frequency of changes in the area, and the length of time the SOP is in operation. The following review frequency period is recommended:

- o 3 years or less = frequent
- o 3 -4 years = moderate
- o 4-5 years = low
- o As needed = depends on site needs, requirement, or urgency of situation

The above review frequencies should be treated as guidelines. Sites may adopt a more appropriate frequency based on SOP criticality and local operational needs.

Risk Control:
The results of the risk assessment (i.e. identification, analyses, and evaluation of potential risks) help identify the levels of risks confronting the sites with respect to potential issues encountered with SOP management and the pertinent requirements to keep them current.

The use of a risk management approach will allow sites to reach a balance between benefits, risks, and resources as they are now able to set priorities and effectively use available resources to address the review/revision of SOPs. After reaching a well-informed decision, a suitable SOP review period can be assigned for each SOP with a frequency that is reasonable and relevant to the site's own experiences. With a defined

SOP review period based on a risk assessment, sites can effectively reduce the risk identified through proper utilization of resources by focusing first on more critical ones and deferring on others but with calculated knowledge of its outcome. The following approaches are recommended which may help effectively manage the tasks involve in
keeping the site SOPs current to meet the site requirements and regulatory expectations.

1. Site SOPs should be grouped into categories consistent with the Site business operations that will make it convenient to perform the risk assessment

2. After performing risk assessment, assign each SOP a review frequency based on the site's own experiences which may include knowledge of the compliance status of each unit of operations (e.g. validation, laboratories, etc.), and the critical nature of the operation or past regulatory inspectional findings.

3. If technology is available at the site, manage the SOP review period due date on an automatic/electronic notification program.

4. If an SOP has a revision prior to the scheduled periodic review due date, reset the next periodic review due date based on the approval date of the latest revision.

5. Designate trained personnel for each SOP category or in each unit operation with the responsibility to coordinate, monitor or review SOP requirements and to submit request for SOP status change.

6. Create a site team consisting of individuals representing each unit of operation who have responsibility over SOP management to meet specific goals which may include: