

How to Create and Maintain Procedural Documents

Fran Germann
Bristol-Myers Squibb
PCF Congress
November 11, 2009

Background

- **To the agencies and monitors that audit our companies, our documents reflect how well we manage and communicate the basic activities required to run our businesses.**
- **In a sense, in their eyes,
“We are our documents”**
- **The goal of robust creation and management of policies and procedures is to demonstrate that a company is well organized and that it communicates requirements effectively and efficiently.**

A Consistent Approach

- **Building a repository of procedural documents to support a robust compliance initiative begins with consistency in:**
 - **Document Hierarchy**
 - **Document Contents (templates)**
 - **Access/Taxonomy**
 - **Access/Systems**
 - **Governance**

Benefits

- **Creates a common understanding of principles and goals.**
- **Enables clear and consistent communication of work responsibilities and accountabilities.**
- **Improves quality.**
- **Enhances efficiency and effectiveness.**
- **Expands access to all who need to know.**
- **Facilitates compliance audits and investigations.**
- **Enables leveraging of knowledge between Business Units**

Document Hierarchy

- **When deciding how many document types to use consider the intent and approval requirements**
 - **Too few document types may impede the approval process by having high level signatures on documents subject to frequent change**
 - **Too many document types may make it difficult for people to know where to find specific information**
- **Gatekeeping activities (proposal and review by a central governing body) helps to control the proper use of document types**
- **Define the need to address Corporate (Global) vs. local issues**

Document Contents

- **Use of standard formats saves the time and effort of creation within each department**
- **Standardization should allow for some differences**
 - **e.g.: Defining the sections to be included in each document type and the order in which they appear leaves room for individual design, while maintaining sufficient similarity to facilitate use.**
- **The goal of creating the documents should be efficiency, not use of all document types – flexibility is key.**

Access/Taxonomy

- **Access to documents requires classification that is easy to interpret and easy to maintain**
 - **Use of generic terms facilitates maintenance as organizations and terms change**
- **Use of a central access point eliminates the need for coordination and provides assurance that only the current copy of a document is available for use**
 - **Manuals for hard copy distribution vs. electronic access**

Access/Systems

- **Use of an Electronic Document Management System facilitates the review/approval/access process**
- **Can ensure Part 11 compliance**
- **May require use of “middle ware” for general access**
- **Ease of maintenance is as critical as ease of implementation**

Governance

- **Related policies and procedures operationalize the framework and requirements**
- **Governance within each business unit ensures compliance to requirements**
- **Provides an overview to allow for collaboration on common themes and avoid redundancy.**

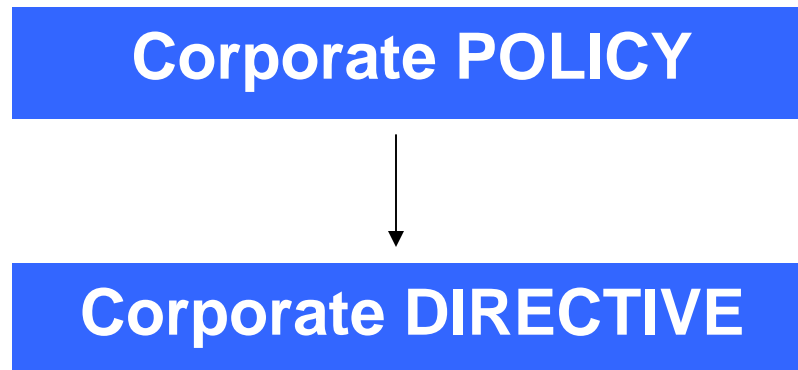
The BMS Experience

Achieving Consensus

- **Established a core team with expertise in procedural documents to help formulate and agree on each major component**
- **The Policies and Procedures Governance Council operates as a community of practice and center of excellence for procedural document practices**

The Important Initial Step

- **A Corporate Policy establishes two types of corporate procedural documents.**



The Process

- **Corporate Policies set forth the highest principles to be applied across the company**
- **Corporate Directives provide the specific requirements to be implemented in accordance with a Corporate Policy and may also contain examples or interpretations to facilitate implementation**
- **Governance is provided in a related SOP (Standard Operating Procedure)**

The Process (Cont'd)

- Gatekeeping is achieved through a **proposal process**
- A cross-functional Council **reviews and approves the proposal**
- A Writing Team with appropriate knowledge and experience **creates** the document(s)
- Appropriate Management Council members (Policy) and Department Management (Directives) ultimately **review and approve the final document(s)**

The Process (Cont'd)

- The department that initiated the proposal creates a training and communication plan
- The Corporate Policy and/or Directive is posted to a central web site
- Documents are then reviewed periodically to ensure they reflect current principles and practices

The Details

- **The information is provided in detail in various corporate procedural documents that are communicated and posted on BMS's Policies and Procedures Portal, our central access point.**

Next Steps- **Business Unit/Staff Function Procedural Documents**

Next Steps

- **Continuing in our efforts to improve compliance, we expanded the principle of consistency throughout BMS to procedural documents in every Division and Subsidiary, at every site.**
- **The governing Corporate Policy and Directive impact how procedural documents are created and managed by Business Units and Staff Functions (BU/SF) throughout the company.**

Document Types

BU / SF POLICY

High level Principles

BU / SF DIRECTIVES

Requirements & Guidelines

BU / SF SOPs

Tasks and interactions

BU / SF WORK INSTRUCTIONS

Detailed step-by-step a single person/role performs

Document Formats

- **A Corporate Directive specifies the sections to be included in each document type, and the order in which they appear in the document**
- **There are no additional requirements that apply to department or BU/SF graphics or logos, or the font and typefaces used in the documents**
- **Legacy documents that require revision must be reformatted into the approved document types and formats that meet the requirements in the governing Corporate Directive only at the time of revision**

Relationship between Corporate and BU/SF Documents

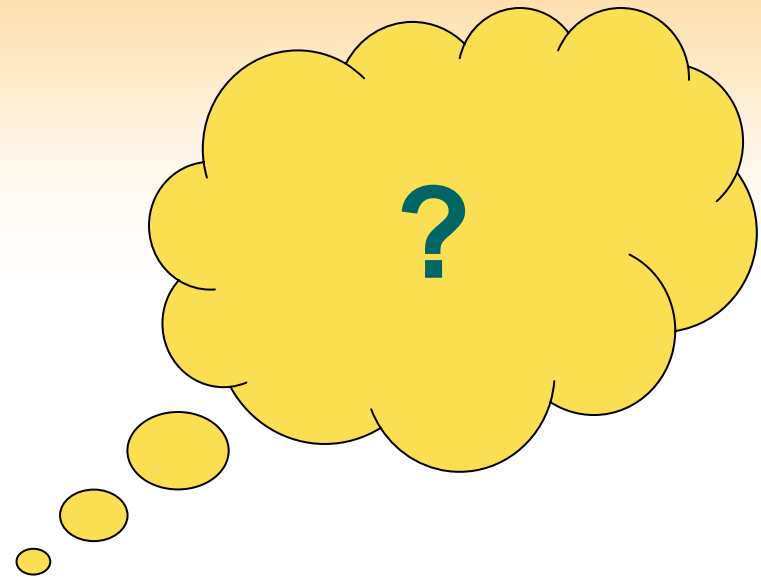
- **Corporate documents address issues where consistency is desired across all of BMS.**
 - **Routinely a BU/SF Policy is not required when a Corporate one exists.**
 - **A BU/SF Directive may be issued, even when a Corporate Directive exists, if the BU/SF has additional requirements. It may expand upon, but not contradict, the Corporate level document.**
- **BU/SF procedural documents may reference either a Corporate level document or one at the local BU/SF level.**

Document Management

- Each BU/SF must determine which of the following will apply:
 - A **single** document management process for the entire BU/SF.
 - **Separate/Independent** document management processes within sub-units.

Document Management (Cont'd)

- **Each BU/SF must provide resources and create written procedures to implement and maintain an appropriate document management process.**
- **Written procedures must be created, implemented and maintained to guide authors through all activities of the document lifecycle.**
- **The procedures must include directions and responsibilities for creation, review, approval, issuance, management, revision, archive and retirement of a procedural document**



Questions