

Title: Cleaning Validation – Guidance for Swab Sampling and Visual Inspection Locations for API Equipment					
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**Cleaning Validation – Guidance for Swab Sampling and Visual Inspection Locations for
API Equipment**

Introduction

This guidance provides recommendations related to the selection and application of swab sampling and visual inspection for various types of API equipment.

Table 1 indicates the type of cleaning or cleaning validation required, the method to be used and additional routine verification to be conducted after validation for change-over cleaning from specified compound types. This Good Practice Bulletin provides guidance in selecting the type of routine verification sampling method to use for particular types of API equipment and recommends locations for where to perform swab and / or visual inspection conducted during cleaning validation and during subsequent routine verification.

Recommendations & Discussion

The cleaning evaluation determines the major contaminant(s) to be sampled and tested for each equipment item. The table on the following pages provides guidance for each equipment type. The table provided below is intended as guidance and does not substitute a thorough consideration of the design of equipment to identify those locations deemed difficult to clean, nor does it mandate the inspection or sampling of suggested locations that would require vessel entry or require undue safety concerns based upon the design, size, or intended use of equipment. Consideration of locations to sample can be documented as part of the cleaning evaluation documentation (e.g. site SOP) conducted for the development of a sampling plan of the equipment system.

Table 1: Type of cleaning or cleaning validation required.