# Additional Q&A from Abby Roth at CriticalPoint, LLC.
# 13-JAN-2021 Webinar
# Developing a Sampling Plan for USP <797> Compliance

**When you have an EM action in critical sample area how does it relate to product impact for compounding? GMP mfg will discard product**

USP 797 requires an investigation into the source and remediation for any exceeded action level, regardless of ISO class. The investigation usually includes a review of work practices, cleaning, and engineering control functionality. Remediation usually includes cleaning, retraining, and resampling.

In most cases the compounded sterile preparations (CSPs) have already been administered to patients when the viable results are received, so there is not much that can be done, except to check if adverse events are reported.

In some cases, the pharmacy prepared a batch with beyond-use dating that exceeds the dating provided by USP. If this is done, the batch would require sterility testing and some may still be around when the viable sample data comes back. The results of the sterility test, and the number of colony forming units (CFU) recovered and the type of microorganism will dictate the next steps. This is on a case-by-case basis and should be done with the help of a microbiologist or if in a hospital, their infection prevention team.

**What does HD mean in the HD Buffer and HD Storage areas?**

HD stands for hazardous drug.

**Please differentiate between Beyond Use Date (BUD) and Expiration Date?**

In section 14.1 Terminology, the 2019 version of USP 797 provides a comprehensive table defining the difference between a beyond-use date and an expiration date. Here is a summary of the definitions.

BUD - Either the date, or hour and date, after which a CSP must not be used. This does not include time required for administration. This applies to compounded sterile preparations only.
Expiration Date - The time during which a product can be expected to meet the requirements of the compendial monograph, if one exists, or maintain expected

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quality provided it is kept under the specified storage conditions. This applies to all conventionally manufactured products, API, and added substances.

BUDs are set based on the shorter of microbial sterility and chemical stability. USP provides recommended BUDs for microbial sterility. If the chemical stability of the drug is shorter than that of the microbial sterility, the chemical stability date would become the BUD. In many ways it is up to the pharmacist to determine the appropriate BUD based on USP provided dates, manufacturer data, peer reviewed chemical stability studies, and their organization's compliance with USP 797 sterile compounding work practices.

**For transfer chamber samples, do you use the ISO 5 action level cut off for CFUs?**

The action level would depend on the ISO classification of the transfer chamber. In many cases the transfer chamber is ISO Class 7, and the air and surface samples would be expected to meet ISO 7. However, there are some RABS where the transfer chamber does not have any HEPA filtration. The use of such a device is not recommended.

**From a risk perspective, how do you evaluate if you should sample personnel or not?**

503A organizations are only required to meet the personnel sampling requirements of USP 797, so sampling is required, but it's more of a question as to how frequent should that sampling be performed. It is recommended that organizations that perform nonsterile to sterile compounding (also known as high-risk compounding) consider performing glove fingertip sampling and media-fill testing weekly. Currently this is only required every 6 months. For those that perform sterile to sterile compounding, gloved fingertip and media-fill testing is only required yearly. CriticalPoint recommends at least quarterly sampling. The 2019 version of the chapter will require all those who perform sterile compounding to perform personal testing every six months.