General Discussion
What minimum standards should be considered by an API manufacturing site for the storage, handling and cleaning of hoses used during cleaning or production of Intermediates or final Active Pharmaceutical Ingredients?

This guidance will only deal with hoses that can be moved and used for multiple purposes rather than flexible lines that are permanently fixed to the equipment (e.g. flanged). A flexible line that is permanently fixed to the equipment should be managed and maintained in accordance with the site maintenance practices.

This document is intended to provide general guidance on:

- Hose Use Procedure
- Considerations When Developing Site Hose Specifications
- Preventive Maintenance
- Visual Inspection (Verification) Prior to Use or Storage
- When and how often should hose inspection be done?
- Labeling and Traceability
- Cleaning of Hoses
- Storage and Handling
- Managing Hose Failure Incidents

This document will assist Site API manufacturing facilities in developing and implementing site-specific hose management practices, if not currently existing, or enhance prevailing hose practices that put emphasis on both Quality and Operational efficiency.

Hose Use Procedure:
GMP sites should have procedures defining the use, specification, storage, handling, cleaning and maintenance of hoses used in cleaning and production of intermediates and APIs in accordance with cGMP guidelines. Flexible hoses should be adequately identified, maintained, and cleaned.

Section 5.2 - Q7A, emphasizes written procedures should be established for cleaning equipment and its subsequent release for use in manufacture of intermediates and APIs. In addition, sites should have standardized hose management practices, including management of change, with written procedures that identify factors to be considered and evaluated.

Considerations When Developing Site Hose Specifications:
Each hose assembly should meet or exceed the applicable requirements in functionality, dimension, characteristic or industry standards. A cross-functional evaluation and approval on hose specifications among site's responsible personnel (i.e., engineering, quality, production/operations, maintenance, and safety representatives) and collaboration with approved hose vendors/distributors in discussing specific hose needs will help assure new hoses are ordered right the first time.

Incorporating such specifications into the appropriate site's hose management procedure is suggested. A matrix showing compatibility of hose assemblies & fittings with required applications would be a helpful tool.

Simplify and reduce the number of hose classifications, as much as possible. Where practical, customize hose specifications for a broader range of uses to make it simpler and safer to use the correct hose.

- Hang
- Allow to drain/dry
- Cap or cover ends
- Label the hose as clean ready to use

There should be an established procedure for the proper storage conditions for hoses. For easy handling, consider using hose racks. The hose should be stored uncoiled with the ends oriented downwards but not touching the floor in a designated storage area. To prevent foreign matter contamination and diminish the potential of undesirable microbial contaminants, covering hose ends with suitable material after the hose is dried is recommended. While in storage, the hose or the area where it is kept should display the hose's cleaning status via a label or tag to allow verification when it is returned to service.

Managing Hose Failure Incidents:

The chemical hose is the weakest link in the chemical transfer system. The tracking of failure incidents as a component of a hose management program will serve an added assurance that an effective system exists for maintaining and monitoring hose condition and performance throughout its life cycle.

Hose failure incidents attributed to damaged physical conditions including failed cleaning results should be treated like any other incident and should be captured in the site deviation system, investigated, and documented in accordance with site SOPs. The investigation should consider:

- Scope, i.e., how many lots were produced using the failed/damaged hose?
- Potential for physical and chemical contamination of the product from the hose Failure.

