

Chapter 7. QMS & its Processes

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0) Introduction

There is only one applicable clause in this chapter. The reason why a whole chapter is devoted to this is because the clause in general is not well understood and/or poorly catered for. Many NCs have been written on this clause alone.

1) 4.4, 4.4.1 QMS and its processes (ISO9001)

(Clause Description-Paraphrase)

The organization shall establish a QMS process, to implement the requirements of this standard. The processes shall include input, sequence and interactions, criteria and methods to measure, resources, responsibilities. Risks and opportunities shall also be included. These processes shall be evaluated and implement any changes /improvements needed to ensure that these processes achieve their intended results.

(Highlights of the clause)

- (Ref to old Standards) This is a totally new clause.
- Organization shall defined the processes needed to support the QMS
- Elements that make up a process shall also be identified e.g. input, output, control methods and criteria, performance indicators, responsibility and authority; and the relevant resources (man, machine, materials and methods), sequence and interactions, risks and opportunities etc.
- This ISO9001 clause is describing about process approach. But in practice, ISO is still far from practicing this method. It is very much of clause-based or element-based approach. Getting organizations now to define sequence and interactions, and details of a process. is definitely a good start towards the goal.
- IATF, on the other hand, has make this into an art form by introducing concepts like Turtle diagrams, Octopus Diagrams and Process Mapping, to document the processes. All elements of the processes are active used to enhance and improve the processes

(Compliance best practice)

4.4, 4.4.1 QMS and its processes

1. To go process approach, you should first identify the processes. One easy way is to amalgamate closely-related procedures into blocks, or 'processes'. See **Exhibit 7-1**.
2. Next is to link up the newly-created processes, in the actual sequence and interaction, to become a process map for your organization.
3. There are several ways to do this. The 3 most-commonly used methods are given below.
 - Type 1, MP-COP-SP Process Mapping. See **Exhibit 7-2**

- Type 2 , Box-and-line business flow chart. See **Exhibit 7-3**.
 - Type 3, PIOR (process input-output resource) Matrix. See **Exhibit 7-4**.
 - To be complete, you need to use Type 1 + Type 2, or Type 3+ Type 2. See **SN-7.5** for explanations.
4. For each individual process, it shall show its elements, which is: a) input-process-output, b) resources i.e. man, machine, method and measurement. One easy way to do this is using the turtle diagram. See **Exhibit 7-5**, and **SN-7.2** for more information

2) SIs & FAQs

No SIs & FAQs for this Chapter

3) Supplementary Notes

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

S/N	Clause	Section	Clarification Subjects
1.1	4.4.1	CBP	SN7.1 What is the difference between a process and a procedure?
1.2	4.4.1	CBP	SN7.2 How to prepare a turtle diagram?
1.3	4.4.1	CBP	SN7.3. Any additional clarifications on turtle diagrams, to guide on compiling them correctly?
			SN7.4 Is turtle diagrams mandatory?
1.4	4.4.1	CBP	SN7.5 What are the differences of the 3 types of process mapping? Which one is better?
1.5	4.4.1	CBP	SN7.6 Is it mandatory to designate processes as MP-COP-SP?
1.6	4.4.1	CBP	SN7.7 What are the criteria to decide MP, COP or SP for processes?
1.7	4.4.1	CBP	SN7.8 What is the optimum number of processes to use?

SN7.1. What is the difference between a process and a procedure?

The two are related, but not identical. The elements of a process include input, process activities, output, resources (man, machine, method, materials etc). Therefore processes tend have a wider scope, which include procedures.

SN7.2. How to prepare a turtle diagram?

The term ‘turtle diagram’ comes from the configuration formed, when placing the elements of I-P-O, and the 4M together.

The elements are: I (input) is the head, O (output) is the tail, P (process activity) is the shell. The 4M becomes the legs: **M1 (machine), M2 (man), (M3) method and (M4) measurement**. Neat and easy to remember.

I (input): Generally includes things that start the ball rolling. In manufacturing for example, the input is the customer P/O, or a work order from the planner. You should also include other supporting information such as process documents (PFMEA, Control Plan, Packing Instructions etc). Materials, CSR, and legal requirements also go in here as input.



O (Output). Output is what we plan to have. In production, it will be products, which we mean conforming products. Scrap can be included, especially you are controlling it. Note that there is a connection with M4 (measures), and therefore M4 should be found in 'O' directly or implied.

P (Process Activity). This is for writing the process name, as detail activities are given in M3.

M1 (Machine) Basically you record key equipment needed for this process. You should also include special facilities and work environment required.

M2 (Man). Basically is about manpower needed for the process. Focus on 2 areas, type and competency. Special competency should be noted e.g. special grade of welding skill. Note that people outside the department may also be included here.

M3 (Method). This includes guiding documents (SOP, WI, formula lists) etc. You should list them out.

M4 (Measurement). KPI goes in here. It must be the same as what you listed out in the KPI list. However, there is no need to put the quantum here. Reference to current KPI list is acceptable.

There is a tendency to add risk and opportunity to the turtle diagram, which is a good development, since these are new and important requirements of ISO.

SN7.3. Any additional clarifications on turtle diagrams, to guide on compiling them correctly?

- **Why is process document, CSR, legal requirements placed in 'input'?**
There is no other suitable boxes for them. Besides, they are input
- **Why are guiding documents place in "M3 method" and not in input?**
These are methods, and there is a special box M3, reserved for them
- **How do we list the competency in M2?**
First list the type of people needed e.g. tool setter. Place the special skill behind within brackets, if any.
- **Do we list down all the details of SOP etc?**
No, just list the names or titles of the relevant documents
- **Why not put the KPI quantum in M4?**
In IATF, objectives setting is annual. Chances for changes are high and you will find a need to revise the turtle diagram. This is a waste that can be prevented.
- **The boxes at risks and opportunities are so small, and insufficient to list down all R&O. What do I do?**
List the top 1-3 R&O is sufficient. Turtle diagram is a pictorial representation of a process. It is an overview and therefore cannot accommodate all information.

SN7.4. Is turtle diagrams mandatory?

No, turtle diagram is not mandatory. There is no prescribed format and you can use one that suits your preference. IATF certified organizations tend to use the turtle diagrams. In Europe other forms of diagrams are use. The use of PIOR (Process Input-output-Resources) chart actually can do away the turtle diagrams as all the process elements are shown here.

SN7.5. What are the differences of the 3 types of process mapping? Which is still better?

Type 1. It is the (MP-SOP-SP) method, showing how the total processes in some sequence. Interactions however cannot be shown here very clearly. Although not perfect, it is simple to understand and conceptualize. This process map is essentially built on the turtle diagrams, where the resources are clearly shown.

Type 2. It is the Box and line diagram. The process flow is very detail showing the entire value-added flow from RFQ to delivery, to customer feedback. This is basically the version used in old ISO9001. The weaknesses



are a) resources are not seen, b) not all the boxes are processes. Some are just activities while some are processes, and becomes somewhat confusing.

Type 3 is the PIOR Chart. It is just a table listing out the various elements of a process. (**Exhibit 7-3**) The inadequacy of this method is it does not show sequence and interaction clearly.

To bridge the gap for any inadequacy, you should use 2: a) Type 1+Type 2, or b) Type 3+Type 2. Then everything is in place. The choice is a matter of personal preference. I personally prefer a) Type 1+Type 2.

SN7.6. Is it mandatory to designate processes as MP-COP-SP?

No, the prefixes are not necessary. You can use other terms or omit them totally. But there are some advantages in using them to set some priorities. IATF auditors also look for priorities this way. COP are priority areas. COP are important because process owners have direct contact with customer, and there could be undetected risks. In management, a term has been invented “moment of truth” on these contact points. They can either make fans or create enemies for the organization.

MP and SP are support processes. While they are integral part of the QMS, they are often carried out behind the scenes, and therefore less urgent and critical. MP and SP differs in the hierarchical level of implementation. MP have direct top management attention, while SP are managed by HOD and specialists on a routine basis.

SN7.7. What are the criteria to decide MP, COP or SP for processes?

There are 2 ways to classify them: a) any direct contacts with customer?, b) are they getting a lot of customer emphasis? In terms of sequence, we should use the first method first, and then modify the picture using the second.

COP: Customer orientated processes are those with direct contact with customers. They therefore should include RFQ, Order Processing, Product design, manufacturing design, customer complaint, customer satisfaction, invoicing and collection.

MP: Management Processes. There is no customer contact and therefore is a support process, but is a higher form of support process. Additionally, management is directly involved or paying close supervision to them. Business Planning, internal audits, management review, continual improvement, strategic analysis should come into this grouping. I sometimes see but never understood why would an organization consider HR and documentation as MP. These 2 processes are not that high up in the operation hierarchy.

SP. Support Processes are the rest of the processes. The routine type of support activities: HR, documentation, purchasing, maintenance, QAQC services including MSA and SPC, calibration, NC output Handling etc, should come into this group.

When you start to use the second method to modify (customer emphasis), production should be included as COP. Production planning may also be included as COP depending if the planner is in direct contact with customer. QAQC may also be included as COP, if customer emphasises a lot on this capability e.g. customer visits frequently to check on this process. Invoicing and collection can be best downgraded to SP. Although there is direct contact with customers, it is normally of low urgencies and not related with quality or delivery directly.

SN7.8. What is the optimum number of processes to use?

There are no rules on this. We often see 2 common and opposing mistakes:

a) splitting the processes too fine, example a process for IQC, first run IPQC, FQC and OQC.



b) exceptional large processes used. Example, Management process that covers business planning, management review, internal audits, continual improvement, strategic analysis, setting policy and objectives, and corporate responsibility.

The ideal picture is somewhere in between. A better deciding factor is the complexities rather than size. Meaning: how many of commonalities that can fit into a single turtle diagram. In the example of a) above (QC), probably 1 turtle can be used for all the 4 processes, due to similarity in the activities. Whereas in case b) (Management) above, the processes should be broken up into 3-4 processes. Business planning and management review can be the same turtle, internal audit another turtle etc.

A process can have several turtle diagrams to make thing clearer. For example, for purchasing, you can have a turtle diagram for purchasing process, (from PR to PO to tracking to receiving), and another turtle to deal with supplier control. This is a case of 1 process, 2 turtles.

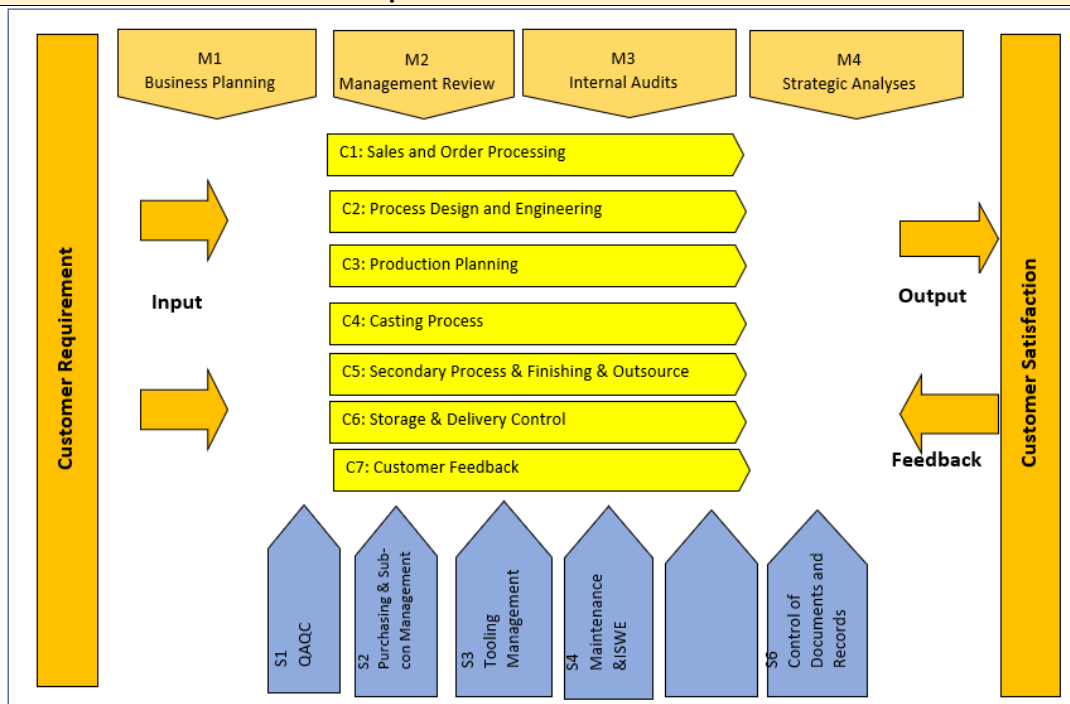
The number of processes should not be a key consideration. But for people to memorize easier, stick close to the departments in existence. 20 processes \pm 3 should be optimum, depending on the size of your organization and responsibilities.

4) Exhibits

Exhibit 7-1. Forming Processes from Procedures

Procedures	Management Oriented Processes MP
QMR-QSP-06 Business and Resource Planning	MP1.Business Planning
QMR-QSP-01 Management Review	MP2. Management Review
QMR-QSP-03. Internal Audit-System Audit QMR-QSP-04 Manufacturing Process Audit QA-QSP-09 Product Audit, Layout Inspection and Functional testing QA-QSP-02. Internal Quality Audit	MP3.Internal Audits
QA-QSP-03 Corrective action & Preventive Action	MP4.Corrective and Preventive Actions
Procedures	Customer Oriented Processes COP
SAL-QSP-01Customer Order Review	COP1: Sales and Order Processing
ENG-QSP-01APQP and Control Plan QA-QSP-05 PPAP ENG-QSP-02 FMEA QA-QSP-06 SPC QA-QSP-07 MSA/GRR ENG-QSP-03 Control of Engineering Change	COP2: Process Design and Engineering
SAL-QSP-01Customer Order Review PDN-QSP-03. Production Planning	COP3: Production Planning Process
Procedures	Support Oriented Processes SP
QA-QSP-01 QA Inspection QA-QSP-02 Control of Non-Conforming Product QA-QSP-03 Corrective And Preventive Action QA-QSP-04 Control Of IMT Equipment QA-QSP-08 Internal Laboratory and Control QA-QSP-09 Product Audit, Layout Inspection and Functional Testing	SP1. QAQC
PUR-QSP-01 Purchasing PUR_QSP-02 Management of Suppliers	SP2. Purchasing & Sub-con Management
<p>Remarks here explain on the exhibit. Do not include them as part of the document</p> <ul style="list-style-type: none"> • A procedure is a series of activity implemented to achieve a defined outcome. • In QMS, a process is generally larger than a procedure, to represent blocks of interrelated activities, which can include many procedures, as shown in the above diagram. A process must have a clear input & output of the activities. • The purpose of organizing procedures into processes is facilitate process approach. • The above example showed only 3 processes, due to space constraint 	

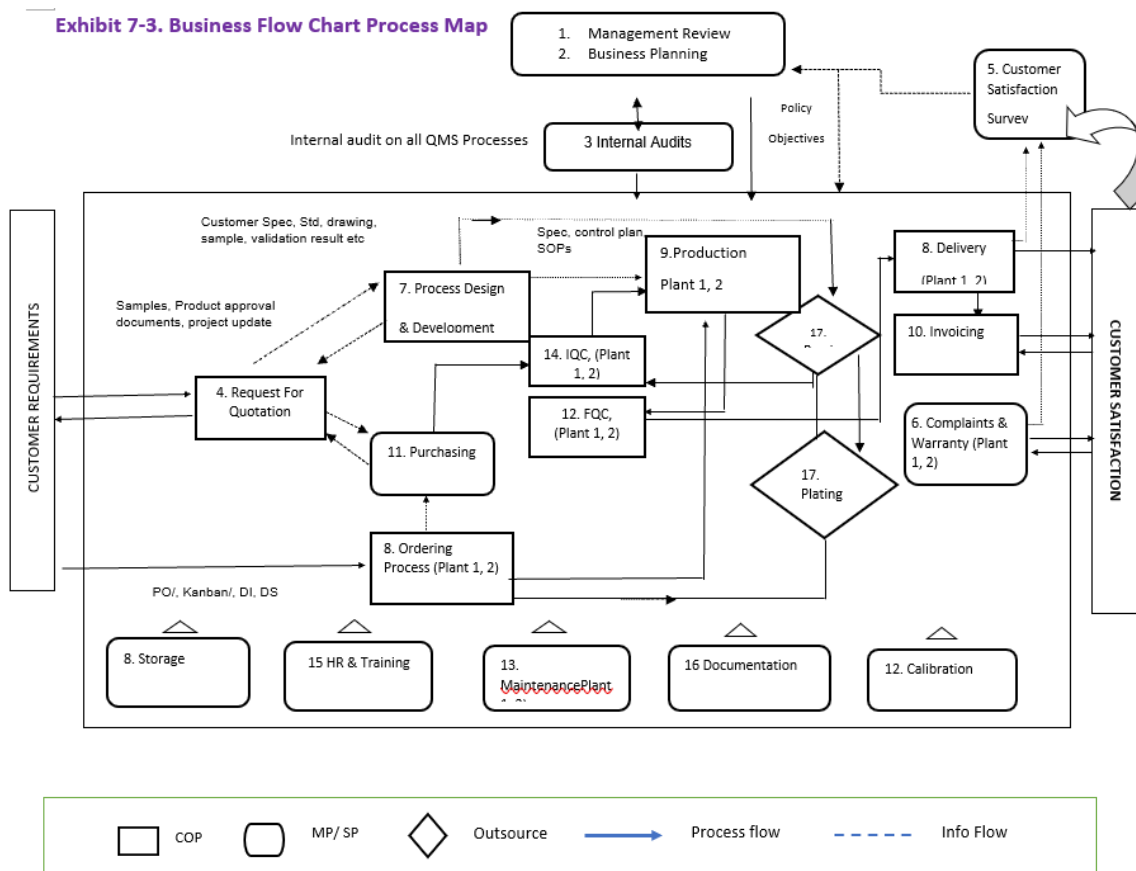
Exhibit 7-2. MP-COP-SP Process Map



Remarks given in this section explain on the exhibit. Do not include them as part of the document

- This is only one method of showing a process map and the processes are categorized as MP-COP-SP.
- But this is not the only type you can use. In IATF auditor's training, we are exposed to some 10 types
- This map however does not show sequence and interaction well. You normally require a business flow chart to complement this map. See Exhibit 7-3.
- Also note that you may be asked where are the context and interested party analysis. They are shown inside the process map as M4. Strategic Analyses. This method is neater than showing them outside the map and connected by arrows.
- Also note that you may be asked where is outsourcing. They are shown inside the process map, as C5 secondary process and outsource (for this fictitious case)
- Note that the processes shown may not be appropriate for your case. Do modifications as required.

Exhibit 7-3. Business Flow Chart (box and line) Process Map



Remarks given in this section explain on the exhibit. Do not include them as part of the document

- This is one of the best methods of showing sequence of interaction, which the other 2 types of process mapping lack
- For this particular process map, the different types of processes, including outsourcing are indicated by shapes of the box. Processes having companywide responsibilities are placed the bottom. Non-process tasks are shown without the outer boxes.
- The weakness of this map is resources are not shown. Therefore this is best use a supplement with one of the other 2 process maps.
- Unfortunately if you are using this to edit, you need to re0draw this from the beginning, as some part of the chart is not editable, for some unknown reasons

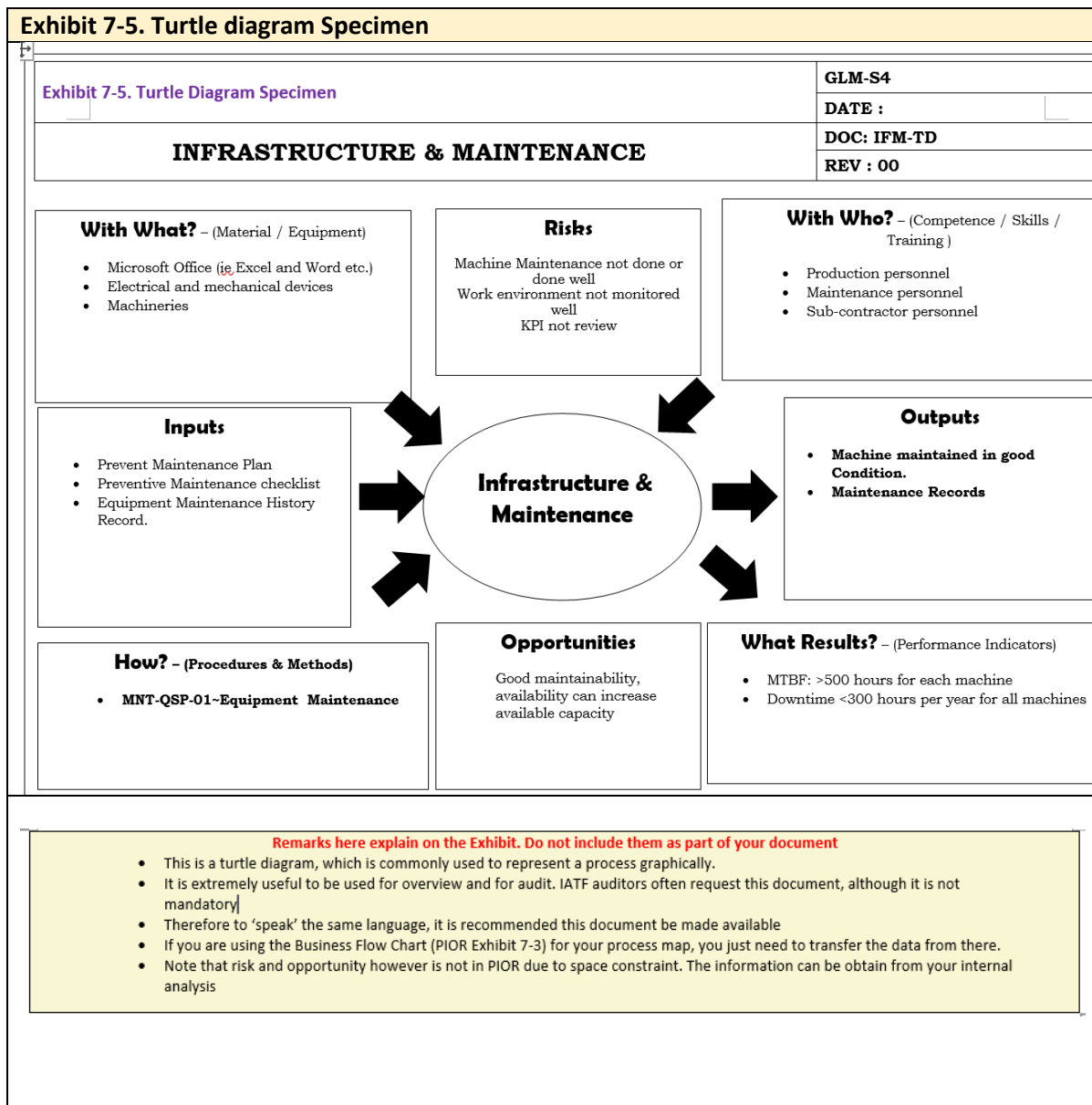
Exhibit 7-4. Process Input-Output, Resouces Chart (PIOR)

No	Process	Input	Output	Resources	KPI	PIC
1	Strategic Analysis	External Context Analysis, Internal Context Analysis, Interested Parties and their needs and expectations. Scope considerations.	<ul style="list-style-type: none"> Internal & External Risk and Opportunities analysis reports, Scope Statement, Interested parties analysis report. Action Plans for open issues 	Office facilities, external training	Review before internal audits	QMR, HOD GM (as needed)
2	Management Review	Previous Management Reviews, QMS performance results, internal and external audit results, Continual improvement projects & outcome. Business Plan.	<ul style="list-style-type: none"> Management Reviews Minutes, Monthly Performance data and reports 	Office facilities, external training	Completed 3 weeks before external audit	MD, QMR
3	Internal Audits	Previous Internal Audits results and external audit results, customer complaints and feedback	<ul style="list-style-type: none"> Internal audit program Internal audit results (3 types) Corrective actions for CAR 	Office facilities, external training, competent internal auditors	Internal audit CAR to reply within 5 working days	QMR
4	HR. Human Resources (Training)	Job Description, Organization Knowledge, TNA input,	<ul style="list-style-type: none"> Training schedule, Orientation records, OJT records and Training Evaluations Annual Training Plan and evaluations 	Office facilities, external training, competent internal and external trainers	Min 90% completion of annual training plans	HOD
5	Infrastructure and Work Environment	Infrastructure & Work Environment (ISWE) requirement Master lists of Equipment and Maintenance schedule	<ul style="list-style-type: none"> ISWE maintenance activities Maintenance records ISWE review results and improvement actions 	Maintenance equipment, facilities & relevant skills	MTBF: Min 400 hours	Workshop HOD

Remarks given here explain on the exhibit. Do not include them as part of the document

- Turtle diagram is most famous for showing a process. This is another method of showing processes and their elements
- Each row is actually a turtle diagram. Input-output-resources, KPI and responsibilities are all shown
- The only shortcoming is lack of the sequence and interaction, otherwise it can also be considered as a complete process map
- When used together with a Business Flow Chart Exhibit 7-3, it forms a comprehensive process map.

Exhibit 7-5. Turtle diagram Specimen



>> End of Chapter 7 <<