The Joint Commission will be implementing the new Medication Compounding Certification (MDC) program for hospitals, critical access hospitals, and home care pharmacy organizations in the state of Michigan on 1/9/17. This Certification will assess organizations' compliance with Joint Commission standards based on the USP Chapter <797> requirements on sterile compounding. The Joint Commission has received a number of questions about the standards in this new program and this FAQ document was developed to address them:

Number	Question	Answer	Comment
1	What is the definition of compounding?	The MDC Certification glossary contains a definition of compounding. The glossary, along with other helpful MDC documents, can be found at this link: https://www.jointcommission.org/certification/medication_compounding.aspx	
2	How can I access the MDC Certification standards?	The standards are available on our website. https://www.jointcommission.org/certification/medication_compounding.aspx	
3	Is it sufficient to use an SOP and attach it to the management operating directive (a type of policy specific to the organization) to use as a policy?	No.	
4	In the proposed update to USP Chapter <797>, the requirement for garbing is cleanest to dirtiest. The current USP Chapter <797> requirements for garbing is dirtiest to cleanest. Which will you be looking for to be in compliance?	The proposed USP Chapter <797> changes have not been finalized or approved. The reviewers will be reviewing organizations using the MDC Certification standards, which are based on the current USP Chapter <797> requirements which state garbing is dirtiest to cleanest.	
5	Can an ante room be ISO Class 8 or if there is negative pressure, can it be ISO Class 7?	Based on the definition in USP Chapter <797>, the Ante Room should be ISO Class 8 or better.	

6	Does the buffer room have to be ISO Class 7? If it is ISO Class 5, is it okay if you re-alcohol?	Based on the guidance in USP Chapter <797>, the buffer room must be ISO Class 7 or better. If the buffer room is ISO Class 5, once items are entered into the direct compounding area, staff must re-alcohol these items (USP Chapter <797>, suggested SOPs 17, 18, 19).	
7	In the organization, the ER has a compounding area (unclassified) with an ISO Class 5 laminar flow hood. What is considered a good segregated compounding area? Does this room need to be a physically separated area, or is a room with an area demarcated acceptable?	Joint Commission engineers do not answer specific pharmacy infrastructure and design questions (or review infrastructure designs) prior to construction. The organization should refer to USP Chapter <797> requirements when planning for construction or changes to their compounding pharmacy. Any hospital or home care organization engaging with a consultant and/or contractor to construct these types of areas should consider whether or not the person engaged and overseeing the process has working knowledge of USP requirements. Another resource that may be of help are the Guidelines for Design and Construction of Hospitals and Outpatient Facilities, 2014, at Sections 2.1-4.2 entitles "Pharmacy Services".	
8	The new expanded list of hazardous medications contains many which are compounded for immediate use. Will reviewers only be looking at antineoplastics or will they look at other hazardous drugs for immediate use?	Reviewers will very likely look at antineoplastics, but they may also look at other hazardous medications that are being compounded. See the new NIOSH list of hazardous medications: https://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf	
9	Several standards about the physical environment (such as MDCSN.3, MDCN.3, MDCS.1) often refer to USP Chapter <797>. With the pending changes that will occur with USP Chapter <800>, is there an engineering matrix or flow chart	The USP Chapter <800> requirements do not go into effect until July 1, 2018. The surveyors will be surveying to the MDC Certification standards, which are based on the current USP Chapter <797> requirements.	

	for everything including ACPH, pressure relationships, temperature and humidity, and monitoring of these?		
10	If we are going to do construction (including the clean room, chemo room, etc.), what is the allowable time frame that this will need to be completed to obtain certification?	When the Certification report is completed and submitted, the organization has 60 days to submit their Evidence of Standards Compliance (ESC) report. The organization will have from 3-6 months to complete any construction needed to meet the standards. If the construction necessary will require a longer timeframe, it will be reviewed by the Standards Interpretation Group and engineers when the 60-day ESC and their plan are submitted.	
11	If the organization does not have funding to start and complete the construction within the 3-6 month period, is there a "waiver" that can be requested until funding is available?	No, at this time there is no waiver or extension process that allows for a delay in construction until funds are available.	
12	The ACPH (exchange and fresh air) requirements for hazardous compounding were mentioned as "going away" when USP Chapter <800> goes into effect. Is this true? What are the requirements that we should be following?	The USP Chapter <800> requirements do not go into effect until July 1, 2018. The reviewers will be using the MDC Certification standards for the onsite review, which are based on the current USP Chapter <797> requirements.	
13	What HEPA filtration is required for meeting the current and USP Chapter <800> requirements?	Current USP Chapter <797> requirements related to HEPA filtration can be found in sections: IX. Hazardous Drugs as CSPs, and XIII.C. Facility Design and Environmental Controls MDC Certification standards with HEPA filtration include: MDCSN.03, EP11 and MDCS.08, EP5.	

14	Do you have a schematic outlining pressure differentials for USP Chapter <797> vs USP Chapter <800>?	No, we do not have this. Please refer to USP Chapter <797>; USP Chapter <800> is not yet in effect, so you will not be reviewed to USP Chapter <800>.	
15	For low and medium risk compounding, media fill and fingertip testing is a requirement in USP Chapter <797>, but it does not address immediate use needs (for nurses). Work is being done in a laminar flow hood, not on a table top. Do these nurses need to be in full PPE during the immediate use compounding?	Media fill and fingertip testing is not required for nurses doing immediate use compounding. Use didactic and observational methods to assess nursing competency. Note: For the initial reviews in MI, reviewers will not visit nursing units to observe nurses performing compounding for immediate use. Reviewers will only visit the main pharmacy and satellite pharmacies. Nurses are to use aseptic technique, and wear sterile gloves.	
16	Can people wear hospital scrubs over their own garments in the clean room? We have many employees who wear head scarves and long sleeved garments for religious reasons. It is not recommended to wear garments from outside in the clean room.	Per USP Chapter <797>, Appendix 1, "compounding personnel shall remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck." These should all be removed prior to putting on scrubs to wear in the clean room.	
17	What is the definition of compounding medications in the OR suites? Do all medications given in the OR need to be mixed by a pharmacist?	The MDC Certification review will only observe medication compounding in the Surgery department if there is a satellite pharmacy with a compounding pharmacist located in the Surgery department. Compounding in the OR suites will not be observed in the initial reviews in MI.	
18	We are building a new clean room in one of the OR pharmacies	These questions all relate to your organization's pharmacy infrastructure and new construction. You need to consult the USP Chapter <797>	

	and have several construction questions concerning materials used for the walls, counter tops, flooring, paint, lighting, and doors. We also have questions about the number and type of required air exchanges in the buffer room and clean room.	requirements for these items, and work with your engineers to ensure that the work is done properly. For example, the countertops need to be installed in a manner that prevents the risk of bacterial or infectious process proliferation, and they must be able to withstand the rigorous cleaning required. Joint Commission engineers do not review clean room design plans (or any other infrastructure designs) prior to construction. Any hospital engaging with a consultant and/or contractor to construct the area should consider whether or not the person engaged and overseeing the process has working knowledge of USP Chapter <797> requirements. Another resource that may be of help are the Guidelines for Design and Construction of Hospitals and Outpatient Facilities, 2014, at Sections 2.1-4.2 entitled "Pharmacy Services".	
19	What products are acceptable to be used to wipe down items brought into the clean side of the anteroom? Also, what products can be used to wipe down the clean room hoods and chemo hoods?	The Joint Commission does not provide guidance regarding specific products that are acceptable for proper cleaning. The organization needs to investigate various products to determine which meet the USP Chapter <797> requirements and the needs of the organization.	
20	Unlike most pharmacies, our pharmacists do the compounding. Our pharmacy technicians are only responsible for attaching the vial using the MINI-BAG Plus System and the VIAL-MATE Adaptor Device. Are the technicians required to do Media fill and gloved fingertip testing? Can this function be done	The coupling of MINI-BAG Plus and VIAL-MATE are not considered compounding per USP Chapter <797> and therefore these pharmacy technicians would not be required to complete the training elements required for a compounding employee if they are not compounding. Caution should be made to ensure that these items are being coupled in the ISO Class area required by the manufacturer. If this does involve utilization of the ISO Class 5 or Class 7 buffer areas, then it would be prudent to ensure they have training on that environment and appropriate restrictions to ensure the integrity of that area.	

	outside the clean room by the technicians?		
21	During the overview, it was mentioned you have to use a new alcohol wipe for each entry point. If we are compounding 1200mg Remicade, for example, we could potentially use 30 alcohol wipes. We wanted to confirm that this is what is expected.	Yes, USP Chapter <797> requires that the alcohol swab used to clean a critical point on a vial does not touch any other item prior to its use. Here is the text from USP Chapter <797>: ***Cleaning and Disinfecting the Compounding Area*** *Wiping with small sterile 70% IPA swabs that are commercially available in individual foil-sealed packages (or a comparable method) is preferred for disinfecting entry points on bags and vials, allowing the IPA to dry before piercing stoppers with sterile needles and breaking necks of ampuls. The surface of the sterile 70% IPA swabs used for disinfecting entry points of sterile packages and devices shall not contact any other object before contacting the surface of the entry point. Sterile 70% IPA wetted gauze pads or other particle-generating material shall not be used to disinfect the sterile entry points of packages and devices.* (Note: This was confirmed with USP leadership on 12/20/16.)	
22	Our organization is beginning a renovation to install a hazardous negative pressure room and a positive pressure clean room connected by an anteroom. We need to confirm the type of hood that needs to be installed to meet USP Chapter <800> requirements (Class II Type A2 or B2). Is it possible for us to send our clean room design plans to Joint Commission engineers for review prior to beginning the project?	USP Chapter <800> is not finalized and advice cannot be given to those expectations (this does not go into effect until July 1, 2018). The organization is encouraged to review the information currently available (USP Chapters <797> and <795>) and make decisions based on their review. Joint Commission engineers do not review infrastructure and design plans (or any other infrastructure designs) prior to construction. Any hospital or home care organization engaging with a consultant and/or contractor to construct these types of areas should consider whether or not the person engaged and overseeing the process has working knowledge of USP requirements. Another resource that may be of help are the Guidelines for Design and Construction of Hospitals and Outpatient Facilities, 2014, at Sections 2.1-4.2 entitles "Pharmacy Services".	

23	With USP Chapter <800>, the oncology meds need to be stored in the negative pressure room. It was mentioned in the overview that the chemo vials have to be removed from the non-corrugated cardboard boxes before going into the room. We would like to confirm this. We do see some problems if we need to return the medications to the wholesaler. With the cost of these medications, we do send medications back if a patient's treatment changes and won't be needed the product.	USP Chapter <800> does not go into effect until July 2018. Guidance regarding USP Chapter <800> cannot be provided at this time. Organizations will not be reviewed for compliance with USP Chapter <800>.	
24	Are the use of closed system transfer devices a current requirement when compounding hazardous drugs in a Class II Type A2 cabinet in a non-negative pressure room? Will there be a requirement for compounding in a negative pressure room?	Yes, closed system transfer devices are required when compounding hazardous drugs in a Class II Type A2 cabinet in a non-negative pressure room. If the organization does a low volume of compounding of hazardous medications it would be acceptable for the organization to use a CSTD in a non-negative pressure room based on USP Chapter <797>. Optimally, all hazardous medications should be compounded in a hood that is 100% vented to the outside.	
25	Can you explain the master formulary record requirement?	This requirement is for nonsterile compounding, and is based on USP Chapter <795> at: XI. Compounding Documentation. Because we are not reviewing nonsterile compounding for the MI organizations on the first reviews, it does not apply to the initial reviews. For your information, it is addressed at MDCN.07, EP5.	

26	At the MI training, someone mentioned that we need to have a signed Hazardous Drug Risk Acknowledgement for every employee who has reproductive capability. My HR department is pushing back on this a little. Is there someone there that can point me to where this requirement is within the standards or USP chapter?	This is the requirement that addresses the Hazardous Drug Risk Acknowledgement: MDCSN.04, EP6 The organization advises all compounding staff of the risks to their reproductive systems when handling hazardous medications and confirms in writing that staff understand these risks. It is covered in USP Chapter <797> at: IX. Hazardous Medications as CSPs	
27	We are planning on making renovations to our compounding space. We may not be able to begin construction until mid-February and are uncertain about our completion date. We are considering using the glove box until our renovations are completed. Is this a viable option for us? Do you know if the utilization of a glove box (CACI) will meet the MDC Standards throughout 2017?	As long as the glove box (CACI) is in a segregated compounding area, it is a viable option until your construction is completed. Keep in mind that garbing is required just as if using a laminar flow hood in a clean room or a bench in a clean room. For example, hand cleaning, gowns, masks, gloves, etc. and protocol for changing both large gloves and the small sterile gloves per policy and manufacturer's guidelines must be followed. Also, the same compounding staff competencies are required for staff utilizing the glove box. Note: The above is just one suggestion of a way to comply with the standards, but it is not the only way. If the above criteria are met and the organization is in compliance with sterile compounding standards at the time of the review, utilization of the glove box is acceptable.	
28	Our question pertains to the physical requirements of an IV cleanroom/ante room. The current layout is a single room containing both "ante" room and "clean" room designated areas. Additionally, the	This question is specific to your renovation and construction to upgrade your compounding areas. Joint Commission engineers do not answer specific pharmacy infrastructure and design questions (or review infrastructure designs) prior to construction. The organization should refer to USP Chapter <797> requirements when planning for construction or changes to their compounding pharmacy. You can choose to work with your organization's engineers or a	

	room air quality is consistently maintaining an ISO Class 7 environment. We are also in the process of building a new facility, so I need to determine how much renovation needs to occur in our existing facility which we are expected to vacate in 2018.	consultant and/or contractor. Any hospital or home care organization engaging with a consultant and/or contractor to construct these types of areas should consider whether or not the person engaged and overseeing the process has working knowledge of USP requirements. Another resource that may be of help are the Guidelines for Design and Construction of Hospitals and Outpatient Facilities, 2014, at Sections 2.1-4.2 entitled "Pharmacy Services".	