

HEALTH FACILITIES ADVISORY COMMITTEE (HFAC)
MEETING MINUTES

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

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 Mat Martinson

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

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. 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.

Attachments:



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1-30-08\Minutes\HFA



Technical Handbook
Pharmacy Chapter (F



21-15 Security Level
Selection 12-8-05 - W



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797 ACH recommend:

HFAC Approved