<<1.2/4.2.2.a>>

The quality management system shall be relevant to the nature of our organization and products, and to customer and regulatory requirements. For this reason, those requirements of ISO 9001 (2008) that do not apply are excluded from the scope of our quality system. Following rules and criteria are used for excluding irrelevant requirements:

- An ISO 9001 (2008) requirement may be excluded only when both of the following conditions are met:
 - The requirement must be within ISO 9001 Clause 7, Product Realization; and
 - The exclusion may not affect our ability, nor absolve us from the responsibility, to provide product that meets customer and applicable regulatory requirements.
- The Quality Assurance Manager is responsible for identifying those requirements of ISO 9001 that do not apply to our organization or products, and to propose exclusions of such requirements from the scope of the quality system.
- Top executive management has the responsibility and authority for evaluating whether the proposed exclusions are appropriate, and for approving them. Evaluation and approval of exclusions are conducted within the framework of management reviews of the quality system (refer to Operational Procedure 05-06-01, Management Review).
- 4. Any exclusions taken are documented in this section of the quality manual. The excluded requirements are precisely identified with reference to specific clauses and/or statements in the standard. There is also a brief justification why the exclusion is taken and why it is appropriate.

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