

4.1 – General requirements	<ul style="list-style-type: none">• Check that the organization is ensuring outsourced processes are controlled, especially those which affect product conformity with requirements• Check that the control of such outsourced functions is identifiable within the quality management system• Has the organization implemented a documented quality management system and is it maintaining its continued effectiveness in accordance with this international standard and any other applicable regulatory requirements?• Does the organization document the roles undertaken by the organization under the applicable regulatory requirements?• Check whether your organization is determining the processes needed for the quality management system and the application of those processes organization-wide• Check whether your organization is applying a risk-based approach to the control of the appropriate processes needed for the quality management system• Check that your organization is determining the sequence and interaction of these processes• Check whether the organization is determining suitable criteria and methods required to ensure the operation and control of processes is effective• Ensure the availability of resources and information necessary to support the operation and monitoring of these processes• Document and implement actions necessary to achieve planned results and maintain the effectiveness of all relevant processes• Do you monitor, measure, and analyze these processes for adequacy?• Have you established records needed to demonstrate conformance to this international standard and compliance
-----------------------------------	---

	<p>with applicable regulatory requirements for each quality management system process?</p> <ul style="list-style-type: none">• Does the organization monitor and ensure control of any outsourced processes that affect product conformity to requirements?• Does the organization retain responsibility of conformity to this international standard and to customer and applicable regulatory requirements for outsourced processes?• Are the controls proportionate to the risk involved and the ability of the external party to meet the requirements?• Do the controls include written quality agreements?• Check that the organization is clearly documenting procedures for the validation of the application of computer software used in the quality management system• Are records of all such activities as mentioned above being documented, maintained, and reviewed?
--	--