

COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE PHARMACY SUB-COMMITTEE ON ABNORMAL RESULTS

239 Causeway Street, Fourth Floor ~ Room 417A

Boston, Massachusetts 02114

Friday, October 30, 2015

Advisory Sub-Committee Members Present

Rory K. Geyer, PhD (Expert in cGMP)

John Walczyk, PharmD, RPh (Expert in USP<795>)

Karen B. Byers, MS, RBP, CBSP (Expert in Microbiology)

David H. Farb, PhD (Expert in Clinical Pharmacology) – remotely via phone, arrived at 10:40 AM

Antoinette Lavino, RPh, BCOP (Expert in USP<797>)

Anthony M. Cundell, PhD (Expert in USP<71>) – remotely via phone

Eric Kastango, RPh, MBA, FASHP (Expert in USP<797>) – remotely via phone

Advisory Sub-Committee Members Not Present

Francis McAteer (Expert in Microbiology)

Support Staff Present

James Lavery, JD, Director, Division of Health Professions Licensure

David Sencabaugh, RPh, Executive Director, Board of Pharmacy

Heather Engman, JD, MPH, Board of Pharmacy Counsel

William E. Frisch, Jr., RPh, Director of Pharmacy Compliance

Kelly Ann Barnes, JD, RPh, Director of Pharmacy Quality Assurance

Janet Sullivan, Program Coordinator

Colleen K. Collins, PharmD, RPh, Pharmacy Investigator

TOPIC:

1. WELCOME and CALL TO ORDER

10:05 AM

DISCUSSION: At 10:05 AM, J. LAVERY, Director, Division of Health Professions Licensure, called the meeting of the Pharmacy Advisory Sub-Committee on Abnormal Results to order. He asked if anyone in the audience was recording the meeting; no one indicated that they were recording the meeting. He indicated that the meeting was a public forum and the Board was recording the meeting.

The members in attendance were: R. GEYER, J. WALCZYK, K. BYERS and A. LAVINO

This met the 4 member quorum. D. FARB, A. CUNDELL and E. KASTANGO

participated remotely by telephone. Sub-Committee members and Board staff introduced themselves.

TOPIC:

2. APPROVAL OF AGENDA

10:06 AM

DISCUSSION: J. LAVERY asked if there were any changes or questions relative to the agenda.

K. BARNES mentioned that the approval of minutes will be deferred as they are still being finalized. No other changes were noted.

ACTION: At 10:06 AM, motion by J. WALCZYK, seconded by A. LAVINO, and voted unanimously by roll call to approve the agenda with no changes.
R. GEYER:yes, J. WALCZYK:yes, K. BYERS:yes, D. FARB:yes, A. LAVINO:yes, A. CUNDELL: yes, E. KASTANGO: yes

TOPIC:

3. RESPONSE TO ABNORMAL RESULTS

10:07 AM

Director of Compliance W. FRISCH outlined the goals of the meeting:

1. Finalize the memo with approved policy standards guidelines for ISO 7 and ISO 8
2. Reach consensus on the overarching guidance documents on proper remediation of abnormal environmental monitoring (EM) results for the Board to consider.

W. FRISCH referred the group to the memo from William E. Frisch and Kelly Ann Barnes titled "PROPOSED Policy Standards or Sterile Compounding (ISO 7 and ISO 8)", dated October 30, 2015. He asked the group to review the wording and reach consensus on the language or revised language to be brought to the Full Advisory Committee.

Director of Quality K. BARNES reviewed the PROPOSED Policy Standards for Sterile Compounding (ISO 7 and ISO 8).

The language from the memo is indicated in bold below:

Pharmacy maintains policy and procedures defining a remediation plan to address abnormal environmental monitoring results in accordance with "Board Policy 2015-xx: Response to Abnormal Environmental Monitoring Results"

The group agreed that this will apply to ISO 7 and ISO 8 areas.

A pharmacist Manager of Record or pharmacist designee shall notify the Board via email notification within 24 hours of receiving notification of EM results from the microbiologist.
The group agreed that this will apply to ISO 7 and ISO 8 areas and clarified that this is within 24 hours from the *receipt* of such notification.

A pharmacist Manager of Record or pharmacist designee shall submit *Disclosure of Abnormal Results* accompanied by the microbiology reports associated with abnormal environmental monitoring results within 7 days of receiving the reports in accordance with 247 CMR 20.

The group agreed that this will apply to ISO 7 and ISO 8 areas.

A Pharmacy shall immediately assess abnormal environmental monitoring results and may not prepare CSPs until remediation plan is developed and implemented in accordance with "Board Policy 2015-xx: Response to Abnormal Environmental Monitoring Results."

The group agreed that this will apply to ISO 7 and ISO 8 areas. This was noted to be a pause as discussed at previous meeting. The length of the pause depends on the situation.

A Pharmacy shall develop a remediation plan in accordance with "Board Policy 2015-xx: Response to Abnormal Environmental Monitoring Results."

The group agreed that this will apply to ISO 7 and ISO 8 areas.

~~In accordance with USP <797>, a pharmacy shall engage the assistance of a microbiologist, infection control professional, or an industrial hygienist to develop a remediation plan.~~

There was discussion among the group regarding USP <797>, which suggests the assistance in certain circumstances (e.g. highly pathogenic or if consistent elevated levels were trended).

It was proposed to change the statement to:

A pharmacy shall engage the assistance of qualified personnel, such as a microbiologist, infection control professional, or an industrial hygienist to develop a remediation plan.

With the possible exception of A. CUNDELL, the group agreed that this will apply to ISO 7 and ISO 8 areas. The group noted that this can be re-addressed if needed after the other standards are finalized.

[D. FARB arrived at 10:40 AM]

A pharmacy shall properly remediate abnormal environmental monitoring results in accordance with “Board Policy 2015-xx: Response to Abnormal Environmental Monitoring Results.”

The group agreed that this will apply to ISO 7 and ISO 8 areas.

Successful remediation of abnormal environmental monitoring results shall be proven by repeat environmental monitoring microbiology reports demonstrating results within acceptable levels.

The group agreed that this will apply to ISO 7 and ISO 8 areas.

Pharmacy shall submit the completed remediation plan including microbiology report from repeat environmental monitoring to the Board within 30 days of the pharmacy’s initial notification of the results or a timeframe agreed upon by the Executive Director or their designee.

The group agreed that this will apply to ISO 7 and ISO 8 areas.

Pharmacy shall perform repeat environmental monitoring of non-viable air and viable air and surface (bacterial and fungal) as part of remediation to abnormal environmental monitoring results. The pharmacy may limit the repeat environmental monitoring to the affected ISO classified space based on the pharmacy’s environmental monitoring sampling plan unless otherwise directed by the Board (or at the Board’s discretion).

There was discussion on the location of the repeated monitoring. The group agreed that this will apply to ISO 7 and ISO 8 areas.

There was discussion on the proposed USP <797> changes and there was consensus that glove fingertip monitoring should be emphasized and should be done more frequently to monitor the state of control.

The language below in bold from the memo was discussed.

ISO 7 and ISO 8

~~Upon receipt of an abnormal environmental monitoring result in ISO 7 or ISO 8 classified area(s), a pharmacy may resume compounding for low and medium risk CSPs if:~~

- ~~• The routine environmental monitoring results for the preceding month were within USP action levels~~
- ~~• The environmental monitoring data does not indicate 3 or more monthly reports with above action level results since the last certification~~
- ~~• The pharmacy has immediately assessed abnormal environmental monitoring results, and developed and implemented a remediation plan.~~

~~A pharmacy resuming compounding of low and medium risk CSPs during remediation of ISO 7 or ISO 8 abnormal results shall limit the BUDs for CSPs to 24 hours room temperature, 3 days refrigerated until the repeat environmental monitoring reports demonstrate results within acceptable levels.~~

~~Upon receipt of an abnormal environmental monitoring result in an ISO 7 or ISO 8 classified area(s), a pharmacy may not resume compounding until the repeat environmental monitoring reports demonstrate results within acceptable levels~~

~~If:~~

- ~~• During the preceding month, an environmental monitoring results was above USP action levels, OR~~
- ~~• The environmental monitoring data indicates 3 or more reports with above action level results since the last certification.~~

~~Upon receipt of an abnormal environmental monitoring result in an ISO 7 or ISO 8 classified area(s) the pharmacy may not engage in high risk compounding or freeze any CSP until repeat monitoring reports demonstrate results within acceptable levels.~~

There was much discussion. It was suggested to add clarity to the timing of the last certification. A. LAVINO suggested that in summer months, there are times when environmental contaminants can be an issue in the ISO 8, and it could occur sequentially. The group decided to start with the ISO 7 Buffer Room and strike ISO 8 for now, especially considering the water contaminants typically found in an ISO 8 classified area.

K. BARNES noted that batch freezing was not originally added to the recommendations as the thought is that they did not want registrants batch producing and freezing medications without knowing the state of control of the area. J. WALCZYK commented that the freezing BUDs might be too short for an outpatient medication such as vancomycin eye drops. E. KASTANGO noted that many pharmacies do not have the correct type of freezer, and home freezers also are unpredictable and added that it may depend on how it is made (high risk, from a commercially available product, etc). J. WALCZYK noted that you are giving the product high risk dating and had concerns with continuity of care for ambulatory patients. K. BARNES suggested that this

type of activity may need to be allowed based on the clinical discretion of the Executive Director of the Board (or designee) and suggested to add “or a timeframe agreed upon by the Executive Director or their designee...” A. CUNDELL stated that Table 8 in USP <797> suggests BUDs for compounds in a frozen state that it is given a 45 day BUD, suggesting that the committee felt that freezing is a risk mitigation strategy. K. BARNES asked for consensus on the freezing statement as written. R. GEYER noted that there are other data points that can be considered (media fills, glove fingertip, etc). K. BARNES noted they do not want batch production to occur at pharmacies at times when the state of control is unknown. J. WALCZYK noted that he was more concerned with patient specific medications rather than batching. D. SENCABAUGH noted that the registrant would have to discuss this type of situation with the Executive Director of the Board, or designee and they would have to look at the specific situation.

There was a lot of continued discussion on resuming compounding. A. LAVINO suggested clarifying wording on the data sampling stating “consecutive” sampling.

Based on the discussions, the Committee decided to change the above stricken language to:

ISO 7 Buffer Room:

Upon receipt of an abnormal environmental monitoring result in the ISO 7 buffer room, a pharmacy may resume compounding for low and medium risk CSPs if:

- **The environmental monitoring data does not indicate 3 or more consecutive sampling reports with above action level results within the last 6 months, and**
- **The pharmacy has immediately assessed abnormal environmental monitoring results, developed and implemented a remediation plan and scheduled the repeat monitoring.**

A pharmacy resuming compounding of low and medium risk CSPs during remediation of ISO 7 buffer room abnormal results shall limit the BUDs for CSPs to 24 hours room temperature, 3 days refrigerated or a timeframe agreed upon by the Executive Director or their designee until the repeat environmental monitoring reports demonstrate results within acceptable levels.

A pharmacy may not resume compounding if the environmental monitoring data indicates 3 or more consecutive sampling reports with above action level results within the last 6 months.

A pharmacy may not engage in high risk compounding upon receipt of an abnormal environmental monitoring result in an ISO 7 buffer room if the environmental monitoring data indicates 2 or more consecutive sampling reports with above action level results.

A pharmacy may not freeze any CSP upon receipt of an abnormal environmental monitoring result in the ISO 7 buffer room until repeat monitoring reports demonstrate results within acceptable levels unless otherwise approved by the Executive Director or their designee.

ACTION: At 1:09 PM, motion by K. BYERS, seconded by A. LAVINO, and voted unanimously by roll call to approve the Proposed Policy Standards for Sterile Compounding for the ISO 7 areas and bring it to the full Advisory Committee.

R. GEYER:yes, J. WALCZYK:yes, K. BYERS:yes, D. FARB:yes, A. LAVINO:yes, A. CUNDELL: yes, E. KASTANGO: yes

A. LAVINO noted that the ISO 8 and ante room will need to be discussed and decided on as well. K. BARNES noted that there will be homework for the Sub Committee with regards to this topic. J. SULLIVAN will send out the finalized memo. H. ENGMAN reminded the group to comply with Open Meeting Law.

TOPIC:

4. CLOSING REMARKS/ADJOURNMENT

1:16 PM

DISCUSSION: None.

ACTION: At 1:16 PM, motion by J. WALCZYK, seconded by D. FARB, and voted unanimously by roll call to adjourn.

R. GEYER:yes, J. WALCZYK:yes, K. BYERS:yes, D. FARB:yes, A. LAVINO:yes, A. CUNDELL:yes, E. KASTANGO:yes

LIST OF EXHIBITS USED DURING THE MEETING

1. Agenda for the October 30, 2015 Pharmacy Advisory Sub-Committee Meeting on Abnormal Results
2. Memo from Janet Sullivan to David Sencabaugh, James Lavery, Timothy St. Laurent, Heather Engman. Advisory Sub-Committee meeting – October 30, 2015.
3. Memo from William E. Frisch and Kelly Ann Barnes. PROPOSED Policy Standards or Sterile Compounding (ISO 7 and ISO 8) – October 30, 2015.
4. Draft Minutes of the Pharmacy Sub-Committee on Abnormal Results. August 28, 2015. ²
5. UPDATED Memo from Janet Sullivan to David Sencabaugh, James Lavery, Timothy St. Laurent, and Heather Engman. Advisory Sub-Committee meeting – October 30, 2015.
6. UPDATED Memo from William E. Frisch and Kelly Ann Barnes. PROPOSED Policy Standards for Sterile Compounding (ISO 7 and ISO 8) – October 30, 2015.

Respectfully submitted,

Colleen K. Collins, PharmD, RPh
Pharmacy Investigator