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**ISO 9001:2015**

**Control of Improvement**

Approval

The signatures below certify that this management system procedure has been reviewed and accepted, and demonstrates that the signatories are aware of all the requirements contained herein and are committed to ensuring their provision.

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Amendment Record

This procedure is reviewed to ensure its continuing relevance to the systems and process that it describes. A record of contextual additions or omissions is given below:

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1. Control of Improvement
   1. Introduction & Purpose

The purpose of this procedure is to define Manufacturing Made Easy Ltd.’s process for establishing a philosophy of continual improvement throughout our business, which is driven by goals documented in the corporate objectives and policies. Opportunities for improvement are identified and translated into improvement projects.

* + 1. Process Activity Map

Output

* Process improvement
* QMS improvement
* Customer satisfaction
* Conforming processes
* Revised policy & objectives
* New targets/programmes

How

* KPI schedule
* Internal audit reports
* Process audit checklist
* SWOT analysis

With what measure

* Improved KPIs
* Trends non-conformities
* Audit scores
* % of satisfied customers

With what

* Policies and objectives
* Trends and data

With who

* Top management
* Quality Manager

Activity

Continual improvement of the QMS, to ensure its continuing suitability, adequacy, effectiveness and alignment with our strategies

Input

* Customer complaints
* Risks and opportunities
* Audit findings
* Management actions
* Internal suggestions
  + 1. References

| **Standard** | **Title** | **Description** |
| --- | --- | --- |
| BS EN ISO 9000:2015 | Quality management systems | Fundamentals and vocabulary |
| BS EN ISO 9001:2015 | Quality management systems | Requirements |
| BS EN ISO 9004:2018 | Quality management systems | Guidelines for performance improvements |
| BS EN ISO 19011:2018 | Auditing management systems | Guidelines for auditing |

* + 1. Terms & Definitions

| **Term** | **ISO 9001:2015 Definition** |
| --- | --- |
| Management | Coordinated activities to direct and control an organization (3.2.1) |
| Review | Determination (3.11.1) of the suitability, adequacy or effectiveness |
| Corrective action | Action to eliminate the cause of a non-conformity (3.6.9) and to prevent recurrence |

* 1. Application & Scope

This procedure applies to all staff at all levels. Continual improvement is more of a philosophy than a process or system. It requires everyone as a participant to adopt, as part of their normal work, a mind-set of continuously looking for ways to improve processes and systems, i.e. to make them more efficient and effective.

Manufacturing Made Easy Ltd uses the PDCA-cycle is used to coordinate our continuous improvement efforts. It emphasizes and demonstrates that improvement programs must start with careful planning, must result in effective action, and must move on again to careful planning in a continuous cycle. It is a strategy used to achieve breakthrough improvements in safety, quality, morale, delivery cost, and other critical business objectives.

1. **Plan** - analysis of what needs to be improved by taking into consideration areas that hold opportunities for change. Decision on what should be changed.
2. **Do** - implementation of the changes that are decided on in the Plan step.
3. **Check** - Control and measurement of processes and products in accordance to changes made in previous steps and in accordance with policy, goals and requirements on products. Report on results.
4. **Act** - Adoption or reaction to the changes or running the PDCA-cycle through again. Keeping improvement on-going.
   1. Improvement Process

Manufacturing Made Easy Ltd.’s QMS embodies an organizational commitment to continually improve our processes and products. Even after the QMS is implemented and well developed, the feedback and improvement cycle will continue.

In order to identify future areas for improvement in the QMS and its process, the improvement processes continue to analyze feedback received from both customers (internal/external) and stakeholders to identify new issues and solutions to address these issues.

* + 1. Identifying Opportunities for Improvement

Opportunities for improvement in operations and processes are identified by functional managers on a continual basis from daily feedback on operations and periodic management reviews. Opportunities for improvement of products and services are identified mainly by the CEO and the Engineering Teams. All employees are encouraged to suggest new ideas for improving:

1. Products;
2. Processes;
3. Productivity;
4. Work environment.

The Quality Manager is required to, evaluate feedback from operational performance and identify opportunities for improvement as appropriate using the *Improvement Activity Form*. Inputs for improvement opportunities are obtained from the following sources:

1. Customer satisfaction;
2. Customer complaints and feedback;
3. Market research and analysis;
4. Inputs from employees, suppliers and other interested parties;
5. Internal and external audits of the quality system;
6. Records of product or process non-conformances;
7. Data from process and product characteristics and their trends.

Opportunities for improvement may also be identified on a special project basis. The following are examples of such projects:

1. Non value-added use of floor space;
2. Excessive inspection/testing;
3. Excessive handling and storage;
4. Excessive failures and costs to quality;
5. Machine set-up changeover times.
   * 1. Analyzing Current QMS Processes

Internal (technical) audits and process audits provide a mechanism to analyze our QMS processes from both technical and management perspectives. These audits assist in documenting what is happening in the process at that time and how well it is being done using the *Process Effectiveness Assessment Form*.

The result can be used to identify areas for improvement in our processes. In addition to the use of those audits, improvement teams and participants provide suggestions on how to improve the quality or efficiency of the process from their unique perspective using various mechanisms designed to obtain candid feedback.

Identification of customer needs is a part of the QMS and customer feedback is used as a basis to periodically asses how well their needs are being met and to determine ways our processes and products can be improved to better meet expectations. By periodic assessment of customer satisfaction, and determining new requirements, our QMS can continue to improve and evolve.

* + 1. Identifying Issues & Problems

The input from internal and external parties involved in our QMS processes and the analysis of metrics yield a list of issues that benefit from further evaluation. Input may be submitted through written documentation or oral communication.

Each issue that is identified through a source or performance metric has a reason behind its existence. In some cases, the issue has a particular root cause such as a type of barrier not allowing performing their job better. By understanding the correct root cause, the solutions are more likely to be effective.

* + 1. Developing Solutions

If root causes of issues and barriers to better performance in the QMS are not identified, it will be difficult to develop potential solutions that work to improve our processes. Because multiple issues may exist, a formal process may be needed to prioritize which issues to address. A team or focus group approach may be used to concentrate on developing particular solutions for an issue.

* + 1. Tracking Metrics

Once a solution has been evaluated by the team/focus group, metrics will identify what can be tracked and used to determine whether or not the solution is effective. The metrics will be carefully chosen so they will reflect improvements directly related to the original issue and the solution being implemented.

Information from these metrics can put in place the structure for continual improvement of the action/solution taken. After the implementation of the solution has begun, the metrics are monitored on a regular basis. The metrics will reveal whether or not the objectives of the solutions are being met.

If the objectives are not being met, then the team/focus group will review the results and determine areas for improvement. It is possible the solution is not being implemented correctly, the solution is not a good choice, or the solution focuses on resolving the wrong problem. This philosophy follows the traditional quality improvement approach of Plan-Do-Check-Act

* + 1. Evaluation, Prioritization and Implementation

Opportunities for improvement from daily feedback on operational performance are evaluated by the Quality Manager and are typically implemented through the corrective action system. Opportunities for improvement from analysis of longer-term data and trends are evaluated and implemented through the management review process and are prioritized with respect to their relevance for achieving corporate objectives

* + 1. Review

When opportunities for improvement are no longer supported by the current policy and objectives, top management will establish new quality objectives and possibly change the policy. The process for this evaluation and prioritization is described in the *Management Review Procedure*.

Longer-term improvement projects are initiated through the management review process, as well as the corrective and preventive action system. Product improvement opportunities are evaluated by CEO, Engineering Team.

* 1. Improvement Activity Worksheet

| **Activity** | **Purpose** | **Tools** |
| --- | --- | --- |
| 1. Select an improvement opportunity | Select and prioritise improvement opportunities. Review process – are there existing process-work goals?  Ensure process goal is linked to business strategy  Survey internal-external customers, consider customer needs to help identify where value can be added, or time, money and energy reduced  Identify key activities, roles, functions and customers – touch points with other groups or individuals | - Brainstorming  - Graphs  - Process flow chart  - Customer feedback  - Interviews, surveys |
| 2. Form a team | Agree on improvement team’s key roles and responsibilities.  Appoint an (external) Process facilitator, Process team leader. Process Facilitator briefs team on process improvement tools and methods |  |
| 3. Analyse the current situation | To describe the problem-opportunity – test assumptions. To identify any immediate improvements to be made. To collect and analyse any available data on aspects of the current situation to understand the problem-opportunity  Use data to establish a target or process goal. To develop a current situation As Is process map that reflects actual work flow. Identify next in-house-user or customer requirements. Identify multiple methods of performing the process if there is more than one. Identify process constraints | - Check lists  - Process maps  - Flow charting  - Graphs  - Pareto charts  - Cause & effect diagrams |
| 4. Take improvement action | To develop and implement an Action Plan (address the ‘who, what, when, where, how and why’). To re-design the process or process flow to better add value to the flow of activities, better meet the needs of the customer or interested parties.  Plan and implement action to improve process or resolve the problem. Agree and make process or process flow changes. Create a draft To Be process map. To select the monitoring measures | - Check lists  - Graphs  - Pareto charts  - Cause & effect diagrams |
| 5. Study the results | Confirm the action(s) taken achieved the target. Determine if the process has been improved, confirm level of effectiveness. Did the results correspond or confirm expectations?  Identify the reasons target was met or not met are understood. Analyse constraints. What additional actions are required (if target not met) | - Check lists  - Process maps  - Control chart  - Graphs  - Histogram |
| 6. Standardise and monitor solution | Plan for change to make it stick, identify change management issues. Establish clear and measurable process measures. Create end of line measures that are important to the customer.  Insert measures with their goals at critical junctures (hand over points, i.e., between function/roles) in the process map  Everyone understands the new process. Revised methods and procedures published. Training on new process took place. Periodic review points established. Areas for replication considered | - Change management planning  - Check lists  - Control chart  - Graphs  - Histogram |
| 7. Review improvement strategy | Review the outcomes and outputs against original goals, objectives and targets. Review the strengths and weaknesses of the entire process improvement activity and the team activities, to schedule and conduct period process review (s). Results documented and feedback provided to stakeholders.  All aspects of the process improvement, task and team activities evaluated for their effectiveness. Personal and professional development needs identified and addressed. Process improvement efforts celebrated | - Check lists  - Flow chart  - Control chart  - Pareto chart  - Run chart |
| 8. Plan for the future –  Embrace continuous improvement | Review of the means established to monitor the process and identify future improvement to the process.  Plan further to address any remaining process problems and opportunities.  Review lessons learned relating to problem solving skills and group dynamics. Institute periodic reviews of the performance of the process (include in future management reviews, quality plans)  Ensure that actions are in place to lock in and maintain the gains that have been realised.  Ensure that a process of continual process review and improvement is established.  Ensure that a process exist for gathering and evaluating other opportunities from the team’s findings | - Brainstorming  - Process improvement storyboarding |

* 1. Forms & Records

All documentation and records generated by the improvement process are retained and managed in accordance with the *Documented Information Procedure*.

| **Title & Description** |
| --- |
| Improvement Activity Form |
| Process Effectiveness Assessment Form |