Implementing Change Management in a Regulated Environment

Valerie Arraj
Managing Director
Compliance Process Partners

- Service Management-focused consulting, automation and training organization
- Uses IT Service Management good practice and control objectives with focus on:
  - Compliance to regulatory and governance guidelines
  - Efficient and effective IT process and automation
  - Assisting companies for 8 years with ITIL-based consulting and training
- ITIL Expert, ISO 20000 & ISO 27000 Certified Consultants
Content

- Change Management Landscape for Regulated Environments
- Approach and Process Overview
- Benefits and Critical Success Factors
Regulated Environments

- Regulations Affecting IT
  - Privacy Laws for Personally Identifiable Information (PII) e.g., 201 CMR 17.00 (Massachusetts)
  - Sarbanes Oxley – Public Companies
  - HIPAA – Health Care
  - 21 CFR Part 11 – Biotechnology & Pharmaceutical
  - PCI – Retail
  - Gramm-Leach-Bliley Act – Financial Services
  - Federal Information Security Management Act – Gov’t Agencies

Manage Risk & Security
Change Management is Key
Why Service Management & ITIL?

✓ **Good Practice is Foundational**
  ✓ Aligns business with technology
  ✓ Promotes effective use of technology
  ✓ Improves the quality and reliability of IT services offered
  ✓ Optimizes IT resource utilization
  ✓ Provides well-defined processes that support business scalability
  ✓ Internationally adopted framework that enables consistency within enterprise IT organizations as well as with external service providers

✓ **Facilitates adherence to regulatory requirements**
Regulated Environments: Change Landscape

**BEFORE**

<table>
<thead>
<tr>
<th>Applications &amp; Infrastructure</th>
<th>Regulated</th>
<th>Non-Regulated</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Many regulation-specific change management processes</td>
<td>• Informal change management process.</td>
</tr>
<tr>
<td></td>
<td>• Each technology area runs its own change management process</td>
<td>• No change management process.</td>
</tr>
</tbody>
</table>

**AFTER**

- ✓ One Risk-Based Process for IT
  - ✓ Reduce compliance deviations
  - ✓ Balancing “Slowing things down” versus deploying changes that don’t destabilize service operation
- ✓ Eliminate the distinction between “Regulated” and “Non-Regulated” services
Approach

WHERE ARE WE NOW? WHERE DO WE WANT TO BE?

Phase I

Executive/Team Overview
ITSM Capability Assessment

Phase II

ITIL Foundation Training
RCV Capability Training

Phase III

Enterprise-Specific Process Training Across IT

GETTING THERE

PEOPLE

PROCESS

TECHNOLOGY

WHERE ARE WE NOW?
WHERE DO WE WANT TO BE?

Phase I

Executive/Team Overview
ITSM Capability Assessment

Phase II

ITIL Foundation Training
RCV Capability Training

Phase III

Enterprise-Specific Process Training Across IT

• Change Management

• Configuration Management

Technology Implementation

• Additional Processes as Prioritized in Assessment

Incident/Problem/Service Level Mgt/Capacity …
Configuration and Change Management

- Processes go hand-in-hand
  - Every decision needs configuration information
  - Every decision results in a configuration change

- Implement:
  - a CMDB (CMS)
  - Strict change management

... to ensure accurate decisions
  (manual or automated)
- The automation journey must address both

Forrester Research, Glenn O'Donnell
Taking this One Step Further....

The CMDB can:

- Assist in change categorization
- Identify assessors and reviewers (CAB)
- Guide workflow steps
Approach for Change & Configuration Management

Agree on:
- Change Definition
- Scope
- Change Models
  - Standard
  - Predefined
  - Normal
  - Emergency
- Approvers
- Level of detail for Configuration Items
- Decide on Service Types (Business (Core) vs Technical (Enabling))
- Modeling techniques (accommodating virtualization & cloud)
- RACI matrix

- Targeted sessions with cross-functional stakeholder teams
- Steering committee for guidelines and arbitration
- Use case walkthroughs and prototyping
An Example: Business and Technology Services

Application Service

Kronos

Payroll

Core Business Service

Supporting Business Service
Primary Service CI (parent)
Can stand on its own as a core service

Server Administration [Infrastructure Service]

Database Administration [Infrastructure Service]

Storage Administration [Infrastructure Service]

VMServer1

VMServer2

DB1

VMServer3

VMServer4

Storage Array X

Supporting Business Service
Primary Service CI
Can stand on its own as a core service

VMServer1

VMServer2

DB1

VMServer3

VMServer4

Storage Array X

Supporting Business Service
Primary Service CI
Can stand on its own as a core service

VMServer1

VMServer2

DB1

VMServer3

VMServer4

Storage Array X
### Risk-Based Change Types

#### Standard & Pre-defined

- Part of routine, recurring maintenance and/or support
- Implementation procedures are well understood and documented.
- Does not alter baseline business functionality of primary or related service(s)

#### Normal Changes

<table>
<thead>
<tr>
<th>Risk</th>
<th>Minor</th>
<th>Significant</th>
<th>Major</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approver</td>
<td>Federated Change Manager</td>
<td>Change Advisory Board</td>
<td>CAB + Sr. Management</td>
</tr>
<tr>
<td>LOW</td>
<td>Impact to other services</td>
<td>Resources, time, cost to implement</td>
<td>Existing – Technology/Skill – New</td>
</tr>
<tr>
<td>HIGH</td>
<td>Baseline business functionality impact</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Pre-approved or functional manager**
## Change Models

<table>
<thead>
<tr>
<th>Model</th>
<th>Category</th>
<th>Description/Characteristics</th>
<th>Approval</th>
</tr>
</thead>
</table>
| Standard      |          | • Work which is part of routine, recurring maintenance and/or support; changes under applicable procedures.  
                           ‒ Well understood; does not alter baseline business requirements/functionality of primary or related service(s)  
                           ‒ Risk is well understood  
                           ‒ May include repair (break/fix) activities or like-for-like swaps                                                                                           | • Pre-Approved                                                          |
| Predefined    |          | • Part of routine, common support changes under applicable procedures.  
                           ‒ Well understood; does not alter baseline business requirements/functionality of primary or related service(s)  
                           ‒ Follows a predefined set of steps in association with a procedure or work instruction                                                                 | • Requires approval from a specified individual(s) or role(s)           |
| Normal        | Minor    | • Changes of additions to configurable elements without significantly altering the business requirements  
                           ‒ Little or no impact to the validated state of the computerized system or software  
                           ‒ Require very few resources and minimal time to complete  
                           ‒ Risk of change to Service is generally assessed as low.                                                                                                              | • Change Manager  
                           This could be a Federated role in large organizations.                                                                                 |
|               | Significant | • Changes considerably alter a system’s requirements or creating a considerable amount of new functionality or capability  
                           ‒ A sizeable number or resources and amount of time are required to implement                                                                                                          | • Change Advisory Board (CAB)                                            |
|               | Major    | • Changes will alter system requirements and create substantial new functionality or capability  
                           ‒ Large number of resources and substantial amount of time required.  
                           ‒ Substantial estimated cost to the organization, often large, capitalized projects                                                                                                                   | • CAB and Senior Management                                               |
|               | Emergency | • Unplanned changes requiring immediate action.  
                           ‒ To restore a service or protect electronic records/data, product or IT hardware.  
                           ‒ Urgent business needs such as modification necessary to meet an immediate regulatory requirement.                                                                                                           | • Emergency CAB (ECAB)                                                   |
The Change Management Process

Open RFC

Is Emergency?

No

Business Impact Review

Yes

Technical Impact Review

Compliance Impact Review

Compliance Impact Reviewer (Compliance-Related Services)

Technical Impact Reviewer

Change Manager / System

RFC Categorize

Is Minor

Is Significant

Is Major

Change Manager or QA Lead Approval only

CAB RFC Review (CAB Approval)

CAB RFC Review (CAB + Senior Mgmt Approval)

Emergency CAB

Implement (Schedule, Release & Turnover)

Change Manager or QA Lead Approval only

CAB RFC Review (CAB Approval)

CAB RFC Review (CAB + Senior Mgmt Approval)

Emergency CAB

Release Management

Change Manager/CAB Release Manager

RFC Closed

PIR

Change Manager

Change Management – Normal Changes

Links To SDLC

14
Moving a CI Through the Workflow

- **On Order/Inventory:**
  - CIs that are purchased.

- **Reserved**
  - CIs that are available or earmarked for an application/org.

- **Being Assembled:**
  - CIs that are being set up & prepared for use in target environment (development, test, staging, production).

- **Deployed:**
  - Represents CIs placed in target environment and are in production (live).

- **Decommissioned:**
  - Represents CIs that are decommissioned from their original use.
    - **Redeploy:**
      - Represents CIs being reconfigured for a new purpose.
      - Move CI from Decommissioned to “Being Assembled” state.

- **Retired:**
  - Past its useful life. No longer in use.
Configuration Item Types & Attributes: The Drivers to Change

**Hardware Attributes**
- Hardware Description
- Hardware Type
- Server Use
- Server SubType
- Network Subtype
- Storage Subtype
- Power Device Subtype
- Service Tag
- Asset Tag
- Manufacturer/Model
- OS

- IP Address(es)
- Hostname(s)
- # Processors
- # Cores
- # of Network Ports
- Memory
- Location
- Rack
- Other
- Administrator Primary
- Administrator Alternate

**Software Attributes**
- Software Description
- Software Type
- Manufacturer
- Version
- Build
- Number Of Licenses
- Notes
- Software Admin Primary
- Software Admin Alternate

**Common Attributes**
- CI Id
- CI Name
- Created Date
- Description
- CI Status
- Item Type
- Environment

**Service Attributes**
- Service Description
- SLA Type
- Compliance Implications - None/GxP/SOX/HIPAA/Other
- Service Criticality
- Service Provider
- Service Consumer
- SLA Status
- Service Tech Primary
- Service Tech Alternate
- Service Business Owner
- Service Business Owner - Alternate
- Service IS Owner
- Service IS Owner - Alternate
- Service Business Admin Primary
- Service Business Admin Alternate
- Additional CAB Reviewers
- Additional Watchers

Contribute to Categorization Algorithm
Contribute To Assessment
Contribute To CAB
## Configuration Management Roles / Contacts

<table>
<thead>
<tr>
<th>Role</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Business Owners</strong></td>
<td>Primary business liaison responsible for the service</td>
</tr>
<tr>
<td><strong>Service Owner</strong></td>
<td>The IT Owner of the Service (Product Manager)</td>
</tr>
<tr>
<td><strong>Business Relationship Manager</strong></td>
<td>IT lead responsible for interfacing to the business.</td>
</tr>
<tr>
<td><strong>Technical Lead(s)</strong></td>
<td>Primary and alternate individuals with technical responsibility for the service or underlying configuration item</td>
</tr>
<tr>
<td><strong>Implementers</strong></td>
<td>Individuals assigned to the work associated with building and deploying changes</td>
</tr>
</tbody>
</table>
Assessing Risk

• The 3 dimensions of risk: Criticality, Complexity & Compliance
  – Criticality = Business impact
  – Complexity = Technical impact
  – Compliance = Compliance to Regulation & Internal Standards

• Applies to both New Services & Changes
• Service risk is pre-determined and populated into the CMDB
• Change risk is determined by Change Initiator and assessors
## Categorization Algorithm

### Normal Change Categorization

<table>
<thead>
<tr>
<th>Category</th>
<th>Field</th>
<th>Choose the Appropriate Value From Dropdown</th>
<th>C</th>
<th>Category</th>
<th>Total Score</th>
<th>Fields</th>
<th>High Score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Business Assessment Values</strong></td>
<td></td>
<td></td>
<td></td>
<td>Risk</td>
<td>40</td>
<td>Technical Type</td>
<td>13.3</td>
</tr>
<tr>
<td></td>
<td>Cost</td>
<td></td>
<td></td>
<td>Cost</td>
<td>0.8</td>
<td>Technical Complexity</td>
<td>6.7</td>
</tr>
<tr>
<td></td>
<td>Value</td>
<td></td>
<td></td>
<td>Value</td>
<td>10.0</td>
<td>Service Criticality</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td>Priority</td>
<td></td>
<td></td>
<td>Priority</td>
<td>10</td>
<td>Business Criticality</td>
<td>10</td>
</tr>
<tr>
<td><strong>Technical Assessment Values</strong></td>
<td></td>
<td></td>
<td></td>
<td>Technical Type</td>
<td>6.7</td>
<td>Business Cost</td>
<td>3.3</td>
</tr>
<tr>
<td></td>
<td>Technical Complexity</td>
<td></td>
<td></td>
<td>Technical Complexity</td>
<td>6.7</td>
<td>Technical Time</td>
<td>1.7</td>
</tr>
<tr>
<td></td>
<td>Cost</td>
<td></td>
<td></td>
<td>Cost</td>
<td>0.4</td>
<td>Compliance Cost</td>
<td>1.7</td>
</tr>
<tr>
<td></td>
<td>Cost</td>
<td></td>
<td></td>
<td>Cost</td>
<td>0.4</td>
<td>Compliance Time</td>
<td>1.7</td>
</tr>
<tr>
<td></td>
<td>Value</td>
<td></td>
<td></td>
<td>Value</td>
<td>10</td>
<td>Business Value</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Priority</td>
<td></td>
<td></td>
<td>Priority</td>
<td>10</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>SUM</td>
<td></td>
<td></td>
<td>SUM</td>
<td>100</td>
<td></td>
<td>100.0</td>
</tr>
</tbody>
</table>

### Compliance Assessment Values

<table>
<thead>
<tr>
<th>Category</th>
<th>Field</th>
<th>Choose the Appropriate Value From Dropdown</th>
<th>C</th>
<th>Category</th>
<th>Total Score</th>
<th>Fields</th>
<th>High Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Risk</td>
<td></td>
<td></td>
<td>Compliance Risk</td>
<td>13.3</td>
<td>Business Criticality</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Cost</td>
<td></td>
<td></td>
<td>Compliance Time</td>
<td>1.7</td>
<td></td>
<td>1.7</td>
</tr>
<tr>
<td></td>
<td>Cost</td>
<td></td>
<td></td>
<td>Compliance Cost</td>
<td>0.4</td>
<td></td>
<td>0.4</td>
</tr>
</tbody>
</table>

### Service Criticality

<table>
<thead>
<tr>
<th>Category</th>
<th>Field</th>
<th>Choose the Appropriate Value From Dropdown</th>
<th>C</th>
<th>Category</th>
<th>Total Score</th>
<th>Fields</th>
<th>High Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Risk</td>
<td></td>
<td></td>
<td>Service Criticality</td>
<td>30</td>
<td></td>
<td>30</td>
</tr>
</tbody>
</table>

### TOTAL SCORE

84

**Category MAJOR**

<table>
<thead>
<tr>
<th>Category Legend</th>
<th>Major: &gt; 66</th>
<th>Significant: 34-66</th>
<th>Minor: &lt; 34</th>
</tr>
</thead>
</table>

**Spreadsheet Instructions**

To use this spreadsheet choose a value from Column C, which is a drop down list box containing valid values for each field. By manipulating those values you will be able to see what type of a total score category a given change will have and can run varied scenarios through the model.

To change the scoring algorithm fields in BLUE in the column "Category" above may be modified in order to do "what if" analysis against the scoring method. All other numbers and values in this spreadsheet are calculated. Please note that if you change the values you should do so such that the SUM at the bottom should always equal 100.

The Column Labeled "Choose the Appropriate Value from the Dropdown" derives its data from Sheet2. Do not manipulate anything in Sheet 2 unless you want modify the text values of the of the dropdown.
Value Added

**Configuration Management Metrics:**
- **Services**
  - Business or Infrastructure
  - Impact of Change to underlying CI
  - Regulatory implications guidelines (GxP, HIPAA, SOX, etc)
  - Location
  - Subscribers
  - Consumers
- **Servers**
  - Physical or virtual
  - Application installed
  - Connections
- **Contracts**
  - For Service or any underlying CI
  - Expired or expiring contracts
  - Contracts by contract type (outsourcing, support or maintenance)
  - Software licenses
- **People/Contacts**
  - Primary and secondary support person for hardware or software
  - Business Owner of a given service
  - IT Owner of a given service

**Change Management Metrics:**
- Number of changes by device, service, application
- Date of changes by device, service, application, database
- Number of changes successful
- Number of changes needing to be backed out
- Change schedule
- Changes that have some regulatory/compliance impact (need QA involvement)
- Changes that have no regulatory/compliance impact (no QA involvement necessary)
- Number of changes by category
- Changes by requestor
- Changes that have been approved
- Changes that have been rejected
- Average time to approve a change
- Average time to approve a change by approver
- Average time to close a change by type of change
Realized Benefits

- Consistent change process across the board
- More efficient and compliant process
  - Integration with CMDB provides enhanced visibility of impact and risk of changes to focus work
  - Integrating compliance review into process from beginning reduces rework and ensures that regulated services are maintained in a validated state
Critical Success Factors - CMDB

- Don’t underestimate level of effort to maintain the repository
  - Integration with HR systems is vital in order to keep contact information up to date with organizational changes
  - Auto discovery tools are necessary for faster adoption and to maintain data accuracy

- Visualization is key!
  - Self-service auditing of CIs is difficult to do without visual cues for dependencies
Critical Success Factors

- Include business customers during process definition and rollout
  - Individuals need to buy-in and understand the responsibilities associated with their role in the process

- Integrate with Portfolio Management Office (PMO)
  - Coordination between Change Manager and PMO is needed to ensure proper scheduling & resources, RFCs need to be balanced with project portfolio support
Thank you

Contact details:
Valerie Arraj
valerie.arraj@cppit.com
888-718-1708