797CompoundingIQ Gap Analysis

Organization	Survey Site	Date
[redacted] Infusion and Pharmacy Services	Test Gap Tool	7/23/2009 12:03:13 PM

[redacted]

I. Compliance : 74%

Domain	Score
A. Demographic Information	*not scored*
B. General Compounding	*not scored*
C. Low Risk Level CSPs with 12 Hour or Less BUD	60% (3 of 5 items in compliance)
D. Single and Multi-dose Vials	66% (2 of 3 items in compliance)
E. CSPs for Immediate Use	71% (5 of 7 items in compliance)
F. Primary/Secondary Engineering Controls	33% (2 of 6 items in compliance)
G. General Facility Design	90% (9 of 10 items in compliance)
H. Compounding Facility Management: Cleaning and Disinfecting	90% (10 of 11 items in compliance)
I. Compounding Facility Management: Equipment Calibration	100% (5 of 5 items in compliance)
J. Compounding Facility Management: Temperature and Humidity Monitoring	80% (4 of 5 items in compliance)
K. Compounding Facility Management: Airflows and Pressure Differential Monitoring	50% (1 of 2 items in compliance)
L. Quality Management: Environmental Sampling Program	75% (3 of 4 items in compliance)
M. Quality Management: General Viable Air and Surface Sampling Considerations	100% (5 of 5 items in compliance)
N. Quality Management: Viable Air Sampling - A facility metric	100% (5 of 5 items in compliance)
O. Quality Management: Surface Sampling - A personnel metric	100% (5 of 5 items in compliance)
P. Quality Management: Incubation	0% (0 of 1 item in compliance)
Q. Quality Management: Non-Viable Particle Testing	100% (3 of 3 items in compliance)
R. Quality Management: General	66% (4 of 6 items in compliance)
S. Quality Management: Patient/Caregiver Training	60% (3 of 5 items in compliance)
T. Initial and Ongoing Training and Competency Measurement	80% (4 of 5 items in compliance)
U. Gloved Fingertip Sampling	100% (3 of 3 items in compliance)
V. Hand Washing and Garbing	100% (3 of 3 items in compliance)
W. Personnel Media-Fill Challenge Testing	100% (5 of 5 items in compliance)
X. Aseptic Technique	83% (10 of 12 items in compliance)
Y. Beyond Use Dating	0% (0 of 2 items in compliance)
Z. Sterility Testing	71% (5 of 7 items in compliance)
AA. Sterilization Methods	100% (1 of 1 item in compliance)
AB. Sterilization by Filtration	33% (1 of 3 items in compliance)
AC. Sterilization by Dry Heat	*n/a*
AD. Steam Sterilization	*n/a*
AE. Depyrogenation by Dry Heat	*n/a*
AF. Bacterial Endotoxin Testing	50% (1 of 2 items in compliance)
AG. Filter Integrity Test	0% (0 of 1 item in compliance)
AH. Final Release Checks	88% (8 of 9 items in compliance)
AI. Inventory Storage and Handling/Delivery of CSPs	83% (5 of 6 items in compliance)
AJ. Hazardous Drug Compounding	53% (7 of 13 items in compliance)
AK. Radiopharmaceuticals as CSPs	55% (5 of 9 items in compliance)
AL. Allergen Extracts as CSPs	66% (6 of 9 items in compliance)

II. Action Plan Detail

The information contained in this section, Action Plan Detail, lists all of the action plan items within each domain that need to be addressed based on your responses to the gap analysis questions. To view the full detail of each question answered and your response please refer to Section III. Action Plan Detail by Trigger Question.

A. Demographic Information

None.

B. General Compounding

None.

C. Low Risk Level CSPs with 12 Hour or Less BUD

- Institute daily and monthly cleaning in the SCA as described in USP <797> which includes:

  1. Establishing written policies and forms on SCA cleaning.

  2. Training staff who will perform cleaning. Note: The inside of Primary Engineering Controls may only be cleaned by trained compounding personnel. Other personnel such as those in Environmental Services, may be trained to perform other cleaning of the SCA.

  1. Before performing cleaning duties, staff must successfully demonstrate and document competency.
  2. Cleaning must be documented on approved forms.

- Environmental Sampling must be perfomed according to the requirements of viable and non-viable environmental testing in USP <797> which includes:

  1. Certification of primary engineering controls (LAFWs or CAIs) every 6 months in accordance with CETA's "Certification Guide for Sterile Compounding Facilities".
  2. It is suggested that total particle counts be taken in the LAFW/CAI as well as in the SCA itself.
  3. Viable Air Sampling at least every 6 months during room/PEC cerification.
  4. Viable Surface Sampling must be performed regularly according to institutional policy.

- Document locations for surface sampling on the Environmental Sampling Plan Diagram and Surface Sampling documentation form.

- Surface sampling must be performed in all ISO classified areas on a regular basis. The frequency of and timing of Surface Sampling is dependent upon the following:

  1. Compounding risk level (more frequently at high risk level);
  2. Environmental sampling results history (more frequently at compounding facilities with no environmental sampling history);
  3. Tenure of compounding staff (more frequently when many compounding staff are new, inexperienced or when staff have not established a sampled history associated with environmental sampling; gloved fingertip sampling or media-fill testing);
  4. Other factors which may impact work practices (i.e., more frequently during periods of short staffing; more frequently if custodial staff are assuming cleaning activities).

- Either the plate method or swab method of collection is acceptable, however even with the swab method; plates are still required and must be 24-30 cm2 in size. For low and medium risk level compounding, tryptic soy agar medium with polysorbate and lecithin added to neutralize cleaning agents (TSApl) are used. High risk operations must use media that support the growth of fungi such as malt extract agar (MEA).

- Samples must be taken in order from the cleanest to the dirtiest and the following locations may be

sampled:

- ISO Class 5 PECs (suggest 1 sample per 4 linear feet of PEC);
- ISO Class 7 Buffer area locations which are representative of the environment and at greatest risk such as work surfaces near ISO 5 areas, counters near doors, walls, and pass through surfaces;
- ISO Class 7/8 Ante-area surfaces

If there is more than one distinct buffer room, complete all sampling in one buffer room prior to beginning the next.

Recommended surface sampling microbial contamination Action Levels are as follows:

- ISO Class 5 surfaces: > 3 CFUs/plate;
- ISO Class 7 surfaces: > 5 CFUs/plate; and
- ISO Class 8 surfaces: > 100 CFUs/plate.

D. Single and Multi-dose Vials

- Single dose vials or containers that are initially opened in ISO Class 5 air or better, are partially used and intended for further use must bear the date/time of entry and may be used for up to 6 hours.

- Single dose vials or containers opened in air that is worse that ISO Class 5 must be safely discarded within 1 hour of opening or entry.
- Open, single dose ampule containers may not be stored.

E. CSPs for Immediate Use

- Evaluate CSPs that qualify for the Immediate-Use exemption which must meet all of the following criteria:

  1. Compounding involves simple transfer of not more than 3 commercially manufactured packages of sterile, non-hazardous products (including diagnoistic radiopharmaceutical products from their original manufacturer's packaging) AND not more than 2 entries into any one container of sterile infusion solution/administation container.
  2. Compounding procedure is continuous and does not exceed 60 minutes.
  3. Aseptic technique is used and finished CSP is under continous observation ensuring protection from contamination until it is used.
  4. Administration must begin no longer than 1 hour from the beginning of the preparation.
  5. The CSP must bear a label listing patient identifiers; names/amounts of all ingredients; name/initials of person who prepared it and the exact 1 hour beyond use date (BUD) and time *UNLESS* it is immediately and completely administered by the person who prepared it (or administration is witnessed by the person who prepared it).
  6. If administation of the CSP has not begun by within 1 hour from its preparation, then it is promtly and safety discarded.

- Establish a policy on those CSPs which qualify for the Immediate-Use exemption at your organization. It is important to consider that compounding in conditions worse than ISO Class5 increases the likelihood of CSP contamination. This is especially true if contaminated CSPs are administered or stored for even a few hours which significantly increases the likelihood of clinically harmful bacterial colonization which may cause patient harm. Risk is significantly increased in patients who are immunocompromised or critically ill.
- It may be necessary to investigate which, if any, CSPs are compounded outside of ISO Class 5 conditions and evaluate how these CSPs may be prepared in the pharmacy if they do not meet all of the conditions for Immediate-Use exemption.
- Educate physicians, nurses, physician's assistants and other applicable healthcare providers about the scope of USP <797> as well as its requirements which seek to safeguard patients and represent the current standard of practice.
- Discuss with prescribers how standardization of drug, dose, diluent combinations allowing anticipatory compounding for CSP that do not meet the Immediate-Use exemption conditions, may actually result in improved patient care by decreasing the risk of contamination while facilitating prompt

administration simultaneously.

- The requirement for CSPs meeting the immediate-use exemption must be those CSPs where the need is emergent or there is a need for immediate patient administration. Examples are cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents or critical therapies where preparation under Low Risk Level conditions would subject the patient to additional risks related to a delay in therapy.

F. Primary/Secondary Engineering Controls

- Anterooms adjacent to negative pressure buffer areas used for hazardous drug compounding maintain ISO Class 7 or better air under dynamic operating conditions to protect the air in the hazardous buffer area since it is negative pressure to the anteroom.
- High risk compounding may NOT occur in facilities utilizing an a displacement airflow design regardless of airflow velocities.
- If the HEPA filtered air is not maintaining ISO Class 7 conditions in the ante area, contact a clean room engineer and request a consultation. It will be important to determine if the ante area was designed to achieve ISO Class 7 conditions initially or if it was not designed to maintain those conditions. Additional HEPA filters may need to be added to achieve ISO Class 7 conditions. It will be helpful to have the records relative to the initial design and build as well as subsequent modifications that may be made. The engineer should be able to assist you to determine how best to achieve these conditions. Also consider that uncartoning of supplies should occur outside of the ante-area so as cause a high particulate burden. It is relatively simple to add an additional HEPA filter to an ante-area ceiling.
- Upon initial placement in their desired location, conduct a smoke study in the critical compounding area of each primary engineering control to verify unidirectional airflow.
- Conduct the initial smoke study inside primary engineering controls under dynamic operating conditions to verify that air flows over and sweeps away from compounding products.
- If smoke studies have never been conducted in an already functioning pharmacy, it is suggested that they be performed during the next certification and sooner if undesireable environmental sampling CFU trends are observed.
- In order to protect the environment in which compounding is occuring and therefore reducing the risk of contamination to CSPs, isolators must meet all of the following conditions if they are to be placed in an area *other than* an ISO Class 7 buffer area . These conditions include:
    - All isolators maintain ISO class 5 conditions during compounding activities which includes transferring ingredients in/out, compounding and during transfer of finished CSPs out of the isolator;
    - All isolators been testing according to CETA guidelines and have successfully passed particle sampling which occurs at approximately 6-12 inches upstream of the critical exposure sites during compounding and demonstrated that they were able to maintain ISO Class 5 conditions;
    - All isolators have been tested according to CETA guidelines with a probe located as close to the transfer door as possible and successfully maintain not more than 3520 particles per cubic meter during material transfer; AND
    - Written documentation is on file from the manufacturer that the isolator/s meet the standards above.
- All classified clean room environments and the equipment that support its operation (Primary Engineering Controls such as LAFWs, BSCs, CAIs, and CACIs) must be tested and re-certified at least every 6 months.
- Routine certification procedures must meet or exceed current and applicable local, state and/or federal pharmacy laws and/or guidelines.
- Verify that the cerification vendors engaged to certify rooms and equipment equipment are familiar with and use standards and methodologies from acknowledged authorities in the industry such as: The Controlled Environment Testing Association. Compounding Guide for Sterile Compounding Facilities; CAG-003-2006; Compounding Isolator Test Guide: CAG-002-2006; Servicing Hazardous Drug Compounding Primary Engineering Controls. CAG-005-2007; The National Institutes of Standards and Technology.

III. Action Plan Detail by Trigger Question

The information contained in this section, Action Plan Detail by Trigger Question, lists each question within each domain that was answered by a NO response and includes a recommended action plan needed to correct the issue.

A. Demographic Information

No negatively-answered questions.

B. General Compounding

No negatively-answered questions.

C. Low Risk Level CSPs with 12 Hour or Less BUD

1. Are the ISO Class 5 compounding environments within the segregated compounding areas cleaned according to the requirements of USP <797>?

   No

- Institute daily and monthly cleaning in the SCA as described in USP <797> which includes:

  1. Establishing written policies and forms on SCA cleaning.

  2. Training staff who will perform cleaning. Note: The inside of Primary Engineering Controls may only be cleaned by trained compounding personnel. Other personnel such as those in Environmental Services, may be trained to perform other cleaning of the SCA.

  1. Before performing cleaning duties, staff must successfully demonstrate and document competency.
  2. Cleaning must be documented on approved forms.

2. Are viable and non viable environmental sampling performed in ISO Class 5 compounding environments located within segregated compounding areas?

   No

- Environmental Sampling must be perfomed according to the requirements of viable and non-viable environmental testing in USP <797> which includes:

  1. Certification of primary engineering controls (LAFWs or CAIs) every 6 months in accordance with CETA's "Certification Guide for Sterile Compounding Facilities".
  2. It is suggested that total particle counts be taken in the LAFW/CAI as well as in the SCA itself.
  3. Viable Air Sampling at least every 6 months during room/PEC cerification.
  4. Viable Surface Sampling must be performed regularly according to institutional policy.

- Document locations for surface sampling on the Environmental Sampling Plan Diagram and Surface Sampling documentation form.

- Surface sampling must be performed in all ISO classified areas on a regular basis. The frequency of and timing of Surface Sampling is dependent upon the following:

  1. Compounding risk level (more frequently at high risk level);
  2. Environmental sampling results history (more frequently at compounding facilities with no environmental sampling history);
  3. Tenure of compounding staff (more frequently when many compounding staff are new, inexperienced or when staff have not established a sampled history associated with

environmental sampling; gloved fingertip sampling or media-fill testing);
4. Other factors which may impact work practices (i.e., more frequently during periods of short staffing; more frequently if custodial staff are assuming cleaning activities).

- Either the plate method or swab method of collection is acceptable, however even with the swab method; plates are still required and must be 24-30 cm2 in size. For low and medium risk level compounding, tryptic soy agar medium with polysorbate and lecithin added to neutralize cleaning agents (TSApl) are used. High risk operations must use media that support the growth of fungi such as malt extract agar (MEA).
- Samples must be taken in order from the cleanest to the dirtiest and the following locations may be sampled:
  - ISO Class 5 PECs (suggest 1 sample per 4 linear feet of PEC);
  - ISO Class 7 Buffer area locations which are representative of the environment and at greatest risk such as work surfaces near ISO 5 areas, counters near doors, walls, and pass through surfaces;
  - ISO Class 7/8 Ante-area surfaces

  If there is more than one distinct buffer room, complete all sampling in one buffer room prior to beginning the next.

  Recommended surface sampling microbial contamination Action Levels are as follows:

  - ISO Class 5 surfaces: > 3 CFUs/plate;
  - ISO Class 7 surfaces: > 5 CFUs/plate; and
  - ISO Class 8 surfaces: > 100 CFUs/plate.

D. Single and Multi-dose Vials

1. Are single dose vials that have been punctured *inside* of air that is ISO Class 5 or better discarded after 6 hours?

   No

- Single dose vials or containers that are initially opened in ISO Class 5 air or better, are partially used and intended for further use must bear the date/time of entry and may be used for up to 6 hours.

- Single dose vials or containers opened in air that is worse that ISO Class 5 must be safely discarded within 1 hour of opening or entry.
- Open, single dose ampule containers may not be stored.

E. CSPs for Immediate Use

1. Does your organization have a written policy on Immediate-Use CSPs?

   No

- Evaluate CSPs that qualify for the Immediate-Use exemption which must meet all of the following criteria:

  1. Compounding involves simple transfer of not more than 3 commercially manufactured packages of sterile, non-hazardous products (including diagnoistic radiopharmaceutical products from their original manufacturer's packaging) AND not more than 2 entries into any one container of sterile infusion solution/administation container.
  2. Compounding procedure is continuous and does not exceed 60 minutes.
  3. Aseptic technique is used and finished CSP is under continous observation ensuring protection from contamination until it is used.
  4. Administration must begin no longer than 1 hour from the beginning of the preparation.
  5. The CSP must bear a label listing patient identifiers; names/amounts of all ingredients; name/initials of person who prepared it and the exact 1 hour beyond use date (BUD) and time

UNLESS it is immediately and completely administered by the person who prepared it (or administration is witnessed by the person who prepared it).

6. If administation of the CSP has not begun by within 1 hour from its preparation, then it is promtly and safety discarded.

- Establish a policy on those CSPs which qualify for the Immediate-Use exemption at your organization. It is important to consider that compounding in conditions worse than ISO Class5 increases the likelihood of CSP contamination. This is especially true if contaminated CSPs are administered or stored for even a few hours which significantly increases the likelihood of clinically harmful bacterial colonization which may cause patient harm. Risk is significantly increased in patients who are immunocompromised or critically ill.
- It may be necessary to investigate which, if any, CSPs are compounded outside of ISO Class 5 conditions and evaluate how these CSPs may be prepared in the pharmacy if they do not meet all of the conditions for Immediate-Use exemption.
- Educate physicians, nurses, physician's assistants and other applicable healthcare providers about the scope of USP <797> as well as its requirements which seek to safeguard patients and represent the current standard of practice.
- Discuss with prescribers how standardization of drug, dose, diluent combinations allowing anticipatory compounding for CSP that do not meet the Immediate-Use exemption conditions, may actually result in improved patient care by decreasing the risk of contamination while facilitating prompt administration simultaneously.

2. Are Immediate-Use CSPs prepared only in emergent or life-threatening situations?

   No

- The requirement for CSPs meeting the immediate-use exemption must be those CSPs where the need is emergent or there is a need for immediate patient administration. Examples are cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents or critical therapies where preparation under Low Risk Level conditions would subject the patient to additional risks related to a delay in therapy.

F. Primary/Secondary Engineering Controls

1. The ante-area is supplied with HEPA filtered air and has been certified to meet at least ISO Class 7 air standards.

   No

- Anterooms adjacent to negative pressure buffer areas used for hazardous drug compounding maintain ISO Class 7 or better air under dynamic operating conditions to protect the air in the hazardous buffer area since it is negative pressure to the anteroom.
- High risk compounding may NOT occur in facilities utilizing an a displacement airflow design regardless of airflow velocities.
- If the HEPA filtered air is not maintaining ISO Class 7 conditions in the ante area, contact a clean room engineer and request a consultation. It will be important to determine if the ante area was designed to achieve ISO Class 7 conditions initially or if it was not designed to maintain those conditions. Additional HEPA filters may need to be added to achieve ISO Class 7 conditions. It will be helpful to have the records relative to the initial design and build as well as subsequent modifications that may be made. The engineer should be able to assist you to determine how best to achieve these conditions. Also consider that uncartoning of supplies should occur outside of the ante-area so as cause a high particulate burden. It is relatively simple to add an additional HEPA filter to an ante-area ceiling.

2. Once primary engineering controls are placed in their desired location, smoke studies have been conducted to verify unidirectional airflow and sweeping action over and away from the critical compounding area.

   No

- Upon initial placement in their desired location, conduct a smoke study in the critical compounding area of each primary engineering control to verify unidirectional airflow.
- Conduct the initial smoke study inside primary engineering controls under dynamic operating conditions to verify that air flows over and sweeps away from compounding products.
- If smoke studies have never been conducted in an already functioning pharmacy, it is suggested that they be performed during the next certification and sooner if undesireable environmental sampling CFU trends are observed.

3. Are your Primary Engineering Controls certified according to the guidelines of the Controlled Environment Testing Association (CETA)guidelines (CAG-003-2006)?

   No

- In order to protect the environment in which compounding is occuring and therefore reducing the risk of contamination to CSPs, isolators must meet all of the following conditions if they are to be placed in an area *other than* an ISO Class 7 buffer area . These conditions include:
  - All isolators maintain ISO class 5 conditions during compounding activities which includes transferring ingredients in/out, compounding and during transfer of finished CSPs out of the isolator;
  - All isolators been testing according to CETA guidelines and have successfully passed particle sampling which occurs at approximately 6-12 inches upstream of the critical exposure sites during compounding and demonstrated that they were able to maintain ISO Class 5 conditions;
  - All isolators have been tested according to CETA guidelines with a probe located as close to the transfer door as possible and successfully maintain not more than 3520 particles per cubic meter during material transfer; AND
  - Written documentation is on file from the manufacturer that the isolator/s meet the standards above.
- All classified clean room environments and the equipment that support its operation (Primary Engineering Controls such as LAFWs, BSCs, CAIs, and CACIs) must be tested and re-certified at least every 6 months.
- Routine certification procedures must meet or exceed current and applicable local, state and/or federal pharmacy laws and/or guidelines.
- Verify that the cerification vendors engaged to certify rooms and equipment equipment are familiar with and use standards and methodologies from acknowledged authorities in the industry such as: The Controlled Environment Testing Association. Compounding Guide for Sterile Compounding Facilities; CAG-003-2006; Compounding Isolator Test Guide: CAG-002-2006; Servicing Hazardous Drug Compounding Primary Engineering Controls. CAG-005-2007; The National Institutes of Standards and Technology.

4. Has your certifier verified that an airflow velocity of at least 40 feet per minute is maintained across the line of demarcation?

   No

- For buffer areas not physically separated from ante-areas, segregation is achieved by displacement airflow which must be demonstrated by measured air velocities of at least 40 feet per minute from the buffer area across the line of demarcation into the ante-area.
- The buffer area must be segregated from unclassified spaces to reduce the risk of introduction of viable and non viable contaminants therefore it is especially important to verify airflow velocities in displacement air designs since there are no physical barriers in place such as walls or doors.
- Displacement airflow controlled compounding environments that are constructed without actual wall separation between the buffer/clean rooms and the ante-area maintain air velocities of 40 feet per minute from the buffer area across the line of demarcation in the ante-area and may only be used in low and medium risk level compounding.
- Placement of PECs, room furniture and work practices of compounding staff can have an adverse effect on airflow and physical plant set up and use reflects that understanding.
- Pressure differentials (or air velocities) must be verified and documented at least daily at the