**Process Change Control Form**

This form is used to request the addition of an operational process, or the revision of an existing one.

Attach documentation to support the requested change whenever possible.

**Change Requested: Tracking #:**

|  |  |
| --- | --- |
| **□ NEW****□ REVISION** | Brief description of proposed change. Attach applicable documentation. |
| **Submitted By** | Name and Tech ID |  | Date |

**Reason for Change Request:**

**□** Change to Computer Functionality **□** Change to Workflow **□** Regulatory Requirement

**□** New Equipment **□** New Use of equipment **□** Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* Complete all assessment checklists below and attach all documentation.

**Customers Impact Assessment**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Question** | **Yes** | **No** | **N/A** | **Comments** |
| * Are any internal or external customers impacted?
 |  |  |  | If Yes, List customers, include staff, patients, public, other depts. |
| * Is a particular shift involved?
 |  |  |  |  |
| * Should customers be involved in the change planning?
 |  |  |  | If yes list phases at which customer participation is desired. |
| * Which staff needs to be involved?
 |  | 🞏 CT 🞏 CLT2 🞏Leads |
| * Is customer notification necessary?
 |  |  |  |  |
| * Is a multi-disciplinary work group necessary?
 |  |  |  | If yes, list departments that should be involved. |
| * Other?
 |  |  |  |  |

**Facilities Impact Assessment**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| * Has the location been determined?
 |  |  |  |  |
| * Does the location layout allow for proper workflow?
 |  |  |  |  |
| * Is there adequate space?
 |  |  |  |  |
| * Are there any workplace safety issues?
 |  |  |  |  |
| * Will the change disrupt workflow?
 |  |  |  |  |
| * Is there sufficient services for the following:
 |  |  |  | If Yes, list necessary upgrades. |
| * Electricity
 |  |  |  |  |
| * Telephone
 |  |  |  |  |
| * Data lines
 |  |  |  |  |
| * Water, domestic or Distilled
 |  |  |  |  |
| * HVAC
 |  |  |  |  |
| * Lighting
 |  |  |  |  |
| * Is additional furniture required?
 |  |  |  |  |
| * Are there biohazard disposal issues?
 |  |  |  |  |
| * Are changes significant enough to require plans, permits, and code review?
 |  |  |  |  |

**Financial/Business Imperatives Impact Assessment**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Question** | **Yes** | **No** | **N/A** | **Comments** |
| * Are additional resources necessary?
 |  |  |  | List types of resources, and how many FTEs if more staff. |
| * Is a contract necessary?
 |  |  |  | Include analysis for potential contractual obligations |
| * Is there an existing contract?
 |  |  |  |  |
| * Is a service contract required?
 |  |  |  |  |
| * Will the change produce revenue?
 |  |  |  | Quantify if possible. |

**Document and Training Impact Assessment**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| * Will documents need to be developed or revised?
 |  |  |  | List any existing documents that will require change, and complete Document Change Control Form. |
| * Who is the audience for the document or training?
 |  | List audience |
| * Is a Training plan required?
 |  |  |  |  |
| * Will the change affect any other processes or workflow currently in place?
 |  | Attach List of processes affected.  |
| * Estimate time required for training plan development and implementation
 |  | Give time estimate. |
| * Other
 |  | Describe and attach documentation. |

**Supplies and Equipment Impact Assessment**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| * Is new equipment required?
 |  |  |  | List any new equipment |
| * Are new supplies required?
 |  |  |  | List any new supplies and quantities |
| * Is a validation necessary?, if so how long will it take?
 |  |  |  | Estimate time required. |
| * Are there any special requirements or systems for new equipment or supplies
 |  |  |  | Itemize |
| * Is Capital available for equipment?
 |  |  |  |  |
| * Is vendor qualification necessary?
 |  |  |  |  |
| * Will current supply inventory be impacted?
 |  |  |  | If yes, explain  |

**Regulatory Impact Assessment**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| * AABB compliant?
 |  |  |  | Attach analysis of current standards |
| * CAP compliant
 |  |  |  | Attach analysis of current checklist |
| * FDA compliant
 |  |  |  | Attach any relevant information |
| **Work/Safety Impact Assessment** |
| * Any chemicals involved?
 |  |  |  | If yes, list with Hazard designation |
| * Any biohazards involved?
 |  |  |  | If yes, describe |
| * Any biohazard disposal issues?
 |  |  |  | If yes, describe |
| * Is PPE required?
 |  |  |  | If yes, list |
| * Is an ergonomic assessment required?
 |  |  |  | If yes, describe |