan on doing hazardous drug preparations, but may do so on a rare occasion to meet temporary patient needs. If the board or governing body is to allow any regular (even if it is low) preparation of hazardous drugs then it should be done in a BSC or other appropriate PEC. Once a governing body makes the decision to do a low amount of HD preparation, the number will only go up over time."

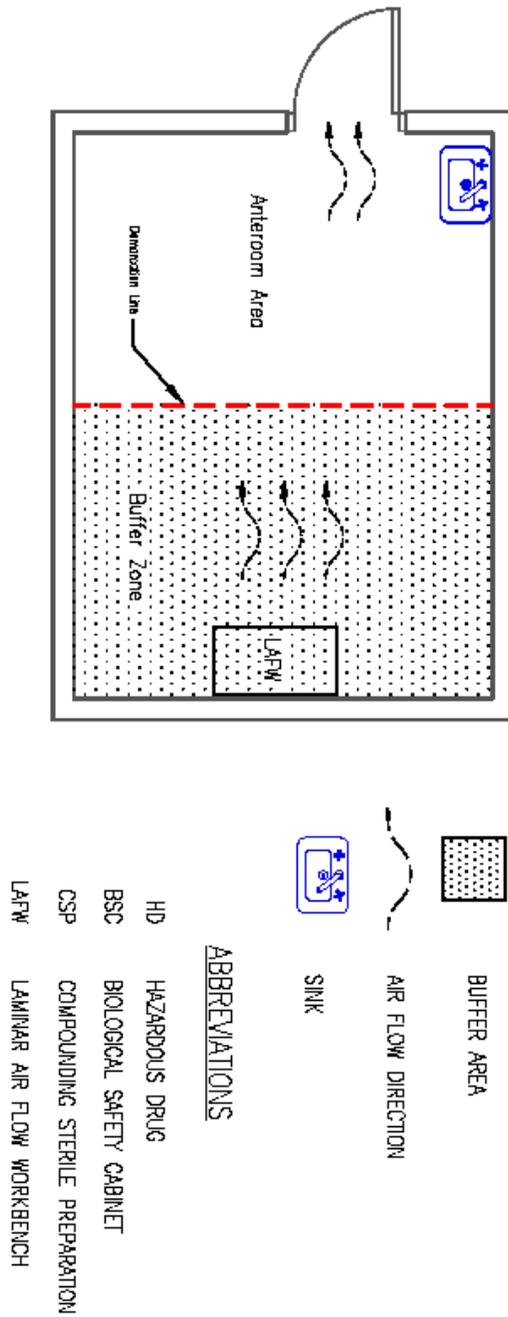
**Note 2:** All cost estimates are in 2007 dollars.

**CSP/HD Decision Matrix – Flow sheet**

Questions 1 & 2 address the “clinical need” for HD’s and/or CSP’s.	
<b>FACTOR</b>	<b>DECISION</b>
If the answer to 1a & 1b are “none”	No HD room/equipment is needed.
If the answer to 2a & 2b are “none”	No CSP room/equipment is needed.
If the answer to 1a & 1b are “low” and The answer to 3a & 3b are “yes”	No HD room/equipment is needed if HD services are provided by another source (IHS or contract) outside of the facility.
If the answer to 2a & 2b are “low” and The answer to 4a & 4b are “yes”	No CSP room/equipment is needed.
All other answer combinations for 1a, 1b, 2a, & 2b will need to be thoroughly evaluated using the information from the remainder of the questionnaire prior to deciding to build or not build a HD/CSP room(s).	
Questions 3 & 4 address the availability of HD and/or CSP services through other facilities (IHS, private/contract). This information should be used in a cost/benefit analysis (contract vs. build).	
Question 5 addresses availability of Pharmacy staff to prepare HD’s and/or CSP’s.	
<b>FACTOR</b>	<b>DECISION</b>
If the answer to 5a & 5b are “no”	No HD/CSP room(s) should be built.
All other answer combinations for 5a & 5b will need to be thoroughly evaluated using the information from the remainder of the questionnaire prior to deciding to build or not build a HD/CSP room(s).	

Question 6 addresses availability of clinical staff (nursing, physicians, etc.).	
<b>FACTOR</b>	<b>DECISION</b>
If the answer to 6a & 6b are “no”	No HD/CSP room(s) should be built.
All other answer combinations for 6a & 6b will need to be thoroughly evaluated using the information from the remainder of the questionnaire prior to deciding to build or not build a HD/CSP room(s).	
Question 7 addresses availability of support staff (maintenance, biomedical, & certifiers).	
<b>FACTOR</b>	<b>DECISION</b>
If the answer to 7a & 7b are “no”	No HD/CSP room(s) should be built.
All other answer combinations for 7a & 7b will need to be thoroughly evaluated using the information from the remainder of the questionnaire prior to deciding to build or not build a HD/CSP room(s).	
Questions 8 & 9 address operational and construction costs associated with the physical room(s) and hoods. This does not address “Pharmacy-related” operational costs (supplies, drugs, staff time, biological monitoring, etc.). This information should be used in a cost/benefit analysis (contract vs. build). A cost multiplier should be used for remote locations to account for shipping, labor, etc. associated with remote locations.	

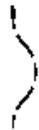
Diagram 1 – Clean Room: Low & Medium Risk CSP's



LEGEND



BUFFER AREA



AIR FLOW DIRECTION

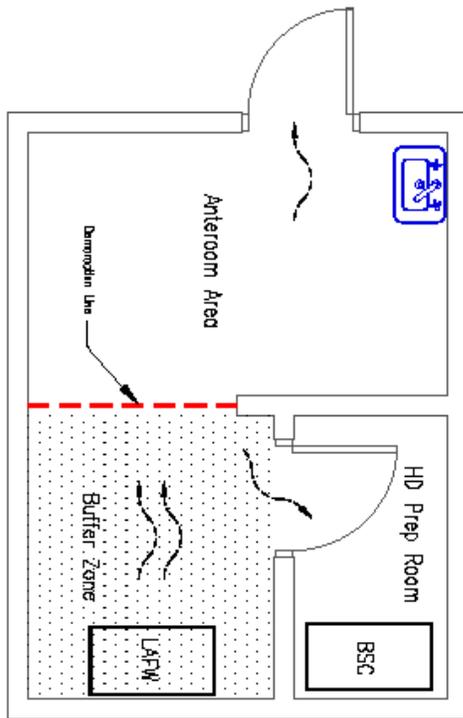


SINK

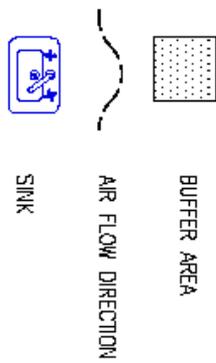
ABBREVIATIONS

- HD HAZARDOUS DRUG
- BSC BIOLOGICAL SAFETY CABINET
- CSP COMPOUNDING STERILE PREPARATION
- LAFW LAMINAR AIR FLOW WORKBENCH

Diagram 2 – CSP & Hazardous Drug Prep Rooms



LEGEND



ABBREVIATIONS

- HD HAZARDOUS DRUG
- BSC BIOLOGICAL SAFETY CABINET
- CSP COMPOUNDING STERILE PREPARATION
- LAFW LAMINAR AIR FLOW WORKBENCH

**ATTACHMENT 4 DRAFT Tech Handbook Security Level Selection**  
**CHAPTER 21-15 - SECURITY LEVEL SELECTION FOR USE IN THE DESIGN OF**  
**NEW FEDERAL FACILITIES**

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**21-15.1 INTRODUCTION**

A. Purpose

The purpose of this chapter is to provide a guideline to the project architect/engineer (A/E) designers, Indian Health Service (IHS) staff, and tribal staff for selecting a security level and security design standards for IHS health care facilities.

B. Scope

This chapter applies to construction of all new IHS health facilities and staff quarters and could apply to renovation, and/or alteration of IHS healthcare facilities and staff quarters.

It addresses only the recommended minimum-security standards and their application to the determined security levels of new IHS facilities and renovated facilities.

C. Background

After the April 19, 1995, bombing of the Alfred P. Murrah Federal Building, in Oklahoma City, Oklahoma, the President of the United States directed the Department of Justice (DOJ) to assess the vulnerability of federal buildings in the United States, particularly to acts of terrorism and other forms of violence. Because of its expertise in court security, the United States Marshals Service (USMS) coordinated this study. The USMS proceeded with this study along two tracks:

- (1) The development of recommended minimum security standards in light of the changed environment of heightened risk, and
- (2) The surveying of existing security conditions.

Since this initial bombing incident, there were terrorist attacks on the World Trade Center, the Pentagon, and several anthrax dispersions at postal facilities. On October 8, 2001, the President established, by executive order, the Office of Homeland Security (OHS), which was mandated "to develop and coordinate the implementation of a comprehensive national strategy to secure the United States from terrorist threats or attacks". In January 2002, the OHS formed the Interagency Workgroup on Building Air Protection, which included representatives from agencies throughout the federal government, including, the National Institute for Occupational Safety and Health (NIOSH), which is part of the Centers for Disease Control and Prevention (CDC). The Centers for Disease Control issued guidance to protect facilities from airborne attacks. The OHS mission outlined in the President's Executive order continued when the OHS became the Department of Homeland Security on March 1, 2003.

With some exceptions, including hospitals, new federally owned and leased facilities must be designed to meet the standards identified in the document entitled "Interagency Security Committee Design Criteria for New Federal Office Buildings and Major Modernization Projects," dated May 28, 2001 (Title 41 - Public Contracts and property Management, Chapter 102 - Federal Management Regulation, Part 102-81-Security. (For information on these regulations, including information on exemption, see [www.access.gpo.gov/nara/cfr/waisidx\\_04/41cfr102-81\\_04.html](http://www.access.gpo.gov/nara/cfr/waisidx_04/41cfr102-81_04.html).) Since the Interagency Security Committee (ISC) design criteria apply to new construction of office buildings and court houses occupied by Federal employees and do not apply to hospitals, no further consideration of ISC design criteria is provided in this chapter.

#### D. Authorities

##### **Presidential Decision Directive 63**

Presidential Decision Directive 63 makes every department and agency of the federal government responsible for protecting its own critical infrastructure. This effort established to address continuing governmentwide security concerns, establish policies and standards for security in and protection of federal facilities and monitor agency

compliance. Most of the agencies reported shared security responsibilities between the agency and GSA. Types of security responsibilities include performing security assessments, providing security funding, providing security forces and security technology, and coordinating security efforts among and within agencies. In May 1998, Presidential Decision Directive 63 was issued with the intent to eliminate any significant vulnerability to both physical and cyber attacks on our critical infrastructure. Critical infrastructures are those physical and cyber-based systems essential to the minimum operations of the economy and government. It makes every department and agency of the federal government responsible for protecting its own critical physical infrastructure. This would include the buildings that house critical cyberbased systems.

**Homeland Security Presidential Directive 7**

This directive establishes a national policy for Federal departments and agencies to identify and prioritize United States critical infrastructure and key resources and to protect them from terrorist attacks. Critical infrastructure and key resources provide the essential services that underpin American society. The Nation possesses numerous key resources, whose exploitation or destruction by terrorists could cause catastrophic health effects or mass casualties comparable to those from the use of a weapon of mass destruction, or could profoundly affect our national prestige and morale. In addition, there is critical infrastructure so vital that its incapacitation, exploitation, or destruction, through terrorist attack, could have a debilitating effect on security and economic well-being.

**Homeland Security Presidential Directive 12**

This directive establishes a national policy for a common identification standard for Federal employees and contractors. Secure and reliable forms of identification for purposes of this directive means identification that is issued based on sound criteria for verifying an individual employee's identity; is strongly resistant to identity fraud, tampering, counterfeiting, and terrorist exploitation; (c) can be rapidly authenticated electronically; and is issued only by providers whose reliability has been established by an official accreditation process. The standard includes graduated criteria, from least secure to most secure, to ensure

flexibility in selecting the appropriate level of security for each application.

#### **National Infrastructure Protection Plan**

The National Infrastructure Protection Plan (NIPP) and supporting Sector-Specific Plans (SSPs) provide a coordinated approach to critical infrastructure and key resources (CI/KR) protection roles and responsibilities for federal, state, local, tribal, and private sector security partners. The NIPP sets national priorities, goals, and requirements for effective distribution of funding and resources which will help ensure that our government, economy, and public services continue in the event of a terrorist attack or other disaster.

#### **E. Definitions**

The term "critical infrastructure" has the meaning given to that term in section 1016(e) of the USA PATRIOT Act of 2001 (42 U.S.C. 5195c (e)).

*The term "critical infrastructure" means systems and assets, whether physical or virtual, so vital to the United States that the incapacity and destruction of such systems and assets would have a debilitating impact on security, national economic security, national public health or safety, or any combination of those matters.*

The term "key resources" has the meaning given that term in section 2(9) of the Homeland Security Act of 2002 (6 U.S.C. 101(9)).

*The term "key resources" means publicly or privately controlled resources essential to the minimal operations of the economy and government.*

All Federal departments and agencies are responsible for the identification, prioritization, assessment, remediation, and protection of their respective internal critical infrastructure and key resources.

#### **21-15.2 GUIDELINES**

- A. IHS Emergency Services, Security Program Services credentialed personnel should conduct a security review as a part of the planning process for each new

facility or quarters project and, where applicable, for each renovation and/or alteration project. A security review report, which contains the Security Officer's determination of the preliminary security level for the facility, will be included as part of each planning document (i.e., Site Selection and Evaluation Report (SSER), Program Justification Document (PJD), Program of Requirements (POR), etc.). The designer must comply with all approved provisions of the most current security review report and incorporate all recommendations in this guideline as applicable.

B. The following are guidelines that address the physical and environmental security of facilities. These guidelines are intended to apply to construction of all new IHS health facilities and staff quarters and could apply to IHS renovation, and/or alteration of healthcare facilities and staff quarters.

(1) The basic recommended minimum-security standards published by the DOJ in Vulnerability Assessment of Federal Facilities, dated June 28, 1995, can be applied to various federal facilities. This document recommends five levels of security; classifying each level of security by the number of employees, size of facility, and the volume of public contact (refer to Appendix A). The recommended security standards cover the subjects of perimeter; entry, interior, and security planning of a facility (refer to Appendix B). Other organizations and/or agencies may have additional standards that apply to and must be addressed in construction of IHS facilities, e.g., the Joint Commission on Accreditation of Hospitals Organization (JCAHO), etc.

(2) The DOJ Table on Recommended Minimum Security Standards in Appendix B has been modified to address the risks and needs of IHS facilities. Additional information and guidance to architects and engineers on basic security requirements can be found in Appendix G of the DOJ Vulnerability Assessment of Federal

Facilities, which references the Security Design Chapter of GSA's Facilities Standards for the Public Buildings Service.

- (3) The IHS Security Programs Services (SPS) "Vulnerability Assessment" must be completed prior to the design and before occupancy. This survey is based upon the criteria established by the Department of Homeland Security. (a copy may be obtained from IHS Emergency Services). The results of this survey may require that a higher level of minimum security be implemented to achieve the desired mitigation or risk management levels.

SPS has established of minimum set of information gathered through the "vulnerability assessment" that can be applied to various facilities. These standards cover the subjects of security personnel, perimeter, entry, and interior security, and security planning.

The standards include:

- Security Personnel
  - Facility Security Personnel
  - Other Law Enforcement in Facility
  - Force Protection
- Perimeter Security
  - Parking
  - Closed Circuit Television Monitoring
  - Lighting
  - Physical Barriers
- Entry Security
  - Receiving/Shipping
  - Access Control
  - Entrances/Exits
- Interior Security
  - Employee/Visitor Identification
  - Utilities
  - Occupant Emergency Plans
  - Day Care Centers
  - Cyber Issues
  - Fire Rescue/Life Safety

- Security Planning
    - Intelligence Sharing
    - Training
    - Tenant Assignment
    - Administrative Procedures
    - Construction/Renovation
- (4) Additionally, there are recommended minimum requirements that can be implemented to enhance occupant protection from airborne chemical, biological, or radiological (CBR) attack. Of particular concern are the airflow patterns and dynamics in buildings, specifically in the heating, ventilating, and air-conditioning (HVAC) systems. Any of these systems can become an entry point and distribution system for hazardous contaminants, particularly CBR agents. The Guidance for Protecting Building Environments from Airborne Chemical, Biological, or Radiological Attacks, jointly issued by the CDC and NIOSH in May 2002, provides preventative measures that should be implemented based on several factors, including the perceived risk associated with the building and its tenants.

C. Design Criteria

- (1) Security level I, II, and III shown in Appendix A are applicable for all new IHS construction projects, as approved in the Program of Requirements (POR) for the project.

The minimum recommended security standards which must be included in the design requirements are as follows:

- (a) Perimeter and Parking Security (only necessary where there is designated parking)
- Provide adequate lighting for facility parking areas as per the Illuminating Engineering Society of North America (IESNA);
  - Provide control of facility parking areas; and

- Provide emergency battery power backup for all outside lighting of facility and facility parking areas.
- (b) Facility Entry Security
- Provide at least a minimal intrusion detection system with central monitoring capability, with the level to be based on the security evaluation;
  - Provide fire detection, fire suppression, and other detection and suppression systems based on the current life safety standards; and
  - Provide high security locks on all exterior doors;
- (c) Interior Security
- Provide security locks to all utility areas; and
  - Provide emergency power to critical systems such as alarm systems, radio communications, computer facilities, and other similar systems, excluding health stations.
- (2) Security levels IV and V are may be applicable to IHS facilities due to the number of employees and size of the facilities. For these facilities IHS has determined that special security platforms and procedures may be implemented beyond normal minimum standards.
- (3) The Guidance for Protecting Building Environments from Airborne Chemical, Biological, or Radiological Attacks, jointly issued by the CDC and NIOSH in May 2002, recommendations that should be implemented in new facilities are as follows:
- (a) Physical Security
- Prevent access to outdoor air intakes;
  - Prevent public access to mechanical areas;
  - Prevent public access to building roofs;

- Implement security measures, such as guards, alarms, and cameras to protect vulnerable areas;
- Isolate lobbies, mailrooms, loading docks, and storage areas;
- Secure return air grilles;
- Restrict access to building operations systems by outside personnel; and
- Restrict access to building information (on building systems operation).

(b) Ventilation and Filtration

- Evaluate HVAC Control options;
- Assess filtration (such as increasing filter efficiency);
- Assess ducted and non-ducted return air systems;
- Consider low-leakage, fast-acting dampers; and
- Provide tight building construction and building pressurization.

(c) Training

- Specify adequate HVAC maintenance staff training on system operation and maintenance, including preventative maintenance and procedures.

D. Questions regarding site specifics should be directed to the IHS Security Officer or his representative.

**21-15.3 REFERENCE STANDARDS**

- A. The Department of Justice's document Vulnerability Assessment of Federal Facilities, June 28, 1995, remains in effect. It addresses two parts:
- (1) Security of existing facilities, and
  - (2) Recommended minimum-security standards and application to security levels of federal facilities (Chapter 21-15 addresses only Part 2 of that document.)
- B. The Guidance For Protecting Building Environments From Airborne Chemical, Biological, Or Radiological Attacks, jointly issued by the CDC and NIOSH in may 2002, DHHS (NIOSH) publication no. 2002-139.

- C. Other useful information may be obtained from the following websites:
- National Institute for Occupational Safety and Health (NIOSH) - <http://www.cdc.gov/NIOSH/homepage.HTML> ;
  - Centers for Disease Control and Prevention (CDC) - <http://www.cdc.gov> ;
  - U.S. Army Corps of Engineers (USACE) [http://enc.ornl.gov/CSEPPweb/data/Guidance%20Documents/CorpBuilding%20Protection/Building\\_Protection.pdf](http://enc.ornl.gov/CSEPPweb/data/Guidance%20Documents/CorpBuilding%20Protection/Building_Protection.pdf) - Protecting Buildings and their Occupants from Airborne Hazards (DRAFT 2001);
  - The United States General Services Administration (GSA) - <http://www.gsa.gov/Portal/gsa/ep/home.do?tabId=0>, specifically [http://www.gsa.gov/gsa/cm\\_attachments/GSA\\_DOCUMENT/8\\_Security\\_Design\\_R2-e-nl-k\\_0Z5RDZ-i34K-pR.PDF](http://www.gsa.gov/gsa/cm_attachments/GSA_DOCUMENT/8_Security_Design_R2-e-nl-k_0Z5RDZ-i34K-pR.PDF), 2003 Facilities (P100) 8 - Security Design;
  - Lawrence Berkeley National Laboratory - <http://securebuildings.lbl.gov>;
  - American Institute of Architects (AIA) - <http://www.aia.org>, specifically [http://www.aia.org/sec\\_default/](http://www.aia.org/sec_default/), Building Security Through Design;
  - American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) - <http://www.ashrae.org>;
  - International Facility Management Association (IFMA) - <http://www.ifma.org> ; and
  - National Institute of Building Sciences (NIBS) - [www.wbdg.org](http://www.wbdg.org) Whole Building Design Guide.

**APPENDIX A - United States Marshals Service (USMS) Classification**  
**Table Recommended Levels Of Security**

Security Level	Employees	Square Meters (m <sup>2</sup> )	Public Contact	Remarks
I	1-10	230 or less	Low volume of public contact	Small store front type operation, such as recruiting office
II	11-150	231-7,430	Moderate volume of public contact	Routine activities, similar to commercial activities.
III	151-450	7,431-13,930	Moderate to high volume of public contact	Law enforcement agencies, court, government archives, or multi-tenant.
IV	Over 450	More than 13,930	High volume of public contact	High risk law enforcement agencies, judicial offices, or government records.
V	Over 450	More than 13,930	High	Such as Pentagon or CIA

**NOTES:**

- A. Security level recommended for new IHS construction projects:
  - (1) LEVEL I - Dental or Health Station;
  - (2) LEVEL II - Hospitals, Health Center, or Quarters Complex.
  - (3) LEVEL III - Medical Centers
  
- B. Security levels shall be defined and approved in the POR based on this classification table. Security levels IV, and V are not applicable to IHS unless justified in the PJD/POR.

**APPENDIX B - Recommended Security Standards Chart For New IHS  
Construction Programs**

Legend:		LEVEL <sup>1</sup>				
1 - Desirable	3 - Standard Based on Facility Evaluation	I	II	III	IV	V
2 - Minimum Standard	3 - Not required by DOJ Report					
<u>A. PERIMETER SECURITY</u>						
1	<b>PARKING</b>					
	Control of facility parking.	2	2	2	2	2
	Control of adjacent parking.	3	3	3	0	0
	Avoid leases where parking cannot be controlled.	3	3	3	1	1
	Leases should provide security control for adjacent parking.	3	3	3	1	1
	Post signs and arrange for towing unauthorized vehicles.	3	3	3	2	2
	ID system and procedures for authorized parking (placard, decal, card key, etc.).	3	3	3	2	2
	Adequate lighting for parking areas.	2	2	2	2	2
2	<b>CLOSED CIRCUIT TELEVISION (CCTV) MONITORING</b>					
	CCTV surveillance cameras with time-lapse video recording.	3	3	3	2	2
	Post signs advising of 24-hour video surveillance.	3	3	3	2	2
3	<b>LIGHTING</b>					
	Lighting with emergency battery power backup.	2	2	2	2	2
4	<b>PHYSICAL BARRIERS</b>					
	Extend physical perimeter with barriers (concrete and/or steel composition).	3	3	3	3	3
	Parking barriers.	3	3	3	3	3
<b>B. ENTRY SECURITY</b>						
1	<b>RECEIVING/SHIPPING</b>					
	Review receiving/shipping procedures (current).	3	3	3	2	2
	Implement receiving/shipping procedures (modified).	3	3	3	2	2
2	<b>ACCESS CONTROL</b>					
	Evaluate facility for security guard requirements.	3	3	3	2	2
	Security guard patrol.	3	3	3	3	3
	Intrusion detection system with central monitoring capability.	2	2	2	2	2
	Design to current life safety standards (fire detection, fire suppression systems, etc.).	2	2	2	2	2
3	<b>ENTRANCES/EXITS</b>					
	X-ray and magnetometer at public entrances.	3	3	3	3	2
	Require x-ray screening of all mail/packages.	3	3	3	2	2
	Peep holes.	3	3	3	3	3

Legend:		LEVEL <sup>1</sup>				
1 - Desirable	3 - Standard Based on Facility Evaluation	I	II	III	IV	V
2 - Minimum Standard	3 - Not required by DOJ Report					
Intercom.		3	3	3	3	3
Entry control w/CCTV and door strikes.		3	3	3	3	3
High security locks.		2	2	2	2	2
<b>C. INTERIOR SECURITY</b>						
<b>1 EMPLOYEE/VISITOR IDENTIFICATION</b>						
Agency photo ID for all personnel displayed at all times.		3	3	3	2	2
Visitor control/screening system.		3	3	3	2	2
Visitor identification accountability system.		3	3	3	2	2
Establish ID issuing authority.		3	3	3	2	2
<b>2 UTILITIES</b>						
Provide security locks to prevent unauthorized access to utility areas.		2	2	2	2	2
Provide emergency power to critical systems (alarm systems, radio communications, computer facilities, etc.).		2	2	2	2	2
<b>3 OCCUPANT EMERGENCY PLANS</b>						
Examine occupant emergency plans (OEP) and contingency procedures based on threats.		3	3	3	2	2
OEPs in place, updated annually, periodic testing exercise.		3	3	3	2	2
Assign and train OEP officials (assignment based on largest tenant in facility).		3	3	3	2	2
Annual tenant training.		3	3	3	2	2
<b>4 DAYCARE CENTERS</b>						
Evaluate whether to locate daycare facilities in buildings with high threat activities.		3	3	3	2	2
Compare feasibility of locating daycare in facilities outside locations.		3	3	3	2	2
<b>D. SECURITY PLANNING</b>						
<b>1 INTELLIGENCE SHARING</b>						
Establish law enforcement/security liaisons.		3	3	3	2	2
Review/establish procedures for intelligence receipt/dissemination.		3	3	3	2	2
Establish uniform security/threat nomenclature.		3	3	3	2	2
<b>2 TRAINING</b>						
Conduct annual security awareness training.		3	3	3	2	2
Establish standardized unarmed guard qualifications/training requirements.		3	3	3	2	2
Establish standardized armed guard qualifications/training requirements.		3	3	3	2	2

Legend:		LEVEL <sup>1</sup>				
1 - Desirable	3 - Standard Based on Facility Evaluation	I	II	III	IV	V
2 - Minimum Standard	3 - Not required by DOJ Report					
3	TENANT ASSIGNMENT					
	Co-locate agencies with similar security needs	3	3	3	1	1
	Do not co-locate high/low risk agencies.	3	3	3	1	1
4	ADMINISTRATIVE PROCEDURES					
	Establish flexible work schedule in high threat/high risk areas to minimize employee vulnerability to criminal activity.	3	3	3	1	1
	Arrange for employee parking in/near building after normal work hours.	3	3	3	3	3
	Conduct background security checks and/or establish security control procedures for service contract personnel.	3	3	3	2	2
5	CONSTRUCTION/RENOVATION					
	Install mylar film on all exterior windows (shatter protection).	3	3	3	2	2
	Review current projects for blast standards.	3	3	3	2	2
	Review/establish uniform standards for construction.	2	2	2	2	2
	Review new design standard for blast resistance.	3	3	3	2	2
	Establish street setback for new construction.	3	3	3	2	2

<sup>1</sup> Only level I, II, and III are applicable to IHS construction programs unless otherwise justified and approved in the PJD/POR.

**ATTACHMENT 5 Memo Mechanical Engineer DES-Seattle to Director DES-Dallas**

Date Feb 21, 2008

From Mechanical Engineer, Division of Engineering Services  
- Seattle

Subject Ventilation for Clinical Pharmacy Clean Rooms – USP 797

To Director, Division of Engineering Services - Dallas

The proposed draft of the IHS Technical Handbook Chapter on pharmacy cleanroom environmental recommendations has been reviewed.

The previous revisions had stipulated (99%) HEPA filters and 12 ACH (air changes per hour). That had correlated with the ventilation recommendations for a Protective Environment (PE) isolation room (*FGI Guidelines for Design and Construction of Health Care Facilities*). The justification had been that if the ventilation for a PE room was satisfactory for a bone marrow patient, then it should be sufficient for a pharmacy clean room.

The current version of the IHS Technical Handbook Chapter promulgates 15 ACH (total) with 90% efficiency filters (MERV 14). This is akin to the recommendation for an "Operating Room" in the *FGI Guidelines for Design and Construction of Health Care Facilities*. The justification is that the air quality/cleanliness for an operating room will provide a sufficiently clean environment for pharmacy clean room.

This differs from the recommendation of the 2008 edition of USP 797, which stipulates 30 ACH. I believe that there insufficient scientific basis to support the air exchange rate specified in USP 797.

I support the 15 ACH indicated in the draft IHS Technical HB Chapter. Specifically, the air changes per hour should be 15 ACH of total air exchanges. The outdoor air recommendations are for 2 ACH of outdoor air. (This differs from the 3 ACH recommended for operating rooms. The rationale is that the occupant density is lower in the pharmacy preparation rooms; and consequently the 3 ACH is not justified. The 2 ACH is similar to the outdoor air recommendations for a PE room.)

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