Continual improvement through ISO 9001 – An evidence based audit conducted in 200 organizations

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Abstract. Continual improvement is the most significant element of ISO 9001. Inadequate research studies are found to make the assessment of Continual Improvement of certified organizations through an onsite audit. Researcher has spent 386 mandays onsite conducting audit of 200 organization to determine the conformance to the criteria laid in ISO 9001:2015. This research study is based on primary data obtained through process observation, reviewing documented information and interviewing concern professionals including the top management. The key factors determined for continual improvement were analyzed to confirm effectiveness, adequacy and suitability of the quality management system. The outcome of the audit was measured against the conformity assessment variable influencing the continual improvement of the quality management system. Research data was analyzed by using the most simple statistical software “Jamovi”. The compliance with the criteria for outcome of the management review, non conformity and corrective action were mapped against the five point Likert scale.

1. Introduction
ISO 9001 Certification needs no special introduction as last year (2019) alone 8,83,521 Certificates were issued across the world. The growing importance and worldwide acceptance of the Quality Management System has also raised serious concerns on the degree of implementation of the criteria as per ISO 9001. Assessment of ISO 9001 does not levy any provision to grade the level of compliance against the requirements of the standard. Therefore its very challenging to attribute the continual improvement through quality management system certification. And hence this research study is based on the primary data gathered through onsite audit with evidence based approach to determine the degree of compliance with the continual improvement element. There are various tools and techniques for continual improvement which are practiced across the world. Some continual improvement tools and techniques were emerged from the actual efforts of world-class industry like: A3, 5S, Catchball, DMAIC, Gemba Walks, Kanban, 5 Why, etc.
2. Research Gap
Most of the research studies in the area of Quality management system are based on the feedback obtained from the sampling organization. The major constrain in this type of methodology is lack of objective evidence. Research pertaining to quality management system would not yield intended output if the data is gathered by mere collection of feedback without objective evidence.

3. Research Methodology
A formal onsite audit is performed in 200 organizations as per ISO 19011. The questionnaire is prepared to determine the conformance to the requirements of the ISO 9001:2015 standard. 386 Mandays were spent onsite to verify the conformance to ISO 9001 criteria. The outcome of this evidence based approach is analysed by using five point Likert scale to quantify the research data.

4. Reliability Analysis
A reliability analysis was carried out 227 questions that were assessed by researcher which were measured through a 5 point Likert type scale. Cronbach’s alpha calculated for the audit questionnaire to reach acceptable reliability ($\alpha = 0.82$) indicating high consistency.

| Scale Reliability Statistics |  |
|-----------------------------|--|
| **Cronbach’s $\alpha$**     | 0.820 |

5. Results
The outcome of the research study through onsite audit was quantified by using statistical tool called Jamovi.

Table-1 presents the results Management Review conformity assessment variable. The Mean is 3.62 and the Median is 4.0 with standard deviation being 0.57. The results indicate the effectiveness of the management review in accordance with the agenda determined in the standard and the outcome of the reviews. The results were inclined towards 3 point on Likert scale which indicate the Management Reviews were conducted as a formality to fulfill the audit requirement and did not yield any fruitful benefit in effectiveness of the quality management system.

| Table: 1, Management Review |
|-------------------------------|
| **Descriptives**              |  |
| Management Review             |  |
| N                             | 200 |
| Missing                       | 0  |
| Mean                          | 3.62 |
| Median                        | 4.00 |
| Standard deviation            | 0.527 |
| Minimum                       | 3  |
| Maximum                       | 5  |
Table-2 represent the frequency of the non conformity on a Likert scale; 4 point resulting 56.5% and the least being 5 point contributing mere 1.0%. Handling non conformity and initiating corrective action was not implemented to its full potential as majority of the organizations attributed this requirement as “Failure” and felt offensive to accept or declare the deviations from the requirement of the standard.

Table-2, Non Conformity and corrective action

| Levels | Counts | % of Total | Cumulative % |
|--------|--------|------------|--------------|
| 3      | 85     | 42.5%      | 42.5%        |
| 4      | 113    | 56.5%      | 99.0%        |
| 5      | 2      | 1.0%       | 100.0%       |

Graph-1 indicate the continual improvement by implementing the quality management system. More than half of the sample does not conform to this requirement and hence continual improvement could not be attributed to the quality management system.

6. Conclusions
1) Effectiveness, adequacy and suitability of the ISO 9001:2015 could be determined by considering outcome of management review, analysis and evaluation.
2) The organization could also address opportunities and needs of the interested parties for continual improvement.
3) Ineffective implementation of ISO 9001 is the major contributing factor for holding the continual improvement of certified organization.

7. Scope for future work
1) Three year performance trend can be studied and analyzed for ISO 9001 certified organizations to establish correlation between continual improvement and the quality management system.
2) Non conformity management and competency requirement for initiating corrective actions could be studied for ISO 9001 certified organizations.
3) Outcome of the management review could be studied to determine correlation with continual improvement.
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