



# UNIVERSITY OF NAIROBI

## ISO 9001:2015 Standard Readiness Questionnaire

| Q#  | Standard normative clause and issues   | Tick✓ |    | Remarks |
|---|--|-------|----|---------|
|   | 4 CONTEXTS OF THE ORGANIZATION   | Yes   | No |         |
| <b>4.1 UNDERSTANDING THE ORGANIZATION AND ITS CONTEXT</b>         |  |       |    |         |
| 1   | Have we determined the external and internal issues that are relevant to our organization’s purpose and its strategic direction?   |       |    |         |
| 2   | Have we determined the external and internal issues that are relevant to our organization and those that affect our ability to achieve the intended results?   |       |    |         |
| 3   | Have we determined the needs and expectations of interested parties that are relevant to the Quality Management System and do we have a way of reviewing and monitoring these on a regular basis?                  |       |    |         |
| 4   | Do we monitor and review information on these issues?  |       |    |         |
| 5   | Have the criteria for managing these been established together with responsibilities, methods, measurements and related performance indicators needed to ensure the effective operation and control?               |       |    |         |
|   |  |       |    |         |
| <b>4.3 DETERMINING THE SCOPE OF THE QUALITY MANAGEMENT SYSTEM</b> |  |       |    |         |
| 6   | Have we determined and documented the boundaries and applicability of our Quality Management System by considering external and internal issues, requirements of interested parties and our products and services? |       |    |         |
| <b>4.4 QUALITY MANAGEMENT SYSTEM AND ITS PROCESSES</b>            |  |       |    |         |
| 7   | Have we established, implemented, maintained and continually improved a Quality Management System including all processes needed; including interactions and sequences of processes and assigning resources?       |       |    |         |
| 8   | Do we maintain necessary documented information to support the processes and have confidence they are being carried out to plan?   |       |    |         |



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| <b>5 LEADERSHIP</b>  |   | <b>Yes</b> | <b>No</b> | <b>Remarks</b> |
| <u>5.1 LEADERSHIP AND COMMITMENT</u>                       |   |            |           |                |
| 9  | Have the requirements for the Quality Management System been integrated into the business processes and have management promoted awareness of the process approach and risk based thinking? |            |           |                |
| 10   | Does top management show leadership with respect to customer focus, customer and statutory requirements, risks and opportunities and enhancing customer satisfaction?                       |            |           |                |
| 11   | Have the policy and objectives for the Quality Management System, which are compatible with the context and strategic direction of the organization, been established and communicated?     |            |           |                |
| 12   | Have the objectives been established at relevant functional, process, departmental and individual levels within the business?   |            |           |                |
| <b>6 PLANNING</b>  |   | <b>Yes</b> | <b>No</b> | <b>Remarks</b> |
| <u>6.1 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES</u>      |   |            |           |                |
| 13   | Has planning for the Quality Management System considered issues and requirements that determine the risks and opportunities to be addressed?   |            |           |                |
| 14   | Has the organization planned actions to address these risks and opportunities and integrated them into the system processes?  |            |           |                |
| <u>6.2 QUALITY OBJECTIVES AND PLANNING TO ACHIEVE THEM</u> |   |            |           |                |
| 15   | Have we established quality objectives for the Quality Management System that are measurable, monitored, communicated, updated and documented?  |            |           |                |
| <u>6.3 PLANNING OF CHANGE</u>                              |   |            |           |                |
| 16   | When Quality Management System changes are needed, are they carried out in a planned manner?  |            |           |                |



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The goal of the actions referred to in pages 1 to 2 is to create an organizational system capable of maintaining a fit between what the organization wants to do and what it should do. To improve the status the organization should:

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|----|---|------------|-----------|--|
|    |   | <b>Yes</b> | <b>No</b> |  |
|    | <b>7 SUPPORT</b>  |            |           |  |
|    | <u>7.1 RESOURCES</u>  |            |           |  |
| 17 | Have we determined the resources needed for the Quality Management System, including internal and external resources, people, infrastructure and the environment necessary for the Quality Management System?                               |            |           |  |
| 18 | Have we identified the resources needed for valid monitoring and measurement of results for product and service conformity including traceability measurement and organizational knowledge necessary for operations?                        |            |           |  |
|    | <u>7.2 COMPETENCE</u>   |            |           |  |
| 19 | Have we determined the necessary competence required of persons who will perform functions within the Quality Management System processes?  |            |           |  |
|    | <u>7.3 AWARENESS</u>  |            |           |  |
| 20 | Have we taken actions to ensure persons doing work within the Quality Management System know the quality policy, quality objectives and how they contribute to the Quality Management System including the implications of non-conformance? |            |           |  |
|    | <u>7.4 COMMUNICATION</u>  |            |           |  |
| 21 | Have we determined the what, when, with whom, how and who communicates for both internal and external communications relevant to the Quality Management System?   |            |           |  |



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|   |  | Yes   | No |         |
| <b>7 SUPPORT (continuing)</b>                     |  |       |    |         |
| <u>7.5 DOCUMENTED INFORMATION</u>                 |  |       |    |         |
| 22  | Have we set up a process to control documented information of the Quality Management System including creating and updating, control of use, adequate protection, control of distribution and changes?   |       |    |         |
| <b>8 OPERATION</b>                                |  |       |    |         |
| <u>8.1 OPERATIONAL PLANNING AND CONTROL</u>       |  |       |    |         |
| 23  | Do you plan and control processes needed for our product or service including criteria for acceptance, resources needed, control necessary and what documented information is needed, including control of planned changes?  |       |    |         |
| <u>8.2 REQUIREMENTS FOR PRODUCTS AND SERVICES</u> |  |       |    |         |
| 24  | Have we implemented processes for customer communication, determining requirements for products and services, reviewing requirements of products and services and updating documents when changes occur?   |       |    |         |
| 25  | Is the provision of products and services carried out in controlled conditions which include: availability of documented information that defines the characteristics of the products to be produced or the services to be provided, documented information that defines the results to be achieved? |       |    |         |
| 26  | Are monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met carried out?   |       |    |         |
| <u>8.3 DESIGN AND DEVELOPMENT</u>                 |  |       |    |         |
| 27  | Have we established, implemented and maintained a design and development process for our products and services that addresses design and development planning, inputs, controls, outputs and changes?  |       |    |         |



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|  |   | Yes   | No |         |
| <b>8 OPERATION (continuing)</b>  |   |       |    |         |
| <u>8.4 CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES</u> |   |       |    |         |
| 28   | Have we taken steps to ensure externally provided processes meet requirements by determining the type and extent of control needed and the information needed for external providers?   |       |    |         |
| <u>8.5 PRODUCTION AND SERVICE PROVISION</u>                                |   |       |    |         |
| 29   | Have we implemented the controlled conditions necessary for our production and service provision including necessary documented information, monitoring and measurement, identification and traceability (where necessary), property belonging to customers or external parties, preservation of product or service, control of changes and post delivery activities associated with our product and service? |       |    |         |
| <u>8.6 RELEASE OF PRODUCTS AND SERVICES</u>                                |   |       |    |         |
| 30   | Have we implemented planned arrangements to verify that requirements have been met before release of products and services?   |       |    |         |
| <u>8.7 CONTROL OF NONCONFORMING OUTPUTS</u>                                |   |       |    |         |
| 31   | Have we implemented a process to identify and control nonconforming outputs of our processes so that they are not unintentionally used until a disposal has been made? Is documented information maintained for this process?   |       |    |         |

The Operations clause (clause 8) relates to primary activities of the organization, which are in the direct value creation chain through which an organization’s primary products and/or services pass through. Process-based and information & analysis practices are critical but require to be enabled by support activities referred to in Support clause (clause 7). This describes good management and any strategic management practitioner would visualize same even without ISO9001 standard. To improve the status we should: \_\_\_\_\_



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|   |  | Yes   | No |         |
| <b>9 PERFORMANCE EVALUATION</b>                             |  |       |    |         |
| <u>9.1 MONITORING, MEASUREMENT, ANALYSIS AND EVALUATION</u> |  |       |    |         |
| 32  | Have we determined the monitoring and measurement needs, how it will be done and when it shall be performed for the processes of the Quality Management System and customer satisfaction?                    |       |    |         |
| 33  | Are analysis and evaluation done on the monitoring and measurement data and information obtained?  |       |    |         |
| <u>9.2 INTERNAL AUDIT</u>                                   |  |       |    |         |
| 34  | Are there audit procedures to evaluate the Quality Management System against the planned arrangements (including adequacy, implementation and maintenance)?  |       |    |         |
| 35  | Are results of audits against the planned arrangements (including adequacy, implementation and maintenance) reported to management?  |       |    |         |
| <u>9.3 MANAGEMENT REVIEW</u>                                |  |       |    |         |
| 36  | Does top management review the data from the Quality Management System to assess the need for change, resource adequacy and the effectiveness of the Quality Management System?                              |       |    |         |
| <b>10 IMPROVEMENT</b>                                       |  |       |    |         |
| <u>10.1 GENERAL</u>   |  |       |    |         |
| 37  | Do we identify opportunities for improvement and implement action to meet requirements and enhance customer satisfaction?  |       |    |         |
| <u>10.2 NONCONFORMITY AND CORRECTIVE ACTION</u>             |  |       |    |         |
| 38  | When a nonconformity occurs do we take action to deal with the consequences, evaluate the need to eliminate the root cause of the nonconformity and review the effectiveness of the corrective action taken? |       |    |         |



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|    |   |  |  |  |
|----|---|--|--|--|
| 39 | After action is taken do we identify any risks and opportunities found during the corrective action and update the Quality Management System, if necessary? |  |  |  |
|----|---|--|--|--|

### Readiness Status

|            | Yes | No |
|------------|-----|----|
| Total      |     |    |
| Percentage |     |    |

### Strengths

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### Areas for Improvement

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### Conclusion:

Based on the data from the questionnaire, it is concluded that practices within the organization are consistent with (please tick what is appropriate):

- Significant aspects of ISO9001:2015 standard
- No or insignificant aspects of the standard