



Chapter 35. Improvement and Continual improvement

Contents:

0) Introduction

1) 10, 10.1 Improvement

2) 10.3 Continual Improvement (ISO9001)

3) 10.3.1 Continual Improvement-Supplemental (IATF16949)

4) 10.2.4 Error-proofing (IATF16949)

5) SIs & FAQs

6) Supplementary Notes

7) Exhibits

0) Introduction

There is 3 related applicable clause in this chapter, but all centering around improvement. The reason why a whole chapter is devoted to this is because the clauses are commonly misunderstood and/or poorly catered for. Many NCs have been written on this clause alone.

1) 10, 10.1 Improvement ISO9001- General

(Clause Description-Paraphrase).

The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. These shall include:

- a) improving products and services to meet requirements as well as to address future needs and expectations;
- b) correcting, preventing or reducing undesired effects;
- c) improving the performance and effectiveness of the quality management system.

NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clauses, 8.5 with no content. So essentially this is a new clause with new requirements.
- The full requirements are given as a) to c). These are things that an organization would do as a matter of course, but now considered as improvement

(Compliance best practice)

10, 10.1 Improvement ISO9001

1. *If you have taken efforts in terms of correction, prevention or reduction of undesired effects, you are in compliance of this clause. IATF Auditors won't be checking on this clause, because you are definitely in compliance.*
2. *But continual improvement is another matter. See next clause.*

2) 10.3 Continual Improvement (ISO9001)



(Clause Description-Paraphrase)

The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system. The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

(Highlights of the clause)

- (Ref to old Standards). There had been similar clauses, 8.5.1, in the older version of ISO9001.
- The old clause was very simple; “The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.
- The old sentence is totally replace.
- Continual improvement in the new clause, comes from results of analysis and evaluation, and the outputs from management review

(Compliance best practice)

10.3 Continual Improvement

1. *This clause refers to continual improvement which is a ‘shall’ item, meaning it is mandatory.*
2. *2 common sources for initiating continual improvement, as given in the clause are: a) results of analysis and evaluation, b) outputs from management review*
3. *However there are others areas to consider: customer requests, process study conclusions, operations meeting output, employee suggestions, specialists recommendations etc.*
4. *Project reports are required, but they need not be full 6-Sigma type. Simpler ones can be just as effective. See **Exhibit 35-1**.*

3) 10.3.1 Continual Improvement-Supplemental (IATF16949)

(Clause Description-Paraphrase)

The organization shall have a documented process for continual improvement. The organization shall include in this process the following:

- a) identification of the methodology used, objectives, measurement, effectiveness, and documented information;
- b) a manufacturing process improvement action plan with emphasis on the reduction of process variation and waste;
- c) risk analysis (such as FMEA).

NOTE Continual improvement is implemented once manufacturing processes are statistically capable and stable or when product characteristics

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clauses, 8.5.1.1 Continual improvement of the organization, in the old version of ISO/TS16949.
- The old clause was very simple: “Organization shall define a process for continual improvement.
- The new clause to have a document process that include:
 - the methodology, objectives, measurement, effectiveness, and record keeping etc.
- A manufacturing improvement plan with emphasis on reduction of variation and waste



- risk analysis

(Compliance Best Practice)

4) 10.2.4 Error-proofing (IATF16949)

(Clause Description-Paraphrase)

10.3.1 Continual Improvement-Supplemental

1. *A documented process is required, most companies don't have this. See **Exhibit 35-2**.*
2. *Improvement is generally on QMS, how to improve the suitability, adequacy and effectiveness of the QMS.*
3. *A manufacturing improvement plan should also be included, with emphasis on reduction of variation and waste risk analysis*

The organization shall have a documented process to determine the use of appropriate error-proofing methodologies. Details of the method used shall be documented in the process risk analysis (such as PFMEA) and test frequencies shall be documented in the control plan. The process shall include the testing of error-proofing devices for failure or simulated failure. Records shall be maintained. Challenge parts, when used, shall be identified, controlled, verified, and calibrated where feasible. Error-proofing device failures shall have a reaction plan.

(Highlights of the clause)

- *(Ref to old Standards). There had been a similar clauses, 8.5.2.2 of same title, in the old version of ISO/TS16949.*
- *The old clause is very simple: "The organization shall use error-proofing methods in their corrective action process" The new clause is a total replacement, requiring:*
- *a documented process.*
- *Process shall include risk analysis. Method and test frequency to be documented in control plan.*
- *testing of error-proofing devices for failure or simulated failure is required. Records to be maintained*
- *Challenge parts, when used, shall be identified, controlled, verified, and calibrated where feasible. Error-proofing device failures shall have a reaction plan.*

(Compliance best practice)

10.2.4 Error-proofing

1. *Procedure is required by the clause. However, not many organizations have provided for this requirement. See **Exhibit 35-3**.*
2. *Error proofing shall be identified on the FMEA and Control Plan.*
3. *Persons-in-charge should know how to use the error proofing devices, and use of challenged parts. Records shall be maintained on use of challenge parts*
4. *Challenge parts shall be identified, protected and maintained.*



5) SIs & FAQs

No SIs & FAQs for this Chapter

6) Supplementary Notes

Legend: HOC= Highlights of Clause, CBP= Compliance Best Practice, S&Q= SIs & FAQ, EXH= Exhibits

Clause	Section	Clarification Subjects
10.1	CBP	SN35.1. If corrective actions are considered improvement, then do I still need to do any continual improvement?
10.3, 10.3.1	CBP	SN35.2. Is there any other sources for improvement ideas, beside the results of analysis and evaluation, and the outputs from management review?
10.3, 10.3.1	CBP	SN35.3. How should the documentation be for continual improvement? Do we need professional documentations like a 6-Sigma project?
10.3, 10.3.1	CBP	SN35.4. Do the team members need to attend 6 Sigma training?
10.3, 10.3.1	CBP	SN35.5. If we have been doing small projects under a Kaizen program, is it consider continual improvement?

SN35.1. If corrective actions are considered improvement, then do I still need to do any continual improvement?

Corrective actions are considered improvement in this new version. Continual improvement is still required. The word 'shall' is used for continual improvement. It is a non-compliance if no continual improvement is carried out.

SN35.2. Is there any other sources for improvement ideas, beside the results of analysis and evaluation, and the outputs from management review?

Customer requests, operations meeting output, employee suggestions, productivity consultant recommendations etc, are also possible sources.

SN35.3. How should the documentation be for continual improvement? Do we need professional documentations like a proper project paper?

Documentation can be simple, such as 'before and after' comparisons. It does not need a 6-sigma format. However, data is still needed for conclusions if the project taken is successful. An improvement project documentation should preferably show: a) name of project, b) purpose, c) objective, d) team & members, e) investigation, f) action plans used, g) results, preferably with photo evidence, h) conclusion & recommendations.

SN35.4. Do the team members need to attend 6 Sigma training?

There is no such requirement from ISO/IATF. However, it will be great and more effective if team members are trained on improvement methodology e.g. 6 Sigma.

SN35.5. If we have been doing small projects under a Kaizen program, is it consider continual improvement?

Yes, but try to have the data to prove it is successful or otherwise.

7) Exhibits

Exhibit 35-1 Continual Improvement Reporting

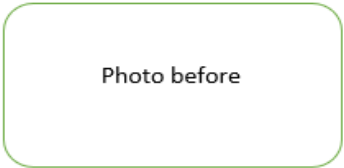
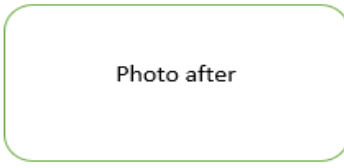
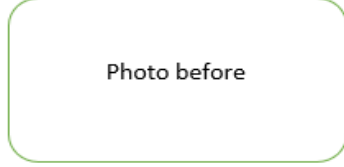
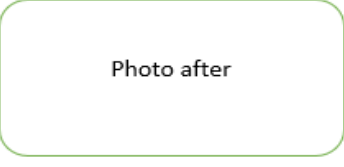
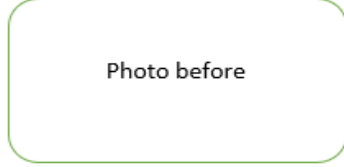
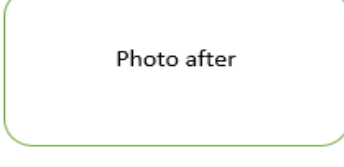
Simple Report for Continual Improvement	
Project No. PDN/01	Team: Xean Row (leader). Linda, Mahira
Project Selected: Assembly area to be re-arranged	Reasons Now very messy, work slow and sometimes accident
Current performance See picture below (before)	Target 1. Special Place for packing material on racks 2. Special location for WIP waiting for inspection 3. New door way to store to cut short journey
Budget requirement USD 20000	Approved XX
Before . Packing Material uncontrolled 	After: Packing Materials on Racks 
Travel route-before (long route) 	Travel route-after (shorter via a doorway) 
WIP no special location 	WIP with dedicated location 
Conclusion: <ul style="list-style-type: none"> • The project took 2 months to implementation • The place looks neater now, with packing material neatly stacked on racks • Finished goods to store is much faster, via a doorway, instead of need to get out of building and go a big round to the warehouse, cut down 70% travelling • With the packing material out of the way, space are allocated here for WIP waiting for inspection • Project viewed by top management and concluded successful 	
Remarks given here explain on the Exhibit. Do not include them as part of your working document <ul style="list-style-type: none"> • The above report is a very simple, no unnecessary story-telling, and direct to the point • The main evidence will be in data and pictures (before and after) • This kind of reporting should be good for continual improvement projects in most situations 	

Exhibit 35-2 Continual Improvement Procedure

Responsibility	Flow Diagram	Description
Kaizen Team	<pre> graph TD A[Note 1 Target Setting] --> B[Note 2 Sources of Projects] B --> C[Note 3 Project Emphasis] C --> D[Note 4 Submission] D --> E[Note 5 Risk Analysis] E --> F[Note 6 Proposal for Project] F --> G[Note 7 Resources & Support] G --> H[Note 8 Implementation] H --> I[Note 9 Conclusion] </pre>	<p>Note 1:</p> <ul style="list-style-type: none"> The kaizen team shall meet at end of the year to discuss about continual improvements. The no of projects to be taken at the end of meeting shall be concluded <p>Note 2: Primary sources for improvement projects are:</p> <ul style="list-style-type: none"> Primary areas are: results of analysis and evaluation, and the outputs from management review Other areas are: customer requests, process study conclusions, operations meeting output, employee suggestions, productivity consultant recommendations etc, are also possible sources. <p>Note 3: Nature of projects to objectives to emphasize are:</p> <ul style="list-style-type: none"> QMS-improve the suitability, adequacy and effectiveness a manufacturing process -reduction of process variation and waste <p>Note 4:</p> <ul style="list-style-type: none"> the meeting shall conclude the number and type of improvement projects Each project shall include: objectives, method, measurement, effectiveness, and conclusion Management will have final decisions on the project selection The approval granted are conditional to risk analysis findings <p>Note 5:</p> <ul style="list-style-type: none"> Risks analysis shall then be conducted on the selected projects, using FMEA

Description	Description
<p>Note 6: Proposal of each project shall consist of the following Information:</p> <ul style="list-style-type: none"> • Project no/title, purpose, background situation, targets, budget & resources, action plan concept, implementation period <p>Note 7:</p> <ul style="list-style-type: none"> • Resources and budget are to be approved by management • QMR will also mobilize further support where necessary 	<p>Note 8:</p> <ul style="list-style-type: none"> • Once approved, the appointed team leader shall lead a core team to implement the plan • Further resources shall be applied through the QMR, who would bring to Management for decision <p>Note 9:</p> <ul style="list-style-type: none"> • Project report shall be submitted at end of the project • The report shall show minimum: project title, date, action plan, implementation period, comparison of before and after situations, conclusions
<p>Remarks given here explain on the Exhibit. Do not include them as part of the document A documented process is required for this clause. This is an example for the procedure</p>	

