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1 Summary

Audit: ✓ Internal Supplier
Organization: _My Sweet Co., LLC_____
Audit dates: 1/27/21 to 1/29/21
Report completed date: 1/29/21
Audit criteria: ✓ 9001 2015
na 13485 2016
na 14001 2015
✓ Org. Management System

Audit Team Lead: Sam Adams, 2 Days_
Auditor: _na_____ Days: ____
Auditor: _na_____ Days: ____

Report accepted by: Julia Sylvester, Quality Manager

2 Opening and Closing meeting attendance

Opening meeting Jan. 27, 2021, 8:00 am

Julia Sylvester, Quality Manager
Bob Gershwick, V. P. of Operations
Barbara Straw, Administrative Assistant
Sam Adams, Lead Auditor

Closing meeting Jan. 29, 2021, 4:00 pm

Julia Sylvester, Quality Manager
Bob Gershwick, V. P. of Operations
Sam Adams, Lead Auditor

3 Outcome

Except for X minor or Y major non-conformities, the organization continued to maintain conformance of its Management System (MS) to the requirements of the audit criteria. The audit team documented Non-Conformities (NCs) and Opportunities for Improvement (OfIs) in the Finding section of this report.

3. SWOT Overall

Strengths: Interviewed personnel showed good knowledge of the relevant processes

Weaknesses: X minor NCs; Y major NCs; examined procedures were excessively wordy and hard to follow.

Opportunities: correct NCs; provide technical writing training to originators of documents or reviewers.

Threats: failure to address opportunities may result in high costs of maintenance of the MS.

4. Findings

NC 1

Statement of non-conformity:

- The organization did not fully implement control of documented information.

Requirement:

- ISO 9001 2015, element 7.5.3.1: "Documented information required by the quality management system ... shall be controlled"

Evidence:

- Quality Manager Job Description was not a controlled document
- There was no evidence of control of the Environmental Matrix.

OfI 1

- Both Management Review Procedure and the Management Review Record Template listed the same topics for review.
- Consider eliminating duplications in the MS.
- Consider management system documentation training for appropriate personnel

5. Management Review

Auditor: Sam Adams

Audited personnel: Julia Sylvester, Quality Manager

Evidence:

- Interview with the Quality Manager
- Quality Manual, Rev 7
- Management Review Procedure Rev. 3
- Management Review Report Template Rev. 2
- Management Review Record, Sep. 21, 2020
- Management Review Record, July 17, 2019
- CI Log, 10/20/21

Evaluation of conformity

- The organization has established and documented a management review process.
- The procedure required annual management reviews.
- Last two examined management review records showed compliance with the schedule.
- An examined record of the recent review demonstrated that the meeting addressed all required process inputs and outputs.
- Personnel required to attend the review were present.
- The review assessed the on-time performance of the Action Items list.
- Implementation of the PM software was delayed due to the unexpected shortage of personnel.
- The action was on hold until the company recovered from the loss.

Process SWOT

Strengths: on-time, full attendance, compliant with the objectives

Weaknesses: not noted.

Opportunities: duplicate information; see OfI 1

Threats: not noted

6. Next process

Auditor:

Audited personnel:

Evidence:

Evaluation of conformity

Process SWOT

Strengths:

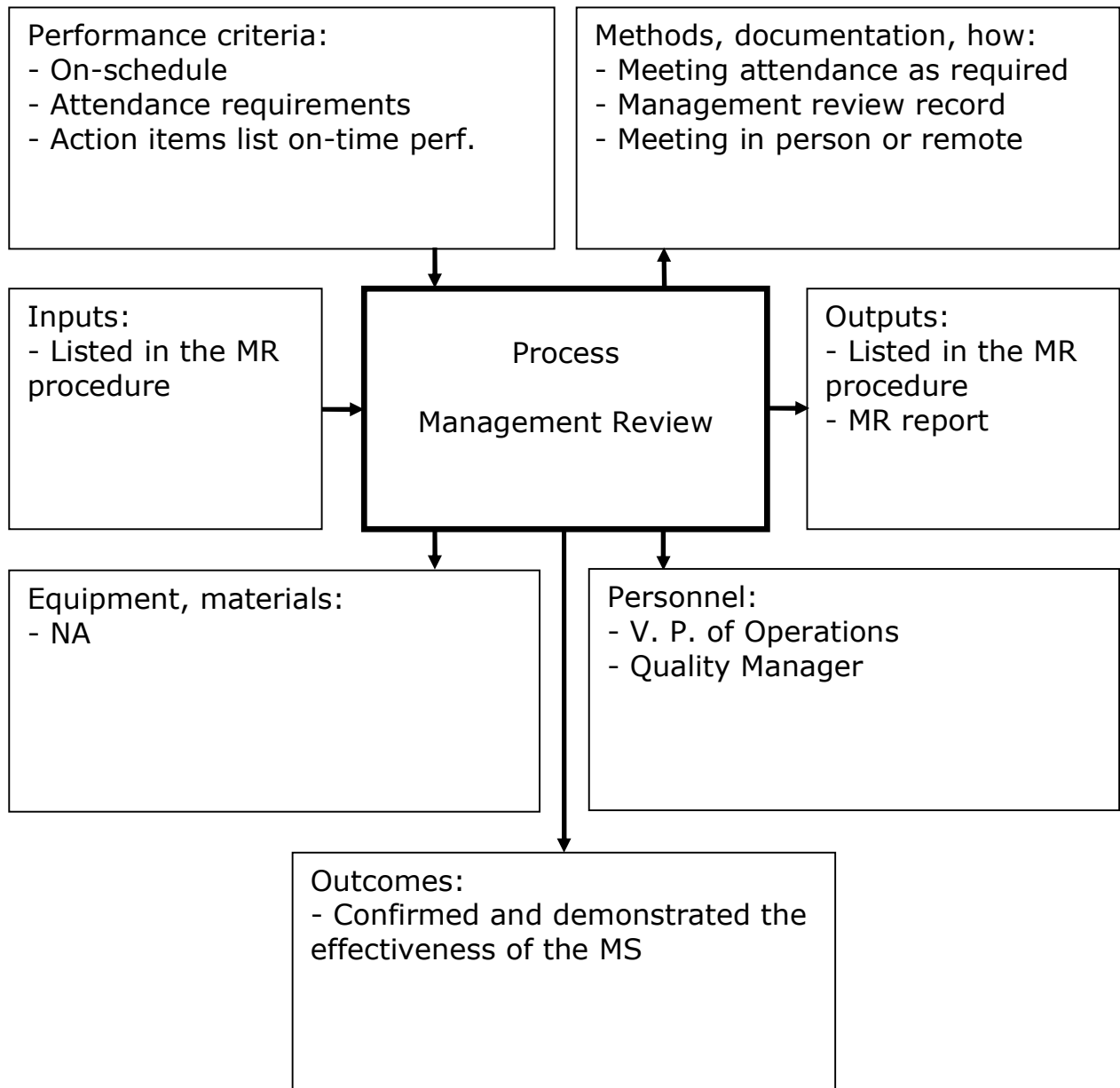
Weaknesses:

Opportunities:

Threats:

7. Attachments:

Audit Turtle Diagram



Updated Audit Schedule 10/20/21

Audit Plan 2020

1. Quality Manager creates annual Audit Plan no later than the end of December of the previous year.
2. Auditors conduct audits ensuring objectivity and the impartiality of the audit process.
3. Auditors complete and distribute Audit Reports no later than five business days from the completions of the audit.
4. Quality Manager updates the plan upon completion of each audit.

Risk, importance				Audit number:												
				00-01	00-02	00-03	00-04	00-05	00-06	00-07	00-08	00-09	00-10	00-11	00-12	
Importance				Planned month:												
				Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	
Previous NCs				Lead auditor:												
				Mark	Reg	Sam	Kelly	Sam	Kelly	Sam	Reg	Sam	Kelly	Mark	Sam	
Detectability				Status												
				Completed	Completed	Completed	Completed	Planned	Planned	Planned	Planned	Planned	Planned	Planned	Planned	
RPN				Area, process												
				Completed	Completed	Completed	Completed	Planned	Planned	Planned	Planned	Planned	Planned	Planned	Planned	
3	1	3	1	Context												
3	1	3	1	Business review												
3	3	3	3	Audits												
3	3	3	3	Continual improvement												
3	1	3	1	Change management												
3	1	3	1	NC-CAR												
3	1	3	1	Complaints, satisfaction												
3	3	3	3	Business objectives												
2	1	2	1	Doc. Management												
2	1	3	1	Training												