

to each procedure is known as its “risk evaluation score”. (See Table 1) The following ranges of risk evaluation score is recommended to establish the ranking of the potential risks:

- 1–3 =Low
- 4–6 =Medium
- 7–9 =High

For instance, a Production procedure for the operation of a Jones Cartoner may have a risk evaluation score of 3 since the equipment is tasked with inserting leaflets containing dosing and product warning information, ensuring the integrity of the secondary package and imprinted the lot code and expiry on the carton, has direct product impact (High -3) yet the procedure for operating it is not subject to change unless the equipment undergoes modification and the fact that there are quality audits in place during operations to monitor the equipment’s performance (Low -1).

Risk Assessment - Identification, Analyses and evaluation of potential risks.

There is no regulation that requires specific periods for review of SOPs. However, the required status for any SOP is to be current. The goals of any site are to assure it will continue to produce quality products and to meet the challenges of a regulatory inspection. Periodic review of SOPs to assure they are current is a critical component to meeting these goals. But this is a difficult task when SOPs may number in the hundreds or thousands at a given site. A risk management approach to periodic review/revision of SOPs is recommended to assure site resources are appropriately applied to meet this challenge.

The risk is the likelihood (PROBABILITY) of having non-compliant or deficient procedures which have the potential to impact product quality or regulatory compliance attributed to lack of timely document review and that could remain unchecked or undetected. In addition, the greater potential of an SOP to impact product quality and regulatory compliance directly corresponds to a greater likelihood of that SOP being reviewed during an inspection. The potential undesired consequence (OUTCOME) under such circumstances is a negative impact on product quality and a regulatory citation from having an SOP in a non-compliant status. Considering the number of SOPs that could be subject of periodic review at a site, a more practical approach is to categorize the SOPs on the basis of potential impact to product quality and regulatory compliance.

- Categorization of SOPs
Site-level SOPs may be grouped into:
 - Quality
 - Validation and Qualification
 - Production
 - Packaging and Labeling
 - Materials
 - Laboratory
 - Facilities, Equipment, and Utilities
- Considerations for Risk Assessment – The following discussion is intended to give guidance for site SOP classification. General examples are provided in Table I.