16. What are the needs and expectations associated with interested parties? (4.2) The organization w i l l n e e d to determine the interested parties that are relevant to the quality management system and the requirements of those interested parties, as outlined in clause 4.2. This does not extend past the quality management system requirements and the scope of this International Standard. As stated in the scope, this International Standard is applicable where an organization needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction.

17. What is meant by organizational knowledge? (7.1.6 ) ISO/TC 176/SC2/N1271 www.iso.org/tc176/sc02/public Organizational knowledge is knowledge specific to the organization; it is gained by experience. It is information that is used and shared to achieve the organization’s objectives. Requirements regarding organizational knowledge were introduced for the purpose of safeguarding the organization from loss of knowledge and encouraging the organization to acquire new knowledge as its business context changes.

19.Why has Purchasing changed to ‘Control of externally provided processes, products and services’? (8.4) This change reflects the fact that not all products, services or processes that an organization acquires are necessarily purchased in the traditional sense. Some may be acquired from other parts of a corporate entity, for example, as part of a shared pool of resources, products donated by benefactors or services provided by volunteers.

20. What has happened to validation of processes or what used to be called special processes? (8.5) Although there is no longer a standalone sub-clause, this requirement continues, and has been incorporated into the sub-clause on control of production and service provision. (Ref. 8.5.1)

21. What is meant by post delivery activities and what is the extent of an organization’s responsibility? (8.5.5) This means that based on customer agreements or other requirements, the organization may be responsible for providing support for their product or service after delivery. This could include, for example, technical support, routine maintenance, or in some cases recall.

22. What is the difference in the standard between improvement and continual improvement? (10) ISO 9001:2008 used the term continual improvement to emphasize the fact that this is an ongoing activity. However, it is important to recognize that there are a number of ways in which an organization may improve. Small step continual improvement is only one of these. Others may include breakthrough improvements, re-engineering initiatives or innovation. ISO 9001:2015 therefore uses the more general term improvement, of which continual improvement is one but not the only component.