Following are general comments to define the final product for all process maps and some specific comments on the process map 7.1 you created relative to <u>Planning of Product Realization</u>..

First , the purpose of a process map is to outline a series of activities from input of materials and labor to output of a product that is either finished or needed for the next process. Each map must reference outside processes, such as purchasing, that impact any of the activities within the process being described. Each referenced process needs its own map.

Each step must be detailed to the extent that people can understand what they are supposed to do, see the flow of work and hopefully find improvement opportunities. To accomplish this, verbs are important. Without the verb, we have no idea what is being done and the flow of logic is broken.

For example, one of the process maps has the words "Mission and Strategy" as a step in an activity. However this does not tell us what is happening. Are you developing, reviewing, revising, or approving the "Mission and Strategy"? Is this a presentation to employees? We need to understand what is being done in this step to analyze its appropriateness to other activities within the process and to the process as a whole.

Second, each page should contain only one process. If the page has so many activities that it is difficult to follow the flow then the process should be analyzed to determine what parts are sub-processes. They should be placed on subsequent pages.

For example, 7.2.1 and 7.2.2, both on one page, were confusing. By analyzing the activities, I determined there were two sub-processes occurring: the steps taken if Division X packages an existing product and the steps taken if it is a new product under consideration for packaging. I have divided the processes accordingly on the next page.

Third, process map identification must be consistent. A numbering system related to the ISO requirements numbering should be developed. Headings and sub-headings must relate to this numbering system with main processes at the highest numeration level then breaking down to sub-processes as needed. Headings should have enough detail to ensure their purpose is understood.

For example, the layout might be as follows:

Sub-Clause number: Main Clause Name
Sub-Clause name
All upper case and bolded. All centered.

6.1: RESOURCE MANAGEMENT
6.1.1: PROVISION OF RESOURCES

Fourth, a Glossary is needed so that a layperson, such as a new employee, can understand the acronyms. Besides assisting in the training of new employees, it ensures you are both speaking the same language.

Fifth, ISO document control requirements must be a part of the document. This means the location of the base document, the location of the revision history, the creation date and the last saved date need to be on the process map. This can be accomplished by creating the map in Visio, inserting it into a Word document then inserting fields into the footer that identify file location and creation and save dates. The words Revision History File, inserted into the footer, would be linked to the Revision file. The document can then be password protected to avoid changes by others when they pull up the file at their workstation but they can still link to the history to ensure they have the latest version.

SUMMARY

Process 7.1 Planning of Product Realization

In Planning of Product Realization, you have two distinctly separate processes, warehousing and packaging. Within packaging, you have two sub-processes, existing product and new product. Below, I have itemized the activities for each process and sub-process.

Planning for all processes will include continual improvement steps such as review of activities and related procedures for suitability, validation and verification activities, changes to regulatory and legal requirements for operational applicability, and setting objectives for improvement.

Warehousing

Warehousing does not involve the ISO processes of design or production and the activities are consistent among customers.

Warehousing involves common steps including ordering product, receipt, inspection, storage, maintenance, selection, and delivery. This applies to both Division Y activities and the warehouse activities. Inspection is minimal. Regulatory and legal requirements are defined when the materials are purchased but should not change much over the life of the product.

Packaging

Packaging does involve the ISO processes of design and production. For existing products most activities are consistent among customers until production and inspection and possibly support. New products require multiple design activities in addition to the "items already produced" methods.

- Items already produced. They involve ordering materials, receipt, inspection, storage, maintenance, disbursement to production, and possible inspection prior to production, production with appropriate inspection points, storage, delivery, support, and record keeping.

- New products. These involve:

  - Approval - your process map 7.2.1 and 7.2.2 HTP,
  - Design - your process map 7.3 with all its sub-clauses that include review of existing processes and procedures to see how they fit for the new product, interpreting regulatory and legal requirements for applicability, verification and validation activities, acceptance criteria, support requirements, and recordkeeping,
  - Budgeting for resources and facilities,
  - Materials including defining, ordering, receipt, inspection, storage, maintenance, disbursement to production, and possible inspection prior to production,
  - Production with appropriate inspection points, and
  - Storage, delivery, support, and recordkeeping.

Both packaging processes can be included in one map with references to 7.2.1 and 7.2.2 Division X and the 7.3 process map.

Impact of Other Processes

In these processes, you see the impact of other processes such as purchasing, receiving, inspection, nonconformity, etc that are affecting the process under study. These impacting processes need process maps of their own and should be referenced by the production process maps.