

ISO-Online Products User Guide

For the ISO 9001:2008 “Premium” Implementation Package as of 12/31/10

ORGANIZE AND BECOME FAMILIAR WITH OUR PRODUCTS

1. **UNZIP (EXTRACT) ALL FILES TO THE SAME DIRECTORY.** THIS IS NECESSARY, **OR THE LINKS** CREATED WITHIN THE DOCUMENTS **WILL NOT WORK!**
2. Our ISO 9001:2008 “Premium” Implementation Package contains 161 individual products:

<u>Individual Products/Item Description</u>	<u>#</u>	<u>Comments</u>
ISO 9001:2008 Quality Manual – in Word format	1	
Overall QMS Process Flow – chart in Visio and pdf format	1	
Customer Oriented Process (COP) Model – in Visio and pdf format	1	
COP Interaction Matrix – in Word format	1	
ISO 9001:2008 Operating Procedures (OP) – in Word format	23	
Deployment Flow Charts (DFC) for OPs – in Visio and pdf format	27	at least one per OP
Organization Chart – in Visio and pdf format	1	
QMS Responsibility Matrix – in Word format	1	
“Turtle” Diagram – in Visio and pdf format	1	
QMS Document Master List – in Excel format	3	internal, external, training
Instruction for Accessing QMS Files – in Word format	1	
ISO 9001:2008 QSA Checklist /Audit Guide) – Excel format	1	
Process Oriented Application of QSA Checklist – in Word format	1	
Other* Work Instructions (WI) – 9 Word, 1 Excel, 1 pdf format	11	
Management Action Request – in Word format	1	
Continual Improvement Form – in Word format	1	
Process Audit Checklist – in Word format	1	
Product Audit Checklist – in Word format	1	
Other* Forms – 30 in Word, 9 in Excel, 1 in Visio and pdf format	40	
Process Assessment Worksheets (PAW) – in Word format	26	At least one per OP
ISO 9001:2008 Overviews – in Power Point format	2	executive, employee
Process Management Overview – in Power Point format	1	
Root Cause Analysis (RCA) Overview – in Power Point format	1	
ISO 9001:2008 Revisions Overview – in Power Point format	1	
ISO 9001:2008 Implementation Guide – in Word format	1	
ISO 9001:2008 Internal Audit Course – Power Point format	1	
Additional Guidance Documents (from ISO) – in Word format	8	
POA&M for Implementing ISO 9001:2008 – in Excel format	1	
Product User Guide – in Word format (start with this product/file)	1	
Total Products / Items	161	in the “Premium” Package

Documents created in MS Visio (flow charting) software are also saved in Adobe (pdf) format. PDF files retain all hyperlink features of the original MS Visio flow chart; further, nearly everyone will be able to open/use Adobe (*.pdf) ... BUT ... you **WILL NEED MS VISIO SOFTWARE TO EDIT DFCs** and other documents created in MS Visio. For more info on accessing all QMS files (including Visio / Adobe files and software) or **IF YOU HAVE ANY PROBLEMS OPENING/VIEWING/EDITING ANY FILES**, see [WI 4.2.3-5](#).

Click here for [a comparison of all ISO 9001:2008 Product Packages](#) .

3. As an opening ‘test’ (and to get familiar with our products), I suggest you open the [Quality Manual](#) template ... and read through it ... clicking on various links to see where they lead ... we think you’ll like the way the links allow you to navigate around your system. Note: some links will not work for appropriate reasons: for example, some links take you to a web site ... and, won’t work unless you’re ‘on line’. However, if you’re ‘on-line’ ... have purchased the “Premium” package, and downloaded all products to a single directory on your computer ... all links should work fine! Let us know if you have trouble unzipping the files ... or if any of the files fail to open ... or the links fail to work, etc. Note: as mentioned above and advised on our web site, you will need MS Visio software to edit the deployment flow charts (DFCs) created in that format. All Visio files are also provided in other formats (mostly Adobe PDF) to enable you to open/view/print/use these documents, even if you don’t have MS Visio. Our [ISO 9001:2008 Requirements Checklist and Implementation Guide](#) contains additional information and resources on flow charting tools/techniques and, of course, a lot of other implementation guidance and resources.
4. Here’s a couple of tips regarding ‘hyperlinks’ we’ve created in many of our documents: you can edit, open, or remove the link within any Microsoft based application by simply placing your mouse over the hyperlink, right clicking on the link, and selecting the desired option from the drop down menu:. Other options include a) MS Word documents: access the link by placing your mouse over the hyperlink and click on the link while holding down the control key; b) MS Excel documents: access the link by placing your mouse of the hyperlink and clicking on it. Keep in mind that all links assume all files are in the SAME directory and that you have not changed any of the file names; changing directories (locations) or file names will cause the link to ‘fail’ (document not found) and you will need to remove the link and ‘insert’ a new link based on the new file name and location within your system. Get some help from your IT folks if you experience problems with links.

FAMILIARIZE YOURSELF WITH THE ISO 9000:2008 STANDARDS

5. Start by reviewing the Overviews ... I would actually suggest looking over the [Process Management Overview](#) first ... not because it talks to specific requirements of the ISO standards, but because it talks about the ‘process approach’ in general, which is probably the most important thing to know. Then I would recommend that you look over the [ISO 9001:2008 Revisions Overview](#) as it explains recent clarifications to that standard (regarding ‘intent’ of certain requirements) that are equally applicable to the same requirements in ISO 9001:2008 ... then look over the [ISO 9001:2008 Executive Overview](#) ... and the [Employee Overview](#). If/when ready, you can tailor these Overviews as desired to make them pertinent to your organization and situation.
6. Then read through the [ISO 9001:2008 Requirements Checklist and Implementation Guide](#). This tool does not address all requirements of ISO 9001:2008 ... as it only summarizes the intent of ISO 9001:2008 requirements and provides examples and suggestions for implementation ... but ISO 9001:2008 is the ‘heart’ of ISO 9001:2008 and (again) recent changes to that standard represent the only significant changes in ISO 9001:2008 ... so I would definitely start there. Then, I would recommend you review familiarize yourself with the [ISO 9001:2008 Quality Systems Assessment \(QSA\) Checklist](#) and read through the [Table for Process Oriented Application of the QSA Checklist](#)” to gain an understanding of the requirements and the overall process approach advocated for adoption by ISO 9000. **Perhaps the key to best utilizing our resources is to know/understand what you have available to you, so you can best determine if/when any of these tools will be useful to you or your implementation team.** Recommend you provide the [Process Management Overview](#) ... to members of your transition/implementation team as a supplemental resource ... handed out in conjunction with the [ISO 9001:2008 Executive Overview](#) you provide them.

CONDUCT A DOCUMENTATION REVIEW OF YOUR EXISTING SYSTEM (gap analysis)

7. Per item 1 of our [POA&M template](#), use the [QSA Checklist and Audit Guide](#) as a tool for conducting a documentation review to identify ‘gaps’ between your current documented quality management system and requirements of ISO 9001:2008. Those transitioning from an SO 9001:2000 based QMS will find our [ISO 9001:2008 Revisions Overview](#) very helpful as these changes represent most of the changes in ISO 9001:2008. Collect and report results of your gap analysis to management ... identifying all needed revisions and/or additions. Remember, ISO 9001:2000 is less ‘prescriptive’ than its predecessors ... merely meaning you will have a variety of options to chose from when documenting your processes (i.e. with a few exceptions, procedures, flow charts, job descriptions, training materials, software programs, etc. are all viable methods for defining your system). Our recommendation is to stick with whatever method you currently use or feel most comfortable with. Our implementation package provides two basic methods for documentation: Operating Procedures (OPs) ... or Deployment Flow Charts (DFCs). In most cases, we think our DFCs will do the trick ... more on that later.

DEVELOP A DRAFT (PROCESS ORIENTED) QUALITY MANUAL (based on your policies)

8. Per item 2 of our [POA&M template](#), conduct a ‘policy development workshop’, with the aim to develop/update your quality system manual. As you set out to develop/revise your quality system documentation, begin by reviewing our [Quality Manual](#) template in detail. There is no ‘prescriptive’ form that your quality manual must take ... in fact, any format is acceptable ... even your ISO 9001/2:1994 (or QS 9000:1998) based manual is acceptable ... as long as it is clear where/how you address each requirement of ISO 9001:2008. A cross-reference chart is preferred by some ... but we recommend you ‘reconstruct’ your quality manual along the lines of ISO 9001:2008. Note: there will not be a need or a recommendation to reconstruct any other document. At any rate, we recommend you use our template as a guide. We also recommend you include a basic ‘business cycle’ flow chart in your manual that depicts the key (or Core) processes of your business (from initial customer contact through product/service planning, provision, verification and customer feedback). In the automotive industry, these key business processes are referred to as “Customer Oriented Processes” (or COPs) and they essentially correspond to things you ‘do’ (i.e. product realization processes corresponding to requirements defined in Clause 7 of ISO 9001:2008). We have identified a ‘typical’ COP model, [COP 4.1](#), for your consideration. You will then need to define the “Support Oriented Processes (or SOPs) needed to effectively implement your COPs. Finally, you will need to define any other business processes required by management and/or the ISO 9001:2008; these are called “Management Oriented Processes” (or MOPs). We have depicted the interaction of COPs, SOPs and MOPs in a ‘typical’ organization in our [COP Interaction Matrix](#), and we have developed a ‘top level’ deployment flow chart (or DFC), [DFC 4.1](#), to depict how all of your key business processes (i.e. COPs, SOPs and MOPs) might be deployed across a ‘typical’ organization. You should use these documents (and other tools we provide) as guides to define your processes and interactions. The key to all of this ‘initial’ work (i.e. focusing on processes) is to enable you to adopt the process approach to run your business ... as advocated by ISO 9001:2008. Ultimately you will need to develop ‘policies’ addressing all requirements of ISO 9001:2008, define the sequence/interaction of processes in place to meet these requirements (and accomplish your organizations objectives), ‘point’ to documents/data in your system where/how these policies are carried out, and, of course, assign related responsibilities for implementation, management and improvement. You should use outputs of the ‘gap analysis’ to determine if/when policies (and related lower level procedures/instructions/systems) require development or revision. It’s not nearly as complicated as it may sound and our tools have been designed to facilitate the identification and definition of such processes. The output of all these activities will be your new/revised Quality Manual ... which must make sense to you or it will be of no real value to you ... or anyone else. We have encouraged the adoption of the process approach in the construction of our [Quality Manual](#) template ... but the actual structure, feel and look may well be different by the time you get finished with it!

9. The most valuable training you do might well be delivery of our [Process Management Overview](#), per item 3 of our [POA&M template](#). Ultimately, everyone in your organization should be introduced to these concepts, and the tools we advocate you use in process management, i.e. deployment flow charts, process assessment worksheets, turtle diagrams. You should definitely start by giving this training to top management and ISO 9001:2008 implementation/transition team members ... as well as existing or potential internal auditors.

MAP OUT 'CUSTOMER ORIENTED PROCESSES' (i.e. things you 'do' for a living)

10. You are now ready to begin building your system per items 4a – 4d of our [POA&M template](#). Form process teams and begin to flow chart the key steps in each of the following processes. Use our [Deployment Flow Chart \(DFC\) templates](#) as guides (note: each column in a DFC represents a function/department ... use of DFCs will quickly show both sequence AND interaction of processes ... both are important and need to be managed to ensure effectiveness of the process ... and related processes that form a system). Also, after flow charting the process, use our [Process Assessment Worksheet \(PAW\) templates](#) and/or associated '[Turtle Diagram](#)' [Form](#) and [Guide](#) to help you summarize the key inputs, controls and outputs associated with each process, BE SURE TO COLLECT ALL QMS FORMS DURING THIS PROCESS ... ALL WILL NEED TO BE ACCOUNTED FOR SOMEWHERE!. Also, try to get the team to identify at least one process measure of effectiveness (it works) and efficiency (at what cost). These measurables, along with the key process controls ... and the key process inputs/outputs ... are the things you will be managing to assure process and system effectiveness to identify improvement opportunities. Again, we recommend you start by having team members meet to develop DFCs and PAWs for each of the following processes (that are derived from Clause 7 of ISO 9001:2008, relate to things you 'do' for a living, and typically would be classified as "COPs" since they typically have significant customer inputs (specifications or expectations) and required outputs (deliverables and performance requirements):
- a) [Product Requirements Identification/Review](#), clause 7.2: includes initial customer contact, estimating/quoting, receipt/review of contracts/orders, and related change management ... usually feeds into all planning processes: quality planning, including APQP (7.1), design planning, including APQP/PPAP, material planning (7.4), equipment/facilities planning (6.3), personnel planning (6.2), and job planning and control (7.5.1).
 - b) [Quality Planning](#), clause under section 7.1: should be before but can sometimes be after acceptance of a contract or order ... includes [advanced quality planning processes](#) (i.e. [APQP](#), FMEA, [PPAP](#)) some of which is also accomplished as part of design (see Section 7.3) and usually results in product quality control plan and/or more generic 'process control plans' depending on the nature of your business.
 - c) [Design and Development Processes](#), clause 7.3 (includes product design, if applicable, and manufacturing process design, ALWAYS applicable to organizations implementing ISO 9001:2008). Includes all design activities associated with products you 'own' (whether you make/deliver the resultant products/services or not is irrelevant) ... starts with development of a design plan and continues through all phases of design including design verification/validation and change management activities; most automotive suppliers utilize the APQP process as their design process and utilize the PPAP process as their production part approval process. Note: again, you must include product design if you 'own' the design to the products included in the scope of your registration; you MUST include all design activities you perform in accordance with customer specifications issued by the design responsible organization (such as manufacturing process design, or tooling design, etc.) ... again, manufacturing process design is ALWAYS applicable to organizations implementing ISO 9001:2008.
 - d) Purchasing, clause 7.4: this includes [Supplier Evaluation](#) (and [Development](#)), the [Purchasing Process](#) itself, as well as verification of purchased product/services; basically this includes making arrangements for verifying incoming product through [Receiving Inspection](#) (per clause 8.2.4) and/or may include verification at source.
 - e) [Production Planning and Control](#), clause 7.5.1: this assumes all needed resources have been planned, acquired, and are available ... and that the process itself has been proven capable of performing as intended (usually through the PPAP process); the job planning/control process itself usually starts from job release and continues through job completion. Inherent in this process is the development and issuance of job 'packs' (containing all materials, control plans, work instruction/information and other resources competent workers need to carry out the job). Note: this also includes Post Delivery Servicing, clause 7.5.1.f); so be sure to identify any 'post delivery' services (installation, post installation service work, warranty work, etc.) and your methods for planning and controlling this work as well.

- f) [Process Validation](#), clause 7.5.2: this includes the ‘prequalification’ of any processes you perform where the product/service cannot be readily/economically verified through subsequent inspection and test ... generally includes qualification of operators/equipment/processes and generally also include the development of detailed work instructions and/or process control plans governing such processes; note: applies to all manufacturing processes, not just ‘special processes’, many (but not all) of which are ‘validated’ through PPAP per clause 7.3.6, as part of manufacturing process design/validation).
- g) [Product Identification and Traceability](#), clause 7.5.3: this includes your process (es) for identifying products (and their inspection/test status) through all stages of processing (from receipt of raw materials through delivery of finished goods); as well as your method of establishing/maintaining and reporting traceability of products/service materials or other traceability data per customer requirements ... or desired by your organization.
- h) [Customer Owned Property](#), clause 7.5.4: generally you will handle customer property using the same processes/controls applicable to your own property, so this process will only need to describe how you maintain appropriate identification and report problems to the customer, and how you communicate unique customer requirements to ensure proper handling.
- i) [Product Preservation](#) (including Storage, Handling, Preservation, Packaging and Delivery Processes), Clause 7.5.5: this includes your process (es) for preserving and protecting products in storage or transit.
- j) [Measurement Systems](#), clause 7.6: this includes Measurement Systems Analysis ([MSA](#)), as well as your program for identifying and controlling/calibrating gages, software and other devices used to inspect/test product/service or process quality.

MAP OUT KEY ‘SUPPORT’ PROCESSES (i.e. processes needed to effectively implement COPs)

11. Now you’re ready to define some of your business processes needed to effectively implement the processes defined in step 6 above, continuing with items 4a – 4d of our [POA&M template](#). (note: process assessment worksheets and/or turtle diagrams of processes defined in step 7 will undoubtedly identify one or more of each of the following processes as ‘support processes’):

- a) [Process Monitoring](#), clause 8.2.3: this includes all ‘operator’ monitoring activities (usually performed in accordance with instructions contained in the applicable ‘job pack’ and/or per training/experience of the worker). This also includes the conduct of process capability studies (usually a part of manufacturing process design activities carried out through the PPAP process; and may also include the use of statistical monitoring tools (SPC) per clause 8.1 if/where applicable and/or any other appropriate or customer mandated process monitoring activities.
- b) Product Monitoring and Measurement, clause 8.2.4: this includes all planned inspection/test activities (whether performed by Quality or operators) for products/services you provide. These activities must be consistent with your quality planning activities (7.1) and includes all [In-Process Inspection](#) activities (including verification of job set ups), [Final Inspection/Test](#) activities, as well as Layout Inspections and Functional Testing.
- c) [Non-conforming Product Control](#), clause 8.3: this includes your process (es) for managing anything that fails a planned inspection/test (8.2.4) or is suspect as a result of process monitoring (8.2.3).
- d) [Employee Qualification and Training](#), clause 6.2.2: this includes defining employee qualification criteria, documenting employee qualifications against such criteria, identifying/providing required training, and assessing effectiveness of training provided.
- e) [Equipment/Facilities](#), clause 6.3: this includes planning/provision/maintenance of needed infrastructure; most notably equipment/facilities planning and maintenance, the utilization of lean manufacturing and materials management techniques and other tools to enhance operations ... and may also include other support systems, such as management information systems, electronic customer communication systems (such as CAD/CAM, EDI, ASN, etc).

MAP OUT 'MANAGEMENT ORIENTED' PROCESSES (and other business processes)

12. Finally, you're ready to define some of the QMS 'management' processes required by ISO 9001:2008 (not already covered) and any other appropriate business processes, continuing with items 4a – 4d of our [POA&M template](#).
 - a) [Management Review](#), clause 5.6: this includes defining your process for collecting/reviewing required inputs (data/trends and recommendations for improvement) and documenting required outputs (improvement actions and plans/resources for carrying them out).
 - b) [Improvement](#), clause 8.5: this includes defining your process for initiating corrective, preventive and improvement actions. Note: separate procedures for corrective/preventive action are not needed (although you must clearly distinguish the difference between the two processes ... because corrective action starts with a failure and the preventive actions deals with potential failures). Also don't forget to use some of our other tools to help set up your improvement program: includes our [Process Management Overview](#), our [Management Action Request Form](#), and our ["8D" Problem Solving Approach](#), and our [Continual Improvement Form](#) - a tool for helping you establish and track progress against quality improvement objectives.
 - c) [Customer Satisfaction](#), clause 8.2.1: this includes defining your complaint handling system as well as your method for collecting/reviewing/acting on other customer feedback.
 - d) [Internal Audit](#), clause 8.2.2: this includes defining your internal audit program ... which should be designed around auditing processes that actually occur in your business ... picking up all applicable QMS elements as you go ... and schedule such audits on the basis of the status and importance of the activity.
 - e) [Document Control](#), clause 4.2.3 and [Record Control](#), clause 4.2.4: to ensure all QMS documents/data and records are properly controlled, including [Internal QMS Documents](#), [QMS \(and other\) Training Materials](#), and [External QMS Documents](#), including customer drawings/specifications as well as ISO standards, as well as records needed to demonstrate performance and/or compliance with all applicable requirements.

DOCUMENT PROCESSES

13. Now that you have mapped out all your key business processes ... you will need to decide if you want to use the DFCs as your formal method of documentation ... or if you want to develop/update more detailed/narrative operating procedures (OPs) before proceeding to items 4e through 4g of our [POA&M template](#). Note: a well constructed DFC accomplishes everything a narrative OP can accomplish, and both can be considered 'documented procedures' according to the definitions contained in ISO 9000:2008. Again, this is your call. Our OP and DFC templates give you models for either ... or you can chose to use both. We find DFCs are great tools for quick reference and improvement ... but miss some of the needed detail traditionally provided by OPs. Accordingly, our product package assumes narrative procedures will be used in all cases (as far as the formal documented system goes) ... and the DFCs and PAWs (and associated 'turtle diagrams') are developed/used as tools for process improvement. Again, your call ... you may, in fact, decide to use both! You will also need to review/revise and/or develop 'floor level' documentation to be consistent with everything you previously done, per to item 5 of our [POA&M template](#).

FINALIZE QUALITY MANUAL (based on what your documented processes show your policies to be)

14. After you've documented your system, you will then need to revisit the [Quality Manual](#) to see if any of the policy needs to be changed. Then you also need to revise all [QMS Training Materials](#) to reflect your system to the greatest degree possible. You're now ready to start training and implementation of your ISO 9001:2008 based quality management system per item 6 of our [POA&M template](#).

SOME TIPS ON USING SOME OF OUR PROCESS MANAGEMENT TOOLS:

DEPLOYMENT FLOWCHARTING and ISO 9001:2008

The key to identifying good process measures is the technique employed to design and/or document the process. One of the best techniques available is a technique called DEPLOYMENT FLOW CHARTING. [DFCs](#) are different from a 'standard' flow chart in five key ways –

- 1) each flow chart is limited to a single page with "links" to applicable "sub-processes",
- 2) all process participants are identified on the flow chart,
- 3) the flow chart is constructed so that all "horizontal" lines identify a "customer/supplier" relationship (whether internal or external) - this helps identify potential sources of too little (or too much) or wrong "stuff" being provided to the "customer",
- 4) all vertical lines represent sequential steps performed by an individual or individual work group, and
- 5) "diamonds" are used to identify go/no go points that identify opportunities for measurement.

This process management approach can be applied to any process. It will be particularly useful in addressing the following 'general' requirements of ISO 9001:2008:

- 4.1 a) Identify Quality Management System (QMS) processes
- 4.1.b) Determine the sequence and interaction of QMS processes
- 4.1.c) Define the criteria and methods required to ensure the effective operation and control of QMS processes.
- 4.1.e) Monitor, measure and analyze QMS processes
- 4.1.f) Implement actions to achieve planned results and continuous improvement of QMS processes.

PROCESS MEASUREMENT and ISO 9001:2008

MEASURES OF "EFFECTIVENESS"

Process outcome measures: anything that measures whether (or not) a process did what it was designed to do - indicators could include internal/external customer satisfaction (or returns, complaints, etc.), product/service performance data (or failures), etc. Most often these are expressed as "failure data".

MEASURES OF "EFFICIENCY"

Process input measures: anything that measures the resources required to generate the desired outcomes - i.e. the people, equipment, methods and materials needed. Most often these are expressed as "ratios" (i.e. input/output ratios) or "cost of quality" data.

Process throughput measures: anything that measures variance occurring during the transformation from inputs to outputs. Most often these are viewed over time - with predetermined "action points".

All process measures need to be trended (looked at over time) to determine if a "systemic" problem exists - requiring a change to the system itself. One or two key measures per quality system element is all you really need and they should jump out at you if you really look at what the process is trying to accomplish, the resources used to accomplish it, the variation within the process, and the people involved in the process.

DEVELOPMENT AND USE OF PROCESS ASSESSMENT WORKSHEETS (PAWS)

Process Assessment Worksheets (PAWs) are tools we developed as an aid for documenting data needed to manage processes per the 'process approach' and 'system approach' advocated by ISO 9001:2008. The same information included on PAWs can also be documented on 'Turtle Diagrams' ... which many prefer because of their 'visual' depiction of the data ... these are only tools ... pick the one you like best.

[PAWs](#) (and/or [Turtle Diagrams](#)) summarize:

measures of effectiveness: (did the process work) ...
measures of efficiency: (with little or no waste)
interrelated processes: (are the 'interfaces' working)
inputs: (are they verified prior to use)
outputs: (are they verified prior to release)
controls: (are they adequate)
steps: (are they clear ... and consistently followed).

In summary, PAWs (and/or Turtle Diagrams) document data useful to the following groups:

Managers can use them to 'define' and manage their processes and systems ... and,
Auditors can use them to assess process and system effectiveness.

PAWs (and/or Turtle Diagrams) can be used in conducting process audits to document or assess:

1. **Process Scope and Boundaries** (start, end, application to particular functions/products, etc.)
2. **Process Flow**, including:
 - 2.1 **Inputs used to effect process completion** (are they verified prior to use?)
 - 2.2 **Events that start process activity** (are they clear, is everything in place?)
 - 2.3 **Activities required to complete the process** (are they defined and appropriate for process complexity and competency of personnel performing them?)
 - 2.4 **Validation that the process is effective** (has been done to prove that the process is capable of performing as intended ... or meeting desired objectives ... before 'launch'? What controls have been established to assess/assure continuing process capability/performance?)
 - 2.5 **Events that signal process completion** (are these and related records clearly defined?)
 - 2.6 **Outputs resulting from process completion** (are they verified as conforming to (internal or external) customer specifications and expectations prior to 'release'?)
3. **Process Measures** (are process metrics, statistics, etc. appropriate, understood and properly applied?)
4. **Process Change Management** (are process changes made in time to prevent recurrence of actual failures and to prevent occurrence of potential failures?)
5. **Tools used to fulfill process requirements** (are they defined and properly used?)
6. **Controlled Documents** (are they appropriate, available, and used?)
7. **Quality Records** (are they completed, legible, and used to demonstrate conformance or effect improvement?)

Should PAWs (and/or Turtle Diagrams) be developed and used to manage ALL QMS processes?

Eventually, yes. Initially you will probably want to focus on using them to assess whether (or not) your 'customer oriented' / product realization processes are working effectively (i.e. those things that you 'do' ... manufacture, design, provide service, etc.) ...

However, in order to do that, your 'support oriented processes' (and 'management oriented') processes should also do what they were designed to do (i.e. management reviews must result in actions/resources ... audits must identify nonconformances that need to be rectified, corrective/preventive actions must eliminate causes of actual/potential problems ... so they do not occur/recur, etc.).

So ... yes ... ALL processes should be managed/measured to ensure they work as intended ... then improvement activity can be focused on those processes that are the 'least' effective ... or have the most significant impact if NOT addressed.

Please remember that PAWs (and/or Turtle Diagrams) are purely 'optional tools' to help you manage your system ... primarily a tool to be used by 'responsible managers' ... so that 'in a nutshell' they can see what the key process inputs/outputs/controls are for processes they 'own' ... and they can use them as a place to document their 'baseline performance data' and any improvement objectives they set for themselves. Once developed, managers can then use these tools for monitoring/measuring their processes ... or internal auditors can use them as tools for assessing process effectiveness ... or to document progress towards achievement of established improvement objectives.

PAWs (and/or Turtle Diagrams) are primarily tools to help managers define and manage their processes ... not clouded up with a bunch of detail or convoluted charts ... it gets to the heart of the matter: 'Does your process work?' and ... 'Is it in need of improvement?' Questions that responsible managers should have answers to ... and these tools give them something to think about ... and document ... as evidence that they truly are monitoring/measuring their own processes ... not waiting on internal or external auditors to tell them that things are out of control (or not working). It's really a 'Phase III' tool ... with 'phases' defined as follows:

Phase I ... is to define the process (in an OP, DFC, WI, training manual, job description, or?) ...

Phase II is to audit the process to be sure people are following the process as defined ...

Phase III is to 'assess the process for effectiveness' (i.e. does it really 'work'?) ...

Phase IV is to assess the process for efficiency (i.e. is there any 'waste'?).

Accordingly, we would recommend using PAWs (and/or Turtle Diagrams) to establish baseline performance measures and to determine if improvement objectives are needed ... but only after a process has been defined (Phase I above) ... and you are fairly sure (through audits, Phase II) that it is being consistently followed ... THEN you're ready to monitor and measure its 'performance' meaningfully.

To summarize, once baseline measures have been established ... establish improvement objectives ONLY if/where needed ... and, if needed, this should be reviewed and approved as an output of [management review](#) ... then you can periodically review progress towards improvement objectives through the use of our [Continual Improvement Form](#) in advance of the next management review meeting (where you would have to report progress against achieving the objective).

Clear? We hope so!

Contact us with ANY questions regarding the content, use/application of ANY of our products!

Your 'Quality Partners' at ISO-Online

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