Process Model Explanation — Requirements of 4.1

Item on the Process Model	What this means
4.1 a identify the processes needed for the QMS and <u>where they apply throughout the organization.</u> Identify any outsourced process with the internal process(es) with which it is associated. The Quality Manual or a written procedure must identify where the rules of a process must be followed in the organization (typically stated in the Scope of an Operating Procedure).	
Process Name and Owner	A process has a name. The person responsible for the process is the Process Owner.
Objective	What the process must achieve
4.1 d ensure that the resources and information needed to operate and monitor processes are made available	
4.1 b determine the <u>interaction of processes</u> (inputs come from another process - this is an interaction) a process can also have <u>dependencies</u> - example: a fork lift needed to move product (this is an interaction)	
4.1 c determine the criteria (requirements for acceptable inputs)	
Inputs:	The <u>criteria for acceptable inputs</u> should be defined. The Supplier process should deliver ready-to-use input to the receiver process. The receiver process (the Customer) should not have to "fix" the input or hunt it down before work can begin.
Materials and information **Equipment/Tools** **Personnel competency requirements**	**Materials**: product, parts **Information:** documents, specifications, or data; outsourced product/service **Equipment and tools**: Stated on the quality plan (traveler) or in documentation **Competency requirements** for the work done must be documented. This is most often found in the job description. <u>Training records</u> must indicate that the person meets the requirements in the job description through education, experience or training. Compare the job description to the training records. The work of a person who is not yet competent must be monitored by a supervisor or other qualified operator.
4.1 c determine the methods to use to ensure that the <u>operation</u> and <u>control</u> of processes are effective.	
Operating the process	Procedure steps and who does them (by title) can be documented in a procedure or not documented. How to perform steps can be documented in a Work Instruction or may be learned through training. Personnel should know and follow the defined procedure.
Control criteria rules or requirements that must be followed The person who performs the process should know the control criteria that apply to the process.	**Set-up and Shut-down conditions**: applies to the set up and shut down of equipment **Operating parameters**: applies to staying within defined limits of the process, for example: feeds and speeds of machines, process times, temperature and humidity, flow rates, clean room requirements, etc. **Policies/Standards, and regulations**: Policies: requirements of the organization that must be followed. Standards: ISO 9001 or other standard, product standard, or the organization's standard. Regulations: laws that must be followed
4.1 e monitor, measure and analyze the system processes	
Control methods	**Monitoring**: all processes (activities) are subject to monitoring. Personnel monitor the processes they perform when they check to see that requirements are met. Supervisors and managers monitor processes. **Inspection or test and review**: methods to measure if a process meets requirements **Analysis / Assessment**: Mgt. determines what data and information to collect (and how frequently) on the performance of identified significant processes. This data is analyzed and assessed to determine where improvements can be made.
4.1 b determine the <u>interaction</u> of processes (outputs go to another process - this is an interaction).	
Outputs **Products, services and information**	**Products/ services/ information**: the requirements for acceptable outputs should be defined. This could be specifications that must be met, requirements for the output, or just to complete the steps defined for performing the work. The criteria for acceptable outputs should consider what the Customer process (the receiver) defines as acceptable input.
A record of results is an output	**Records of <u>results</u>**: A record is anything that indicates that the work to be done was done and that the requirements were met. A record could be: 1. inspection and test results 2. a sign-off on a traveler that indicates the work was done 3. a completed form, document, invoice, or report is a record When an authorized person must review or approve the results, the signature, stamp, or other method used to indicate approval must be present on the record.
4.1 f implement <u>the actions needed </u>to achieve planned results and the continual improvement of processes.	
Reaction Plan **Continual improvement**	The reaction plan is what to do when a known problem occurs; if unusual, ask the lead person. Take action to achieve the planned results. Take action (corrective action) to improve the process when it is determined that action is needed.