



U.S. Food and Drug Administration
Protecting and Promoting Public Health



Panel Questions

Question 1

Mitigating Water Contamination in Heater-Cooler Devices (HCD):

- **Literature provides evidence of nontuberculous mycobacteria (NTM) transmission through aerosolization of contaminated water in HCDs. It's important to note that HCDs are not shipped as sterile devices, nor are they intended to be maintained as sterile in the clinical environment. Therefore, some level of microbial contamination of the water within the HCD will be unavoidable. To mitigate risk of NTM exposure and improve the safety margin for patients undergoing cardiothoracic procedures where HCDs are used, please address the following questions:**

Question 1 (cont.)

- a. **Should existing standards or limits for microbial water quality (e.g., EPA drinking water standard – 500 cfu/ml HPC or water for hemodialysis – 50 cfu/ml) be used as a surrogate when determining acceptable levels of NTM in the circulating water in the HCD water pathways to minimize/mitigate patient infection?**

- b. **Upon release of a new or serviced heater-cooler device from the manufacturer for shipping to a clinical facility, what is an acceptable level of bacterial contamination in the water pathways of the device?**

Question 1 (cont.)

- c. In the clinical environment, should monitoring (i.e. surveillance) of the HCD water for NTM or bacterial contamination be performed? If yes, please consider the following :**
- i. Whether surveillance / monitoring of the HCD water should be implemented by healthcare facilities as a matter of routine or only at those facilities where patient infections have occurred, and in either case at what frequency**
 - ii. The entities that should perform the testing (e.g. hospital-based microbiology laboratories or independent laboratories) and what monitoring would consist of (e.g. microbial water quality, NTM, etc.)**
 - iii. The other indicators healthcare facilities should utilize as part of their monitoring (visual cues, length of time in service, etc.). Whether there is a threshold or trigger that can be identified for removing a device from clinical use**

Question 2

Mitigating Biofilm Formation in HCDs: Overgrowth of bacteria in HCDs is problematic and can lead to biofilm formation. The prevention, detection and removal of biofilm can be challenging.

a. Given a consistent low-level of water contamination in the water pathways, device labeling indicates that regular preventative maintenance is necessary to mitigate / minimize risk of patient infections. What factors would have the most impact on minimization of biofilm formation? Please consider the following points in your response:

i. Frequency of mechanical and/or chemical cleaning before disinfection, and factors that impact frequency (e.g. microbial monitoring, visual cues, operating hours, etc.)

Question 2 (cont.)

- ii. **Maintenance intervals and maintenance procedures as part of regular servicing at hospital facilities**
 - iii. **Device materials, water system designs, microbicidal processes or chemical treatment methods (e.g. combination of cleaning and disinfecting agents)**
- b. **Should cleaning/disinfection servicing performed by the manufacturer be part of routine maintenance to demonstrate an acceptable level of contamination (as discussed in question 1a)? If so, at what frequency?**

Question 3

Case Definition and Patient and Provider Notifications: Once NTM has been detected in the hospital environment or via retrospective review,

- a. What case definition should be used for patient identification and stratification for communication with patients?**
- b. Please discuss what methods could be implemented for identification and tracking of potentially infected patients (e.g. registries, electronic health record, etc.)?**
- c. Understanding the latency period for the onset of symptomology of NTM infection, what would be the best approach and appropriate time periods (for healthcare providers to communicate with their potentially infected patients)?**

Question 4

Present and Future Device Considerations for Reducing Risk of NTM Infections:

- a. In addition to the recommendations in the FDA HCD safety communication and FDA's HCD webpage, what other suggestions do you have for devices already on the market that may help mitigate/minimize patient infections from aerosolized NTM? Things to consider would include revisions to the device labeling/instructions for use; device related considerations that would not adversely affect device performance; and/or environment/use-related considerations**

Question 4 (cont.)

- b. For devices in development, what design features, instructions for use and/or environmental/use-related considerations might you suggest to mitigate aerosolization and minimize patient infection?**

- c. In order to develop a validated disinfection process both currently in use and for future devices, how should manufacturers properly challenge the device in a lab environment that would replicate real-world use (i.e., test organism, mixture vs individual organisms, simulated use, parts of the device to test, microbicidal threshold (6- log, intermediate, high-level disinfection), etc.)?**