After filling out form, print, sign, and mail to: Iowa Board of Pharmacy
400 SW 8th Street, Suite E, Des Moines, Iowa 50309-4688. Deadline for inclusion on Board's agenda is three weeks prior to Board meeting.

Case No. or State ID No.

Rec'd:

(FOR PHARMACY BOARD USE ONLY)

IOWA BOARD OF PHARMACY
Petition for [☒] Waiver [☐] Variance
(check the appropriate box)

PLEASE PRINT OR TYPE ALL INFORMATION IN INK

A waiver excuses the petitioner from the requirements of a rule in its entirety or from a part of a rule; a variance does not. Instead, a variance is a modification to the requirements of a rule or a part of a rule. Example: A rule requires the fencing of certain property and further requires that the fence be at least 6 feet in height. A waiver of that rule would excuse the petitioner from the requirement for fencing the property. A variance would require the property be fenced but would allow the petitioner to maintain the current fencing configuration of 5 feet in height (perhaps the fence was constructed prior to the height requirement). When replacement of the current fence becomes necessary as a consequence of normal wear and tear, the variance would terminate and the petitioner would be required to comply with the 6-foot height requirement.

Note: Statutory requirements that have been repeated in administrative rules are not subject to consideration for a waiver or variance.

Is this petition an initial request or is it a request for renewal? [☒] Initial Request [☐] Request for Renewal
If a request for renewal, explain below why the renewal is necessary.

Petitioner Information (include licensee/registrant name and name of contact person, i.e. pharmacist in charge)

Name: Mercy Medical Center/Del Mandl Phone No.: (712) 279-2935
(include area code)

Address: 801 5th Street

City: Sioux City State: IA Zip Code: 51101

Petition Information

1. Chapter Number and Title.

   657-20.4 (124,126,155A) Sterile Compounding

2. Rule Number(s) and Title(s).

   657—20.4(124,126,155A) Sterile compounding. Iowa-licensed pharmacies that compound sterile preparations for ultimate users in the state of Iowa shall follow the current revision of USP Chapter 797 standards. Additional USP chapters incorporated by reference into USP Chapter 797 shall also be followed.
   [ARC 2194C, IAB 10/14/15, effective 11/18/15]

3. Describe in your own words the essence of each Rule Number(s) and Title(s) that pertains to this petition.

   657-20.4 – To be fully compliant with USP 797 standards the pharmacy would minimize the opportunity for introduction of contaminants into the sterile compounding process.

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4. Describe the specific nature and scope of your petition. In your description, include the anticipated time period (beginning and ending) for which the petition would apply. A waiver or variance may not be requested or granted on a permanent basis; the petition must identify an end date.

   Until the Iowa Board adopted the USP 797 standards, these were guidelines for the best practice of sterile compounding. Mercy Medical Center pharmacy has been utilizing these guidelines to move toward meeting the USP 797 standards, and until the last two certifications from Healthcare Solutions everything with facility design and environmental controls was compliant except the number of air exchanges. The ante room and negative pressure rooms did fall from ISO7 to ISO8 in the last two inspections. However, in the most recent certification by Healthcare Solutions on 4/6/2016 the particle counts were back down and the two rooms met ISO7 standards again. As of today, I have not received the final certification report to send with this waiver petition.

   I invited Sue Mears, Pharmacy Compliance Officer, to perform an assessment of our sterile compounding processes. And although most of her assessments were process enhancements with the ability to implement timely fixes, the inability of the current air handler to meet the recommended minimum air exchanges will require consultation by engineers and architects to discern what can be done to remedy this problem. I have consulted with KCL Engineering and Cannon Moss Brygger Architects and after several meetings we have established two options for meeting the USP797 design and environmental control standards (see attached).

   With the assistance of KCL Engineering and Cannon Moss Brygger Architects it has been decided the only way to meet the USP 797 air exchange standards would be to put in a new air handler serving only the pharmacy. Two options have been recently developed for consideration by Senior Leadership at Mercy Medical Center and have yet to be presented. Option 1 would be to renovate the current sterile compounding area in its current place, and Option 2 would move the sterile compounding area to a side of the pharmacy closest to an outside air source to limit duct work complications. I have been told by the consulting groups both options will take at least one month to complete, and the VP of Finance here at Mercy stated this project cannot start until the new fiscal year, which begins July 1, 2016. Therefore, Mercy Medical Center pharmacy would need this waiver to go through 9/30/2016.

5. Describe the relevant facts and reasons that, in your opinion, justify and provide "clear and convincing evidence" as to why this petition merits consideration for waiver or variance. In your description, explain why the rule(s) poses an undue hardship. If there is a public health, safety and welfare issue associated with this rule(s), or if this rule(s) addresses security or confidentiality issues, also explain how equal protection will be maintained if this petition were granted.

   All previous certifications from both ENV and Healthcare solutions of our sterile compounding area have demonstrated lower air exchanges than recommended by USP 797, and I asked them if I need to address this issue. The response was installing a new air handler, to supply only the pharmacy, so the correct number of air exchanges could be met would be a huge undertaking and expense, and USP 797 are recommended standards and not mandatory at this time. However, with the implementation of USP 797 standards by the Iowa Board of Pharmacy this is no longer a recommendation, but a requirement. As mentioned earlier, the other assessments made by Sue Mears regarding our sterile compounding area were process changes within my control. Conversely, due to the large nature of this project, installing an air handler in confined preexisting space, a major remodel will need to occur. The project is underway as evidenced by the information supplied from both the engineering and architect firms, but Mercy will need to have additional time for completion.

6. Does anyone else (inside or outside state government) possess knowledge relevant to this petition?

   [☐] Yes [☒] No [☐] Do not know

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If yes, list their names, addresses and phone numbers below.

7. Would anyone (inside or outside state government) be adversely affected if this petition were granted?

[☐] Yes [☒] No [☐] Do not know

If yes, list their names, addresses and phone numbers below.

8. Do you know how the Board of Pharmacy has treated similar situations?

[☐] Yes [☒] No

If yes, describe below how similar situations were handled.

9. Have you had any past interaction with the Board of Pharmacy that might impact or relate to this petition?

[☒] Yes [☐] No

If yes, describe below the issue involved and the outcome.

Sue Mears, Pharmacy Compliance Officer performed an assessment of our sterile compounding processes and in her assessment she stated if compliance cannot be attained by May, 2016 the pharmacy would need to submit a waiver to the Board for those aspects of USP 797.

I authorize any person with knowledge of the relevant or important facts relating to this petition to release any pertinent information to the Iowa Board of Pharmacy. I hereby attest to the accuracy and truthfulness of the information contained herein.

Petitioner's Signature

4-15-2016
Date

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Mercy Medical Center

PHARMACY CLEAN ROOMS
SIOUX CITY, IOWA

MECHANICAL AND ELECTRICAL NARRATIVE
APRIL 8, 2016

EXECUTIVE SUMMARY

The existing pharmacy cleanrooms consist of three spaces:

- Negative Pressure (Chemo) Room
- Positive Pressure Room
- Ante Room.

All three cleanrooms must meet ISO Class 7 cleanroom conditions, which dictates the following requirements based on USP 797 and USP 800:

- 30-60 air changes per hour of HEPA filtered air (15 of which must come from the outdoors)
- Less than 10,000 particles per cubic foot sized 0.5 microns or larger, and
- Pressurization to at least +0.02 inches W.C. (positive pressure rooms) and –0.01 inches W.C. (negative pressure rooms).

Because of recent changes to USP 797, the creation of USP 800, and the anticipated adoption of these standards by the state of Iowa legislature, Healthcare Solutions completed a certification review of the pharmacy's clean rooms with respect to these standards in October of 2015. Based on their report dated October 27, 2015, the cleanrooms are not meeting the USP 797 requirements. This could jeopardize the hospital's ability to continue performing these functions on site. Specific shortfalls were:

- Lack of pressurization in Ante Room. (There is currently no door between the Ante Room and the Pharmacy Work Room.)
- Insufficient air change rates in all three rooms.
- Particle count failures in the Negative Pressure Room and Ante Room.

To follow up on this report, KCL Engineering performed a study, in conjunction with CMBA, to determine how the cleanrooms could be brought into compliance. Various measures have been implemented over recent years to try to improve the situation in each individual room. However, the approach has not been holistic to this point, and so the solutions implemented had a narrow view of particular problems in individual areas, rather than considering the pharmacy space as a whole. The state requirements are now forcing the issue of full compliance in all spaces, requiring a broader view of potential solutions.

After several meetings and the evaluation of multiple solutions, two options are now being considered in order to bring the cleanrooms into compliance with USP 797 and USP 800. These options appear to be the most realistic and cost effective for the spaces available.

1) Option 1 – Remodel the cleanrooms in place. Remove existing ventilation systems serving these spaces, and add an air handling unit to serve the cleanrooms. Move services such as IV and chemo preparation off site while construction is underway.
2) Option 2 – Move the cleanrooms to a different part of the Pharmacy department. Add an air handling unit to serve the cleanrooms.

Further implications and advantages/disadvantages of these options are discussed in the architectural portion of this narrative.

Applicable Codes and Standards include the following:

- USP 797 – Pharmaceutical Compounding – Sterile Preparations
- USP 800 – Hazardous Drugs – Handling in Healthcare Settings
- International Building Code – 2015 Edition
- International Mechanical Code – 2012 Edition
- Uniform Plumbing Code – 2012 Edition
- International Fire Code – 2015 Edition
- National Electrical Code – 2014 Edition
- International Energy Conservation Code – 2012 Edition
- FGI Guidelines – 2014 Edition

EXISTING SYSTEMS

The existing Pharmacy department is served by air handling unit AHU-1B, a constant volume AHU located in the southeast mechanical room on the second floor, which is immediately opposite the back wall of the Pharmacy department. This unit is original to the 1982 building, and also serves the remainder of this floor through the elevator lobby. Temperature in each zone is controlled by a thermostat controlling a hot water reheat coil. A split system air conditioner has also been installed in the positive pressure room to help improve cooling performance in this room.

Additional airflow in the Ante Room and Negative Pressure Cleanrooms is provided by fan filter units, installed in 2010. This was done to increase airflow in these rooms, while also attempting to reduce the extreme negative pressure that was being observed in the negative pressure room. These are controlled by standalone wall-mounted control panels.

Pressure is monitored by Paragon Controls "Guardian" space pressure monitors with differential pressure sensors, at three locations:

1) Between the ante room and negative pressure room
2) Between the ante room and positive pressure room, and
3) Between the ante room and pharmacy work room.

Currently these are not monitored by the building automation system, and must be manually recorded by the pharmacy staff on a daily basis.

Most of the air from the cleanrooms recirculates to AHU-1B. However, the chemo hood is exhausted by a 12" round exhaust duct, down through the floor, and through the electrical rooms on first floor to an exhaust fan hung on the outside wall. Since the duct penetrates a rated floor, the exhaust duct is wrapped in 2-hour rated fire wrap along its entire length through first floor.

Table 1 indicates existing room conditions from certification report.

Room	Max. Allowable Particles	Actual Particles	Min. Required ACH	Actual ACH	Required Pressurization in. W.C.	Actual Pressurization in. W.C.
Negative	10,000	16,561	30	28.2	–0.010"	–0.048"
Positive	10,000	15,340	15*	8.8*	+0.020"	+0.021"/+0.020"
Ante	10,000	1,453	30	11.4	+0.020"	0.00"

*Value represents fresh air requirement. Min. 30 total ACH.

Table 1: Existing room conditions.

Existing lighting throughout all of the pharmacy area including the cleanrooms is provided from recessed 2x4 fluorescent lensed fixtures. The fixtures are a 'regressed' lens type which creates a void around the perimeter of each fixture that allows dust and contaminates to settle into this void and not cleanable.

Lighting controls are provided from manual single level on/off switches throughout the space.

Existing power is provided mainly from the emergency branch. Convenience and equipment receptacles appear to have been added or placed where required, however limited as equipment needs have increased.

ENVIRONMENTAL REQUIREMENTS

HVAC requirements below come from USP 797, which applies to the Ante Room and Positive Pressure Room, and USP 800, which applies to the Negative Pressure Room. Additionally, minimum humidity levels come from the 2014 FGI Guidelines.

- ISO Class 7.
- Temperature: 68°F
- Relative Humidity: 30-60% (Note: Mercy typically maintains minimum relative humidity at 40%)
- Air Change Rate: 30 air changes per hour (ACH)
- Filtration: HEPA.
    - HEPA filters are high-efficiency particulate arrestance filters, which must remove 99.97% of particles that have a size of 0.3 microns or larger.
    - HEPA filters can be located either within the air handling unit, or any place between the unit and the room. Studies have indicated that the cleanest room air is achieved by locating the HEPA filters at the diffusers.
- Air must be supplied at the ceiling through laminar flow diffusers, and return air must be low on the wall, in order to provide unidirectional airflow. Laminar flow diffusers supply air at no more than 100 feet per minute (fpm).
- Pressure Differential between spaces: 0.02 inches W.C. This must be continuously monitored. (Negative pressure must be maintained between –0.01 and –0.03 inches W.C. Therefore, –0.02 inches is being recommended.)

Additionally, certain plumbing and lighting requirements apply:

- Handwash sink at least one meter away from Negative Pressure Room.
- Emergency eyewash station "readily available."
- Light fixtures with exterior lenses that are smooth, mounted flush, and sealed.

Note regarding Ante Room: A typical Ante Room would not be required to be an ISO Class 7 cleanroom; ISO Class 8 would normally suffice. However, since this Ante Room opens to the Negative Pressure Room, USP 800 requires the Ante Room to be ISO Class 7 as well.

MECHANICAL AND ELECTRICAL SCOPE OF WORK – GENERAL

Under either option, a new air handling unit would be installed. Refer to Appendix B, Figure 1. The air handling unit would consist of the following components:

- Mixing box with outdoor air and return air modulating dampers.
- Filter rack consisting of 2" MERV-8 pre-filters, and 12" MERV-13 final filters.
- Hot water pre-heat coil.
- Steam humidifier. (The hospital uses FDA approved chemicals in their steam system, and utilizes DriSteem brand direct injection humidifiers.)
- Chilled water cooling coil.
- Supply fan(s) with variable frequency drive (VFD).

A new louver would be installed in an outside wall to bring in ventilation air to meet the ventilation requirements and to pressurize the spaces. A terminal air box with a reheat coil would be installed in each zone to control airflow in response to space pressurization and minimum flow requirements. Temperature control in each zone would occur by modulating flow at the terminal air box, and by modulating heating water flow through the reheat coil. Air would be distributed in each room by ceiling diffusers with integral HEPA filters that can be removed from the space. Air would be returned from each room by low return grilles.

Chilled water, heating water, steam, and condensate piping would be brought from the existing mechanical room to the new air handling unit. Since chilled water is not available below 55-60°F outside air temperatures, a secondary cooling coil will be included, connected to a new condensing unit to be located on a roof or on grade.

It is recommended that the air handling unit be sized for more flow than the minimum required by USP 797. This would ensure that the unit can meet capacity in all weather conditions, and would assist in reducing particulate count in the cleanrooms. USP 797 requires at least 30 ACH for ISO Class 7 cleanrooms; standard industry practice for ISO Class 7 cleanrooms is to provide anywhere from 30 to 60 ACH. Table 2 shows various airflows based on existing room sizes. Recommended total airflows are shown in **bold**. Based on the recommended airflows for each room, the total recommended airflow is around 4,000 CFM.

Room	Volume cu. ft.	15 ACH	30 ACH	45 ACH	60 ACH
Negative	952	238	476	**714**	952
Positive	1,754	439	877	**1,316**	1,754
Ante	3,367	842	**1,639**	2,525	3,367

Table 2: Airflows (in cubic feet per minute / CFM) at various air change rates.

The existing biological safety cabinet (BSC) that acts as the chemo hood in the Negative Pressure Room has an airflow rate of between 280 and 660 cfm. Because this flow can vary based on usage and sash height, a secondary exhaust fan or exhaust terminal air box would be added to maintain this room at a negative pressure at all times.

The existing pressure monitors would be replaced with new pressure monitors that can communicate with the building automation system. This data would be trended at fifteen minute intervals for one year. Some coordination may be required with the hospital IT staff to determine where this data can be stored.

All penetrations through ceilings or walls would be sealed. Sprinklers would be installed/replaced with concealed sprinklers with gasketed cover plates.

OPTION 1 – REMODEL CLEANROOMS IN EXISTING LOCATIONS

Existing ductwork, diffusers, and reheat coils serving the cleanrooms would be removed. Existing fan filter units would be removed. Existing pressure controls would be removed. The sink in the Negative Pressure room would be removed.

A new air handling unit would be installed in the southeast portion of the Storage Room. A new main supply duct and terminal air boxes would be located above the Storage Room, and branch ductwork would extend into each space.

New sealed cleanroom light fixtures would be provided throughout the remodeled areas. All new power would be extended from the existing critical branch for emergency power backup.

Under this option, all cleanroom services, such as IV and chemo preparation, would need to be temporarily moved offsite while construction is underway. The duration of construction would likely be in the range of two months before spaces are final cleaned and recertified.

Refer to Appendix B, Figure 2.

OPTION 2 – RELOCATE CLEANROOMS

New cleanrooms would be created somewhere within the existing Pharmacy department, most likely on the southwest wall. A new air handling unit would be installed in the existing Compounding room. Once the new cleanrooms are occupied, the existing cleanrooms would be renovated into break rooms, office, pharmacy work, and/or storage space. The exact usage of the existing cleanrooms, and the exact locations of the new cleanrooms and associated equipment, would likely be determined through a Kaizen 3P process.

A new main supply duct and terminal air boxes would be installed outside the new cleanrooms, and branch ductwork would extend into each space.

A new surgical scrub sink and eyewash station would be provided in the Ante Room.

New sealed cleanroom light fixtures would be provided throughout the new areas. All new power would be extended from the existing critical branch for emergency power backup.

Under this option, IV and chemo preparation could continue on-site, and equipment such as hoods would be moved to the new cleanrooms once they are final cleaned and certified.

Refer to Appendix B, Figure 3.

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APPENDIX A

MECHANICAL / ELECTRICAL COST OPINION

1) **Option 1 – Remodel Cleanrooms in Existing Locations – $350,000**
   a. Remodel of spaces outside cleanrooms $68,000
   b. Cleanroom remodel $137,000
   c. Air Handling Unit $100,000*
   d. Contingency – 15% $45,000

2) **Option 2 – Relocate Cleanrooms – $440,000**
   a. Remodel of spaces outside cleanrooms $169,000
   b. Cleanroom construction $116,000
   c. Air Handling Unit $100,000*
   d. Contingency – 15% $55,000

*Cost for air handling unit could vary significantly depending on materials selected. Cost listed is for a stainless steel unit, and includes installation.

This opinion of probable cost is based on information in this report, dated 4/8/16. Items not included on this cost opinion:

1) General construction costs – refer to architectural portion of narrative.
2) Owner provided equipment, medical equipment, or furnishings.
3) Costs for moving services off site, particularly under Option 1.
4) Cleanroom certification costs.
5) Future escalation.

Construction costs may vary due to many factors including time of year, cost of petroleum based products, inflation, and contractor availability.

APPENDIX B

MECHANICAL / ELECTRICAL SKETCHES

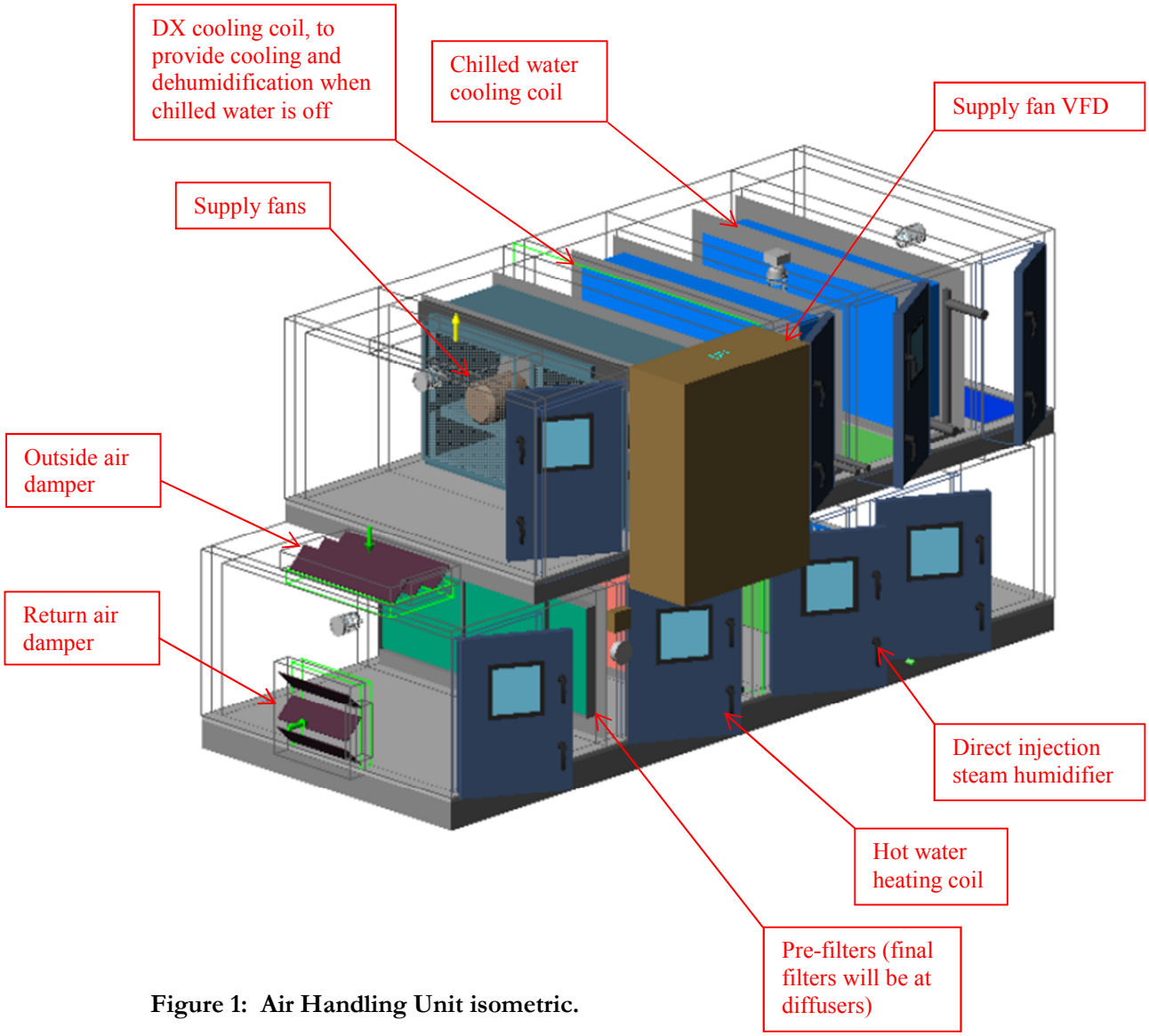
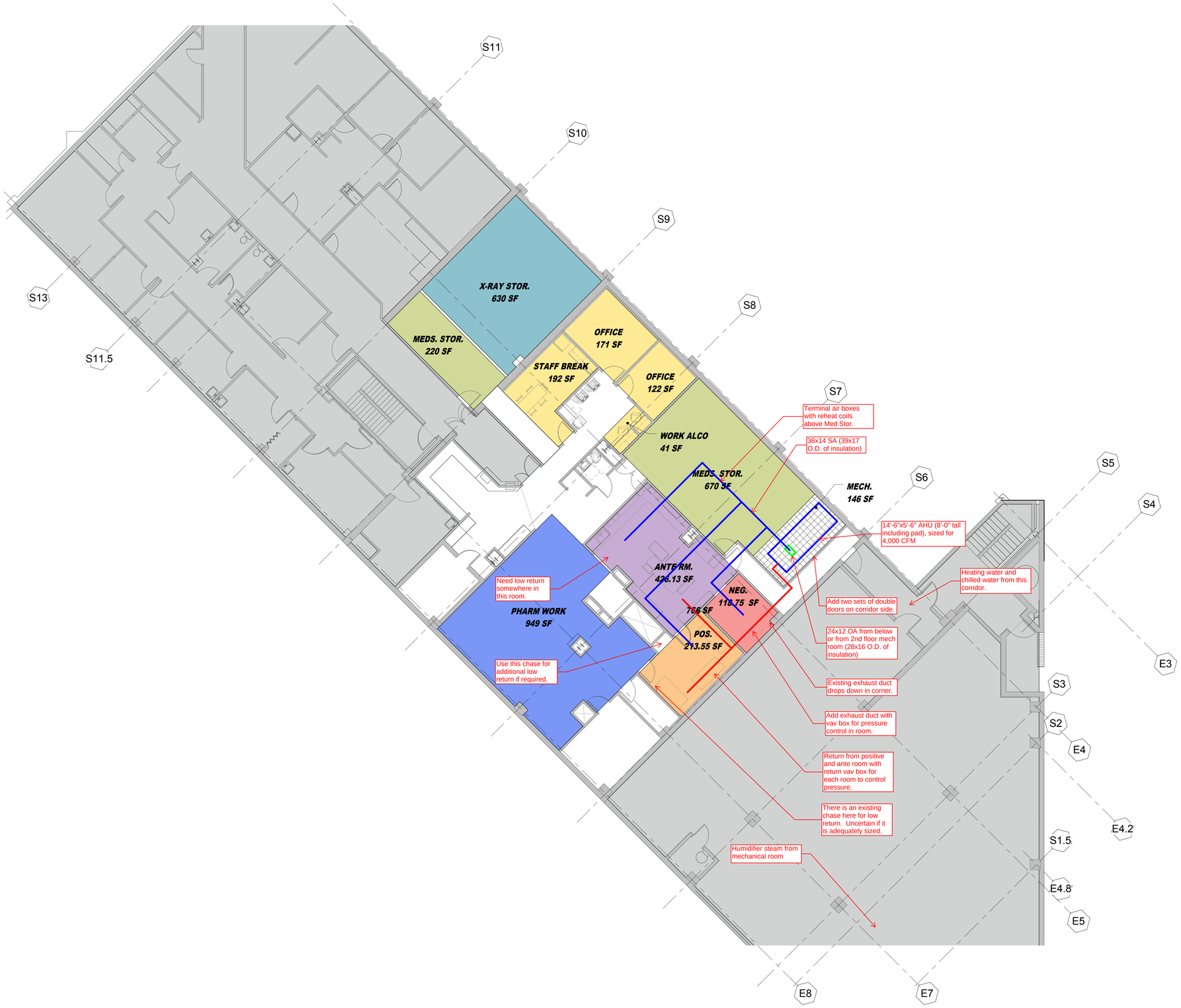


Figure 1: Air Handling Unit isometric.

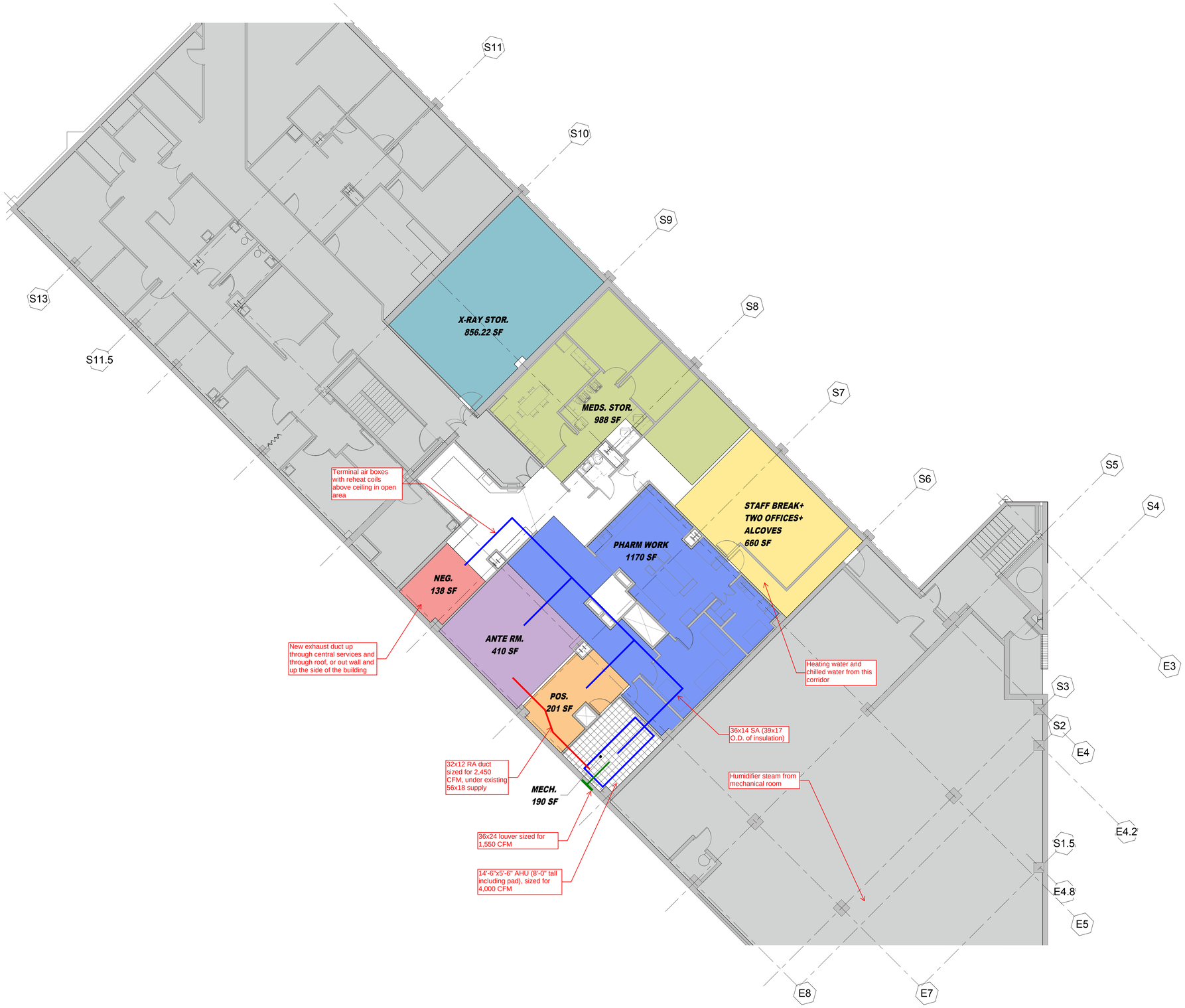
MERCY HOSPITAL
PHARMACY CONTROLLED ENVIRONMENT

FIGURE 2: OPTION 1 - REMODEL IN PLACE



MERCY HOSPITAL
PHARMACY CONTROLLED ENVIRONMENT

FIGURE 3: OPTION 2 - WEST WALL



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Mercy Medical Center
PHARMACY CLEAN ROOMS
SIOUX CITY, IOWA

ARCHITECTURAL NARRATIVE
APRIL 8, 2016

SUMMARY

In order to accomplish the mechanical and electrical work required to bring the pharmacy back into air-quality compliance, some architectural work must also be done. The options listed in the mechanical and electrical narrative will have their accompanying architectural components described here.

OPTION 1 – REMODEL CLEANROOMS IN EXISTING LOCATIONS

The following items are foreseen as necessary:

1. The north and west walls of the ante-room would be extended up to the deck and a door added between it and the pharmacy work area. An existing door between the pharmacy work and the positive-pressure room would be removed and the opening filled. This would be to prevent unwanted air passage from one space to another.
2. The ante-room would receive a new ceiling and light fixtures that prevent air – leakage.
3. A mechanical room would be created in the current meds storage room that would house the new air handler unit. It would get two sets of double-doors that open to the corridor for access.
4. Because of the storage space lost to the mechanical room, some additional storage would need to be created in the current x-ray storage room. This would need an access hall to it through the current break room.
5. Refer to Appendix B, Figure 2.

The phasing required while renovations are underway includes moving the positive-pressure room function temporarily to the x-ray storage room and utilizing a glove-box unit. Chemo work would be outsourced to the local cancer center for the duration of the renovation.

OPTION 2 – RELOCATE CLEANROOMS

The following items are foreseen as necessary:

1. Convert the current compounding room into the mechanical room for the new air-handler.
2. Walls would be erected in the current pharmacy work area to create a positive-pressure room and an ante-room.
3. The current vault would be converted to the negative-pressure room potentially involving removing the block walls and replacing them with metal studs and gyp board.
4. The current meds storage room would become the staff break room and offices.
5. The current break room and offices would be converted to the meds storage room.
6. Refer to Appendix B, Figure 3.

This option would create more challenges in phasing and the re-design of the entire area. However, it could potentially allow the space to be designed to its most efficient use.

ARCHITECTURAL COST OPINION

Option 1 – Remodel Clean Rooms in Existing Locations

• Demo, disposal and patching	$6,000
• Demo and replace ante room ceiling	$2,640
• New walls, doors, general work	$15,000
• Infection control measures	$1,500
• Contractor general conditions	$2,500
• 10% Contingency	$2.765
TOTAL	**$30,405**

Option 2 – Relocate Cleanrooms

• General demo and disposal	$10,000
• Convert vault, remove block	$4,000
• Demo and replace all ceilings	$30,174
• Demo and replace all VCT flooring	$25,145
• New walls, doors, general work	$25,000
• Built-in workstations	$3,000
• Extended construction time	$8,000
• Contractor general conditions	$10,532
• 10% Contingency	$11,585
TOTAL	**$127,436**

Considerations

- Option 1 does not include demo or replacement of any flooring.
- Option 1 does not include replacement of any ceiling other than the ante room.
- Option 2 cost of built-in workstations can vary significantly depending on materials and final layout.
- Option 2 assumes the reuse of existing shelves, cabinets and counters in the new ante room and work room.
- Neither option includes the cost of equipment or furnishings, moving expenses, architectural or engineering fees, certifications or the mechanical and electrical components described in the mechanical and electrical narrative.
- Cost opinions are less precise at this early stage of design. More accurate cost information is possible once plans are developed further. Construction costs can also vary depending on contractor and material availability, economic factors and time of year.