Pharmacy Environmental Investigation (Phase II)

Root Cause Analysis (RCA) and Corrective Action Plan Worksheet AH=Anywhere Health System

If RCA is performed in response to actionable Environmental Monitoring results, complete Phase I prior to Phase II.

Campus/Pharmacy Location Select Location.

Excursion Date If multiple dates, enter the triggering event date/date of first actionable result.

Section 1: Environmental Investigation Background

Section 2: Environmental Root Cause Questionaire (Complete sections that apply.)

A. Facilities and Engineering Evaluation	Yes	No	N/A
1. Were there any recent changes to the facility design, operational processes, including renovation to classified/unclassified spaces within the pharmacy or adjacent areas?	☐	☐	☐
a. If yes, was Engineering and the Office of Design and Construction contacted to evaluate? Explain/Dates: _____	☐	☐	☐
b. Was any work taking place near/on an air handler or near/on the HVAC system supporting the classified space, or had any routine or scheduled maintenance to any air filter or air handler occurred recently? Explain/Dates: _____	☐	☐	☐
2. Were there any upstream issues affecting the clean room? Explain/Dates: _____	☐	☐	☐
3. Were there any environmental concerns (e.g. adjacent to classified space, cardboard around perimeter, etc.) that could have impacted the classified space? Explain/Dates: _____	☐	☐	☐
4. Were any HEPA filters found to be permeated or contaminated?	☐	☐	☐
a. If yes, has a certifier and/or Engineering been contacted for repair/replacement? Explain/Dates: _____	☐	☐	☐
5. Does the facility layout design adequately prevent the influx of poor-quality air and allow for proper personnel/material flow? Explain/Dates: _____	☐	☐	☐
6. Does the facility have adequate physical barriers separating non-aseptic areas, including fully sealed/intact caulk around HEPA filters? Explain/Dates: _____	☐	☐	☐

B. Process, Procedure and Change Evaluation	Yes	No	N/A
7. Were any changes to processes and procedures (activities, traffic patterns, etc.) recently implemented? Explain/Dates: _____	☐	☐	☐
C. Primary Engineering Control (PEC) Evaluation	**Yes**	**No**	**N/A**
8. Were end of shift PEC visual inspections performed and documented appropriately in Compounding360? Explain/Dates: _____	☐	☐	☐
a. If yes, were any issues identified (e.g. inadequate 24/7 running capacity/consistency, filth, damage, leak, permeation or residue, or sources of moisture/contamination in/around the PEC)? Explain/Dates: _____	☐	☐	☐
9. Has any PECs/compounding equipment been recently removed/replaced or relocated? Explain/Dates: _____	☐	☐	☐
a. If deemed necessary, was a smoke study performed in the PEC(s)? Explain/Dates: _____	☐	☐	☐
b. If yes, did any areas display turbulent or disrupted airflow, or any changes compared to the most recent previous smoke study? Explain/Dates: _____	☐	☐	☐
D. Secondary Engineering Control (SEC) Evaluation	**Yes**	**No**	**N/A**
10. Were end of shift SEC visual inspections performed and documented appropriately? Explain/Dates: _____	☐	☐	☐
a. If yes, were any issues identified (e.g. filth/damage/tears to walls/ceilings/floors/caulking)? Explain/Dates: _____	☐	☐	☐
11. After reviewing monthly preventative maintenance records of HVAC by facilities, is a sweep, flush, or clean needed in the ductwork? Explain/Dates: _____	☐	☐	☐
12. Were there any recent and significant pressure deviations? Explain/Dates: _____	☐	☐	☐
13. If deemed necessary, was a smoke study performed in the SEC(s)?	☐	☐	☐

(D. Secondary Engineering Control (SEC) Evaluation (cont.))	Yes	No	N/A
a. If yes, did the smoke study reveal any air flow issues (e.g. leaking caulked areas/sealed compartments or doors, etc.)? Explain/Dates: _____	☐	☐	☐
14. Did the HVAC lose control due to lack of airflow or power loss? Explain/Dates: _____	☐	☐	☐
15. Is the SEC operating the same or like operating conditions at the time of certification (e.g. temperature, humidity, pressure, etc.)? Explain/Dates: _____	☐	☐	☐
16. Did a review of storage of supplies and components within the SEC reveal any issues (excess supplies/overcrowded shelves, corrugate or prohibited materials, such as cardboard/cartons, etc.) Explain/Dates: _____	☐	☐	☐
17. Was the material transfer process conducted in compliance with SOP Sterile Compounding Process? Explain/Dates: _____	☐	☐	☐
E. Secondary Engineering Control (SEC) Evaluation	**Yes**	**No**	**N/A**
18. Were cleaning supplies properly stored in a segregated/designated area? Explain/Dates: _____	☐	☐	☐
19. Were cleaning tool designated for a specific area, only used in the designated area? Explain/Dates: _____	☐	☐	☐
20. Were cleaning tools properly cleaned and disinfected prior to use? Explain/Dates: _____	☐	☐	☐
21. Were cleaning tools in good working condition and free from defects or need for repairs? Explain/Dates: _____	☐	☐	☐
F. Personnel Hygiene and Aseptic Work Practice	**Yes**	**No**	**N/A**
22. Did a review of personnel hand hygiene/garbing procedure and work practices (including aseptic technique) reveal any of the following: History of excursions/microbial recoveries? Explain/Dates: _____	☐	☐	☐

(F. Personnel Hygiene and Aseptic Work Practice (cont.))	Yes	No	N/A
b. Evidence of touch contamination with door openings, items in hood, etc.? Explain/Dates: _____	☐	☐	☐
23. Did any ill employees (as defined in SOP 201.072) access the sterile compounding area? Explain/Dates: _____	☐	☐	☐
24. Did a review of the Cleaning and Disinfection record reveal that procedures were properly followed per WI Cleaning and Disinfecting of Sterile Compounding Areas and SOP Sterile Compounding Process? Explain/Dates: _____	☐	☐	☐
G. Sampling Technique, Personnel, and Equipment	**Yes**	**No**	**N/A**
25. Prior to and during environmental sample collection, were the following standards met? a. Was the sampler's equipment properly calibrated and qualified? Explain/Dates: _____	☐	☐	☐
b. Were the sampler's equipment/supplies properly disinfected prior to introduction into the sterile compounding area and prior to use? Explain/Dates: _____	☐	☐	☐
c. Can the sampler provide written evidence of their disinfection of equipment/material transfer? Explain/Dates: _____	☐	☐	☐
a. Did the sampler perform proper gowning, gloving, aseptic technique and collect samples in the proper order? Explain/Dates/ Observer: _____	☐	☐	☐
c. Were the proper controls, incubation time and temperature utilized and was the media unopened and within the expiry date? Explain/Dates: _____	☐	☐	☐

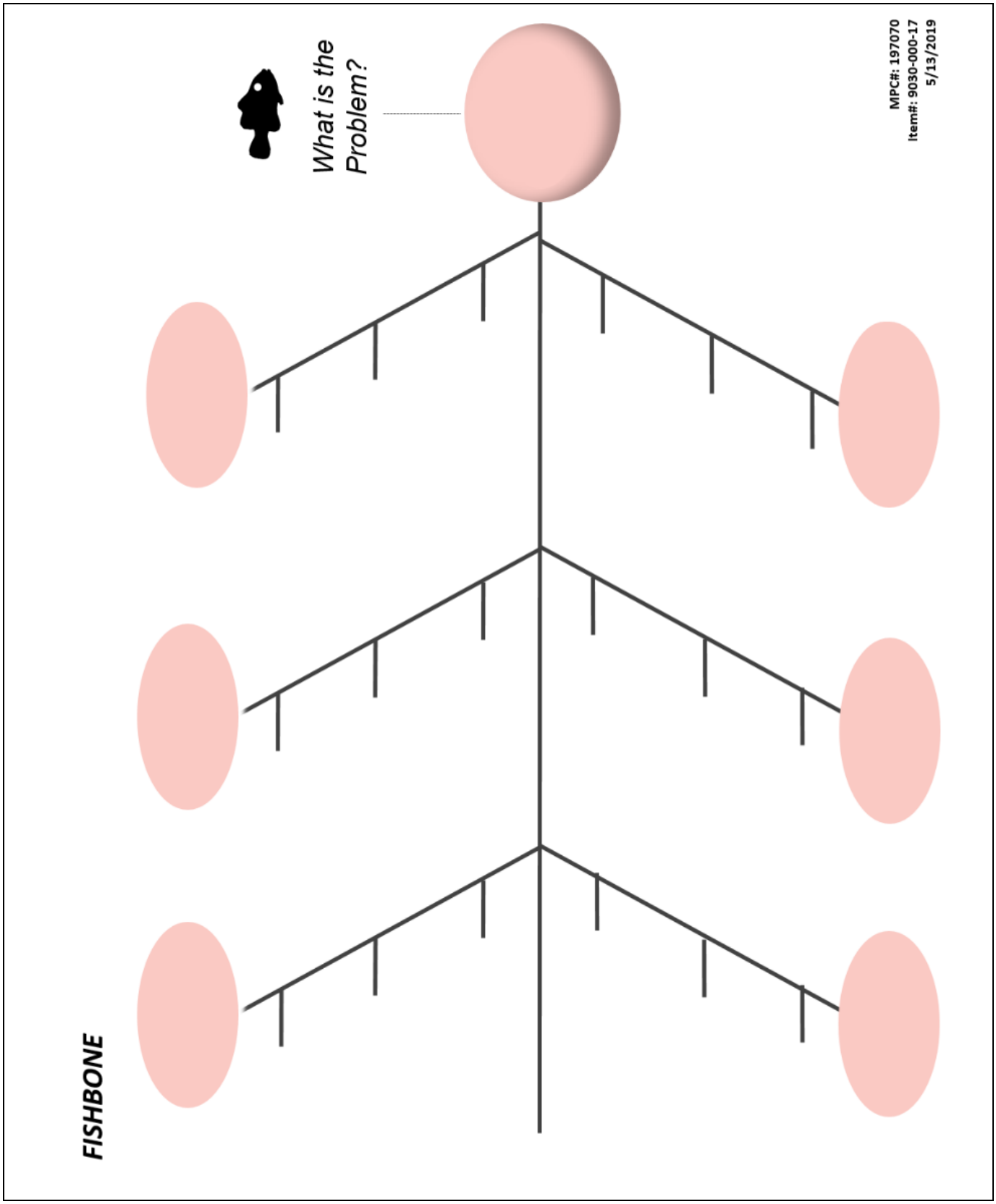
Section 3: Risk Assessment & Patient Safety Assessment (Required unless previously completed as part of Phase 1.)

Assessment	Yes	No	N/A
1. Review RiskMaster for patient events that could be linked to this excursion. Did any events appear to potentially be linked? Explain/Dates: _____ _____ _____	☐	☐	☐
2. Is there a patient safety concern related to the excursion? Explain/Dates: _____ _____ _____	☐	☐	☐
3. Is a recall of product warranted as a result of this excursion? Explain/Dates: _____ _____ _____	☐	☐	☐
4. Was a recall initiated as a result of this excursion? Explain/Dates: _____ _____ _____	☐	☐	☐

Section 4A: Action Plan ☐N/A

Section 4B: Additional Notes ☐N/A

Section 4C: Fishbone Diagram (optional) ☐N/A



Review and Approvals

Route for approvals as applicable. Retain this documentation with associated results (and/or with associated Phase I (if applicable)).

Investigation/Risk Assessment Prepared By

Pharmacy Manager's Name
Designated Person

Additional Investigator(s) ☐N/A

Investigator's Name(s)
Delegated Investigator

Facilities/Engineering Consult/Office of Design and Construction ☐N/A

Facilities/Engineering/ODC Representative

Submit to Infection Prevention

Infection Prevention Review ☐N/A

Infection Prevention

Regional Director/Campus Pharmacy Director Approval (if applicable) ☐N/A

Pharmacy Director's Name
Director of Pharmacy

List Attachments (optional):☐N/A

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