1. **­Purpose**

The purpose of this document is to describe the procedure for assigning expiration dates to all reagents, reference substances, prepared solutions, and other chemicals.

1. **Scope**

This document applies to all reagents, reference substances, prepared solutions, and other chemicals used in the QC laboratory in both USP and non-USP testing.

1. **Responsibility**

QA Lab personnel will be responsible for the proper assignment of expiration dates in the laboratory.

1. **Safety Considerations**

Safety Glasses, Chemical Resistant Gloves, and Lab Coat should be worn.

Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or community.

1. **Materials/Equipment**

N/A

1. **Procedure**

The assignment of expiration dates will be as follows:

* 1. Reference substances will be given an expiration date as specified on the container label or by Certificate of Analysis.
  2. The expiration dates assigned to stock solutions and their dilutions should not exceed one year.
  3. Most purchased chemicals will be given a 5 year expiration date unless information exists otherwise (i.e. manufacturer’s expiration date). The exception to this will be reagents containing ammonia. This is because the ammonia gas will come out of solution over time, and the chemical’s strength will be reduced. Reagents containing ammonia will be given a six-month expiration date after opening, or a one-year expiration date after receipt, whichever comes first.
  4. Solutions prepared from purchased reagents will be given a six-month expiration date after preparation, unless information exists to indicate otherwise. **NOTE: Any visual signs of instability, e.g., precipitate, color change, turbidity, indicated the need to prepare a new solution.**
  5. Solutions of acids and bases where the accuracy of the final concentration is not critical will have a one year expiration date assigned.
  6. pH buffers will be given a two year expiration date for commercially prepared solutions, and a six month expiration date for laboratory preparations.

**Notes:**

1. An expiration date printed on a container by a manufacturer will overrule any others outlined in the procedure. Do not confuse preparation or bottling dates that some manufacturers place onto bottles, with an expiration date.
2. The expiration date of solvents and chemicals will be assigned on the basis of when the material was received.
3. Even solutions that are known to be stable will be provided with an expiration date, beyond which they should not be used. The reason for this is that solutions/reagents are generally used frequently, and the possibility of evaporation of solvent, or contamination increases over time.
4. **Reference Documents**

N/A

1. **Change Information**

New Document