**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 |