

<b>Subject:</b>  <b>Design and Improvement of Processes</b>	<b>Effective Date:</b>  Nov. 14, 2014	<b>Initiated by:</b>  Judy Malsbury Head, Quality Assurance Division
	<b>Supersedes:</b> QA-023 Rev. 1 Dated: 10/17/11	<b>Approved:</b>  Stewart Prager Director

**Management System (Primary):** 12.00 Assurance and Improvement  
**Management System Owner:** Head, Best Practices and Outreach  
**Management Process:** 12.29 Continuous Improvement  
**Management Process Owner:** Head, Best Practices and Outreach  
**Subject Matter Expert (SME):** Head, Quality Assurance; Head Best Practices

**Applicability**

This procedure is applicable to all processes at PPPL.

**Introduction**

This procedure provides tools for the design of new processes or redesign/improvement of existing processes. It can also serve as guidance for the design and improvement of other processes.

Electronic tools that can be helpful in this process are provided at <http://www-local.pppl.gov/qa/Forms/QA-023%20R1%20Tools.pdf>.

Best Practices and Quality Assurance are available to support process improvement.

**Reference Procedures**

- PPPL Assurance System Description
- PPPL Institutional Quality Assurance Plan
- GEN-001, Policy, Procedure, and Mission Statement Development, Review, and Approval
- ENG-033, Design Verification
- QA-025, Management Assessments

**Definitions**

**Process** Any set of activities that has a defined purpose, an initiating event, established inputs, identifiable stakeholders, and expected outputs. The process may be contained within a single organizational unit or span several organizational units.

**Process Metric** Any measure that monitors the effectiveness and efficiency of a process as a whole. Possible areas for measurement include, but are not limited to, cycle time, productivity, quality and consistency of the output, or stakeholders satisfaction.

A subset of process metrics, known as in-process metrics, monitor how well executions of a process for which all the steps have not been completed are working. These metrics provide an indication of a potential problem allowing the opportunity to correct problems as soon as possible. Examples are the percentage of interim milestones met (if low, this is an early indicator that the work may not be completed on time), the number of problems identified requiring rework, cost variances (could indicate that the work may not be completed within cost), or tests of performance after partial installation.

- Process Owner Individual assigned responsibility for developing and overseeing a process.
- Stakeholder Individuals or organizations that have a vested interest in a process, either as a potential user of a process, provider of input to the process, recipient of output from the process, or impacted in some way by the process. These may also include individuals who work within the process, organizations within PPPL who benefit from the process, DOE, Princeton University, State or local government officials, etc.

**Procedure**

This procedure is divided into two parts. The first, Part A, is the design of new process or significant redesign of an existing process. This may be viewed as a “clean slate approach,” in that the designer is beginning a complete and new design. The second, Part B, concerns the improvement of an existing process, where it is anticipated that selected aspects of the process will be redesigned to address identified concerns, but that the process, as a whole, will basically remain the same. For each part, associated flow diagrams are contained in the attachments. The procedure focuses on design and improvement efforts significant in scope to involve the approval of PPPL Management. However, these efforts can also be self-initiated by responsible individuals with the review of direct management.

**A. Design of New or Redesign of Existing Processes [*Clean Slate Approach*] (An associated flow diagram is contained in Attachment 1)**

The process for the design of new or redesign of existing processes consists of the following steps:

1. Establish the project to create a new or redesign an existing process.
2. Define the requirements for the process.
3. Design the process to satisfy these requirements.
4. Implement and monitor the process

**A.1 Establish the project to create a new or redesign an existing process**

**Responsibility                      Action**

- Department Head/ Division Head/ Process Owner 1. Identifies new processes or processes requiring a significant redesign.
- Department Head 2. Establishes an owner for each process (if not already established)

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| Process owner                          | <ol style="list-style-type: none"> <li>3. Assumes responsibility for the following:               <ol style="list-style-type: none"> <li>a) Developing and documenting the process,</li> <li>b) Ensuring that there is effective interaction between interfacing processes,</li> <li>c) Ensuring that process procedures are developed, maintained, and consistent with any existing procedures,</li> <li>d) Ensuring that records required to demonstrate process results are appropriately archived and stored,</li> <li>e) Monitoring and reporting on the performance of the process,</li> <li>f) Promoting improvement in the process,</li> <li>g) Ensuring that the process, including any subsequent changes to it, is aligned with the goals, strategies, plans, and objectives of the Laboratory and the organization.</li> </ol> </li> <li>4. Determines if a team of individuals representing the perceived stakeholders should be created for the design phase of the project. A team may be created if the process is complex, the process has many steps that are performed by a variety of individuals or organizations, the success of the process has significant impacts on ES&amp;H, quality, project success, etc. If not, proceeds to step A.2.</li> <li>5. Develops a charter for the team, identifying the work scope for the team, recommended team members, and time frame. When the work scope is large or complex, it is recommended that someone with process design experience and training be assigned to the team. Training is available via Quality Assurance.</li> </ol> |
| Department Head(s) affected by process | <ol style="list-style-type: none"> <li>6. Approves the charter. If individuals are recommended for the team who are not under the span of control for this manager, seeks approval of the appropriate managers for their participation.</li> </ol>  |

**A.2 Clarify the requirements for the process.**

<u>Responsibility</u>	<u>Action</u>
Process Owner/Team	<ol style="list-style-type: none"> <li>1. Provides a few sentences identifying the purpose of the process. Doing this helps assure that the process has a clear purpose and well defined boundaries.</li> <li>2. Identifies the stakeholders for the process.</li> <li>3. Identifies the requirements for the process including those identified by the stakeholders, the DOE, regulations, ES&amp;H, environmental, quality, economic, and contractual.</li> <li>4. Identifies the organizations or processes providing inputs to the process and the source and timing of these inputs (the suppliers).</li> <li>5. Identifies the outputs of the process for the stakeholders.</li> <li>6. Identifies the functions to be performed that transform the inputs into the outputs.</li> </ol>

**A.3 Design the Process**

**Responsibility**

**Action**

Process  
Owner/Team

1. Generates a flow diagram for the process, using the information from section A.2. This will become an iterative tool as the process is refined during development.
2. Design flow so that as many steps as practicable are parallel instead of in series.
3. Identifies all interfaces for the process being designed. Interfaces typically involve other processes, hardware, software, or human interactions
4. Identifies all error conditions for the process at a high level. When able, design the cause(s) of the error condition(s) out of the process to achieve an optimal process. If unable to eliminate, define the appropriate actions to be taken when the error conditions are encountered.
5. Identifies any tools or modifications to existing tools required to support the process. An example includes changes to the Work Planning System.
6. Identifies the process metrics that will be used to monitor the performance of the process. Such metrics should be SMART – Specific, Measurable, Actionable, Relevant, and Timely. When appropriate, in-process metrics should be identified. Considerations for these metrics include:
  - a. Performance metrics, such as meeting stakeholders requirements or satisfaction, product and service quality, or supplier performance against the requirements of the process,
  - b. Diagnostic metrics that demonstrate how well a process is working and, if needed, why a process is not performing up to expectations, such as process cycle times, cost performance, or financial measures,
  - c. Metrics that can potentially be used to trend data associated with the process,
  - d. Performance of suppliers against the requirements of the process,
  - e. Alignment and consistency with metrics for higher level processes or systems of which this process is a part,
  - f. When possible, metrics for which comparison or benchmark data is available.
7. Identifies records associated with the execution of the procedure and the storage requirements for these records.
8. Develops a deployment approach for the process, documenting it in a deployment plan, as appropriate. The plan should include development or revision of procedures or plans, training, phasing in of the new or revised design, etc.

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| Process<br>Owner/Team | <ol style="list-style-type: none"> <li>9. Conducts a peer review for the process design using ENG-033 as guidance. The peer review shall include those organizations providing inputs to the process, the stakeholders of the process, QA, and ES&amp;H if the process may impact PPPL’s ES&amp;H program or performance. Specific objectives for this type of review may include assuring that:               <ol style="list-style-type: none"> <li>a. The purpose of the process is well defined, with well defined boundaries,</li> <li>b. The appropriate stakeholders have been defined,</li> <li>c. The proper requirements are identified. Requirements should include functional, ES&amp;H, regulatory, quality, reliability, interfaces, and human performance<sup>1</sup>,</li> <li>d. The appropriate inputs and outputs have been defined,</li> <li>e. All interfaces to other processes have been defined and are appropriate,</li> <li>f. Process metrics have been defined that are appropriate and provide the owner the necessary data to monitor the performance of the process.</li> <li>g. Error conditions are identified and appropriate actions for these conditions defined</li> <li>h. And the deployment plan is appropriate.</li> </ol> </li> <li>10. Resolves comments from peer review and updates process, as appropriate.</li> </ol> |
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**A.4 Implement and monitor the process**

**Responsibility    Action**

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| Process<br>Owner/Team                                  | 1. Implements the deployment plan, including developing or updating the associated procedure(s) and training.  |
| Department<br>Head/ Division<br>Head/ Process<br>Owner | 2. Assesses, on a regular basis, the performance of the process using the identified metrics and other data per QA-025 and makes improvements, as necessary. |

**B.    Improvement of Existing Processes *[Improve and enhance approach]*** (An associated flow diagram is contained in Attachment 2)

The process for the improvement of existing processes that is not a redesign consists of five steps:

1. Define - Choosing the process to improve; clarifying the purpose and parameters of the Process
2. Measure - Mapping the selected process; measuring key performance metrics
3. Analyze - Selecting an improvement based on the data
4. Improve - Implementing and evaluating the selected improvement
5. Control - Establishing and implementing controls and monitoring to sustain the improvement, and, when appropriate performance is achieved, closing the Project

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<sup>1</sup> Human performance covers any requirements for the design that relate to the human involved in using the process. irreversible actions, confusing displays, inaccurate risk perception. A list of potential error precursors related to human performance may be found in QA-019, Root Cause Analysis.

**B.1. Define**

**Responsibility**

**Action**

Cognizant  
Manager or  
Process Owner

1. Recognizes that improvement efforts would be beneficial for a process or related set of processes. Processes may be selected based on their criticality to the stakeholder or Laboratory strategic plans, goals or objectives, level of stakeholder satisfaction, the amount of effort required to implement them, known problems or weaknesses, deviation from desired level of performance, input from individuals involved in or effected by a process, or other criteria. Processes may also be selected based on the results of management assessments, Quality Assurance audits, root cause analysis, or failure mode and effects analysis.
2. Develop a project charter. Describes the process improvement project. The following items should be included, recognizing that the information provided at this early stage might be amended as the project proceeds:
  - a. Concise descriptive name for the process improvement project,
  - b. Brief narrative of project description, context, and background,
  - c. Statement describing the problem to be addressed and resolved,
  - d. Project scope identifying what will and will not be included in the project,
  - e. Project objectives describing the desired outcome, what will be delivered to the stakeholders, and when it will be delivered, and
  - f. Delineation of the specific stakeholders for the project.
3. Determines the team members and identifies the key individual responsible for coordinating the team effort. A stakeholder representative for the process should be included on the team. One member of the team should be trained in the methods of process improvement. Training may be obtained via outside courses or from Quality Assurance. Sources for assistance in implementing process improvement include Quality Assurance and Best Practices.

Note: For simple improvement projects, an individual analyst may be assigned, rather than a team. However this analyst should still follow the basic steps of this procedure.

Team or Analyst

4. Identifies the following:
  - a. Purpose of the process
  - b. Whether the process is really needed, e.g., has a clearly defined purpose or requirements to satisfy, or can be eliminated
  - c. How the process is initiated i.e., what are the events that require the process to be executed
  - d. How the process is terminated, i.e., what events complete the process
  - e. The stakeholders of the process and their expected outputs. This step includes a review of the list of stakeholders identified in B.1.2 above for completeness
  - f. The inputs for the process and their sources (suppliers)

**B.2. Measuring the Selected Process****Responsibility****Action**

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| Team or Analyst | <ol style="list-style-type: none"> <li>1. Identifies the following:           <ol style="list-style-type: none"> <li>a. Process boundaries, when the process begins and end</li> <li>b. Major activities of the process</li> <li>c. Inputs to the process</li> <li>d. Outputs of the process</li> <li>e. Sub-processes and flow paths</li> <li>f. Interactions with other processes, including redundancies or overlaps</li> <li>g. Responsibilities within the process</li> </ol> </li> <li>2. Determines the measures (or metrics), some of which may already exist, that will best gauge process performance. Measures of a process can be categorized as input measures, process measures, and output measures. Step 6 of A.3 has additional guidance for metrics.</li> <li>3. Establishes a data collection plan (sampling and frequency). Note that the validity of any good process improvement program will revolve around the measurements, which, if not well thought out, could result in a process improvement effort of limited value.</li> <li>4. Establishes the process baseline from which improvement progress and results will be judged. The process baseline might be the values of the measures identified in B.2.2 before any improvements are made.</li> </ol> |
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**B.3. Analyzing for Improvement****Responsibility****Action**

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| Team or Analyst | <ol style="list-style-type: none"> <li>1. Analyzes the process to identify areas to improve, i.e. bottlenecks, high error rate, repair or rework rates, long cycle times, unnecessary subprocesses or steps within processes, etc. Solicits input from stakeholders.</li> <li>2. Ranks improvement ideas based on cost and expected benefit. Consider consulting stakeholders and including them in the evaluation:           <ol style="list-style-type: none"> <li>a. Benefit potential</li> <li>b. Cost of implementation</li> <li>c. Available resources</li> <li>d. Risks</li> </ol> <p>A brief statement or table providing justification for the rankings should be provided.</p> </li> <li>3. Selects the improvement ideas that will be pursued based on this ranking. When appropriate, determines the actual root cause for the each associated problem.</li> <li>4. Develops an improvement action plan.</li> <li>5. Seeks management approval for the selected improvement and plan.</li> </ol> |
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**B.4. Implementing the Selected Improvement**

<u>Responsibility</u>	<u>Action</u>
Process Owner or Assigned Individual	1. Pilots/tests the improvements.
Process Owner and Team or Analyst	2. Evaluates the effect of the improvements by comparing current process measurements to the process baseline established in step B.2.4 above.
	3. Shares results with process stakeholders and obtain their feedback.
Process Owner or Assigned Individual	4. Formalizes the improvements, if the results are satisfactory, including change management needs such as updating procedures, providing training, or notifying process participants and stakeholders
Team or Analyst	5. Repeats step B.3 above if the results are not satisfactory.

**B.5. Control and Monitor to Sustain the Improvement**

<u>Responsibility</u>	<u>Action</u>
Team or Analyst	1. Develop controls to maintain improvement(s) <ul style="list-style-type: none"> <li>a. Define what needs to be monitored to assure improvement</li> <li>b. Define who is responsible for monitoring controls and frequency</li> <li>c. Define action(s) to be taken if improvement slips</li> </ul>
Process Owner or Assigned Individual	2. Monitors process through ongoing data collection and periodic review.
	3. Confirms results and documents benefits obtained.
Team or Analyst	4. Records and communicates lessons learned. Others may benefit from your effort.
Cognizant Manager or Process Owner	5. Recognizes people and celebrates the success. Improving a process is challenging and usually requires a great deal of effort. Celebrate this!

**Training Requirements**

**Target Audience:** Staff planning on designing or improving a process.

**Instructor:** Head, Quality Assurance (predominately) or Head, Best Practices

**Training Method:**

Read QA-023 prior to performing a process improvement effort

Briefing if requested by user

**Frequency:**

Prior to performing a process improvement effort



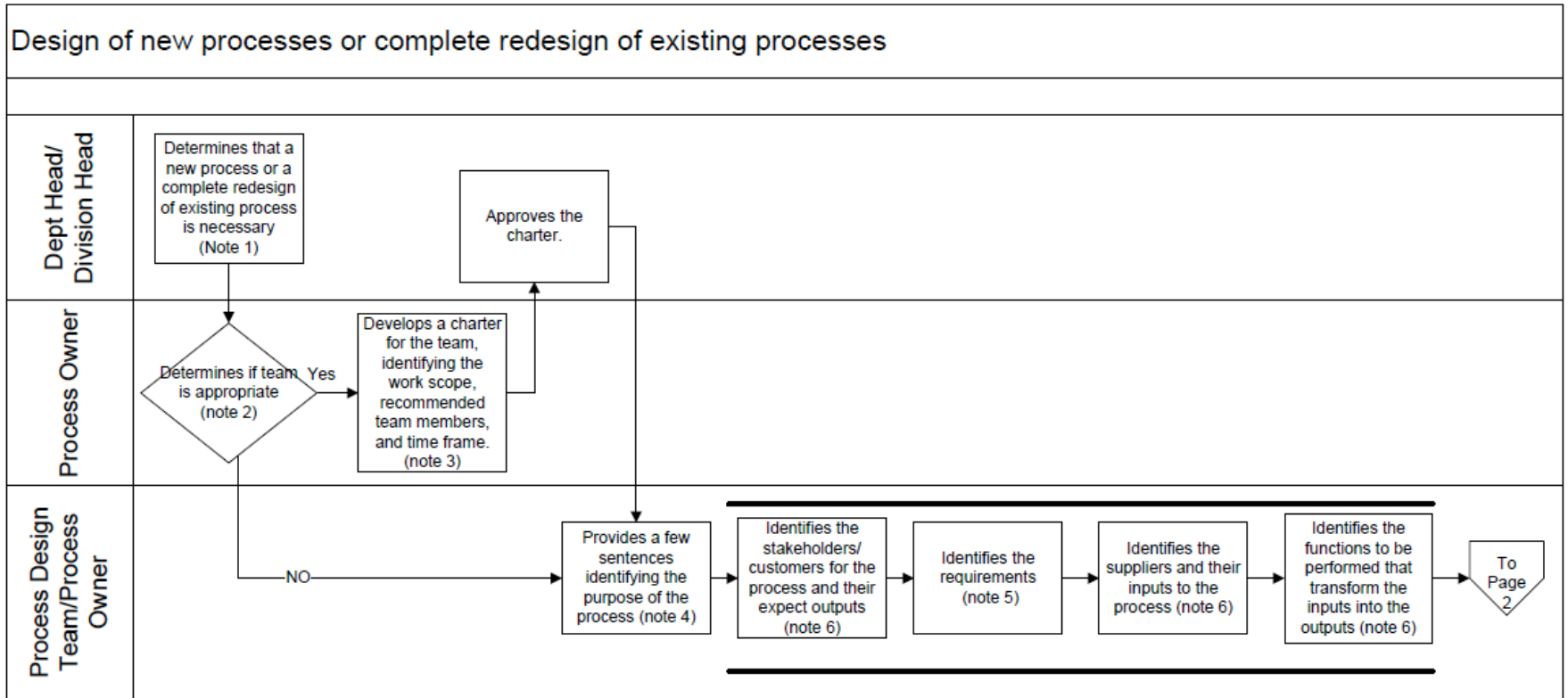
**Records Requirements Specific To This Procedure**

Records Custodians must assure records are maintained as follows:

Record Title	Record Custodian	Location	Retention Time
Project Charter	Process Owner	Department Records Storage	Cut off at the end of FY. Destroy 5 yrs after cutoff  <i>Reference: DOE Admin 16 Administrative Management Records (1.2)</i>
Records associated with the design of new processes redesign of an existing process, including purpose, flow diagram, metrics, process generated record, and deployment plan	Process Owner	Department Records Storage	Cut off at the end of FY. Destroy 5 yrs after cutoff  <i>Reference: DOE Admin 16 Administrative Management Records (1.2)</i>
Records associated with the improvement of existing processes including project charter, data collection plan, improvement action plan, monitoring plan. The latter is a dynamic, living document.	Process Owner	Department Records Storage	Cut off at the end of FY. Destroy 5 yrs after cutoff  <i>Reference: DOE Admin 16 Administrative Management Records (1.2)</i>

**Attachments**

1. Associated flow diagram for design of new or redesign of existing processes
2. Associated flow diagram for the improvement of existing processes



**Notes**

1 – Part of the determination is whether a new or completely redesigned process would be value-added for PPPL. The need could be determined based on management’s insight into the process (identified problems, process metrics, assessments, employees identification of concerns), external events (accidents, failures, events occurring outside of PPPL that might have relevance for PPPL, etc.), or the need to perform a periodic review of the procedure. If process improvements are required, but not a complete redesign, see QA-023.

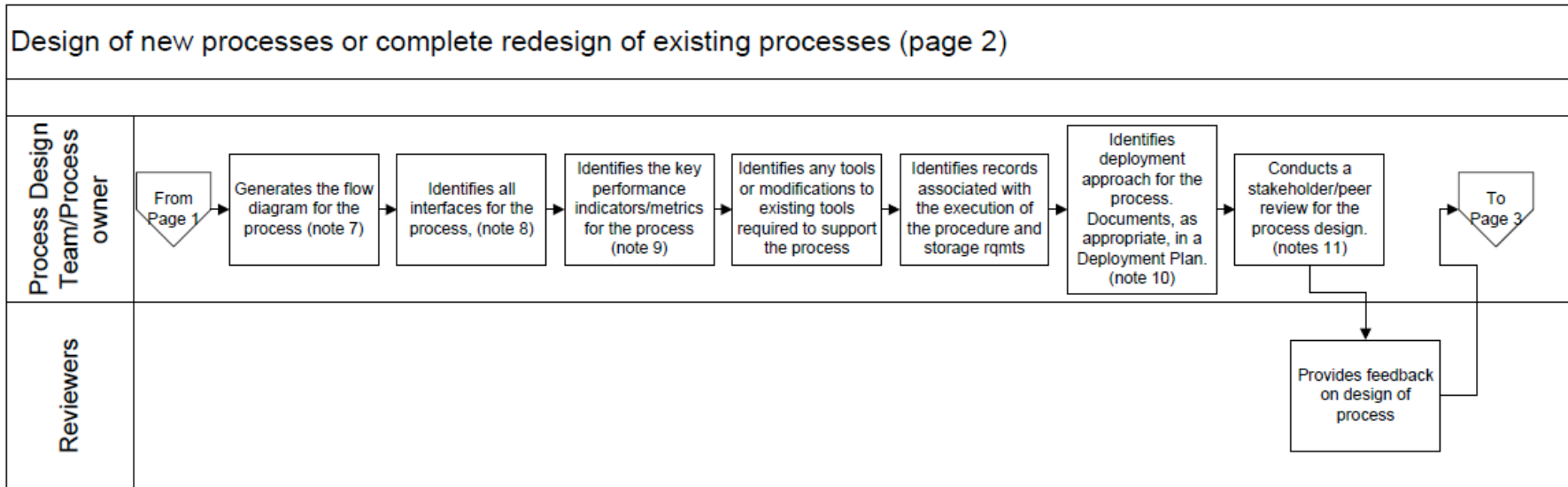
2 - A team might be considered if the process is complex, has many steps performed by a variety of individuals, whose success has significant impacts on ES&H, quality, project success, etc. If a team is not recommended, the steps of process design still are performed but by an individual. In any case, the charter or assignment must provide clear expectations for the work to be done. If the work is not being done by a team, then the normal supervisor/staff interaction may be adequate and a charter is not required.

3 – When the work scope is large or complex, it is recommended that someone with process design experience and training be assigned to the team. Consider consultation with QA or Best Practices.

4 – Doing this helps assure that the process has a clear purpose and well defined boundaries.

5 – Requirements may derive from customers, DOE, regulations, ES&H, environmental, quality, economics, etc.

6 – Suppliers, customers, and stakeholders may be other processes, hardware, people, software, etc. Parallel lines indicate that these steps are reiterative. The SIPOC (supplier, input, process, output, customer) tool is appropriate for this step. See the QA website for more information.



**Notes**

7 – The flow should focus on the success path. Errors conditions, unless of high importance, can be indicated in notes.

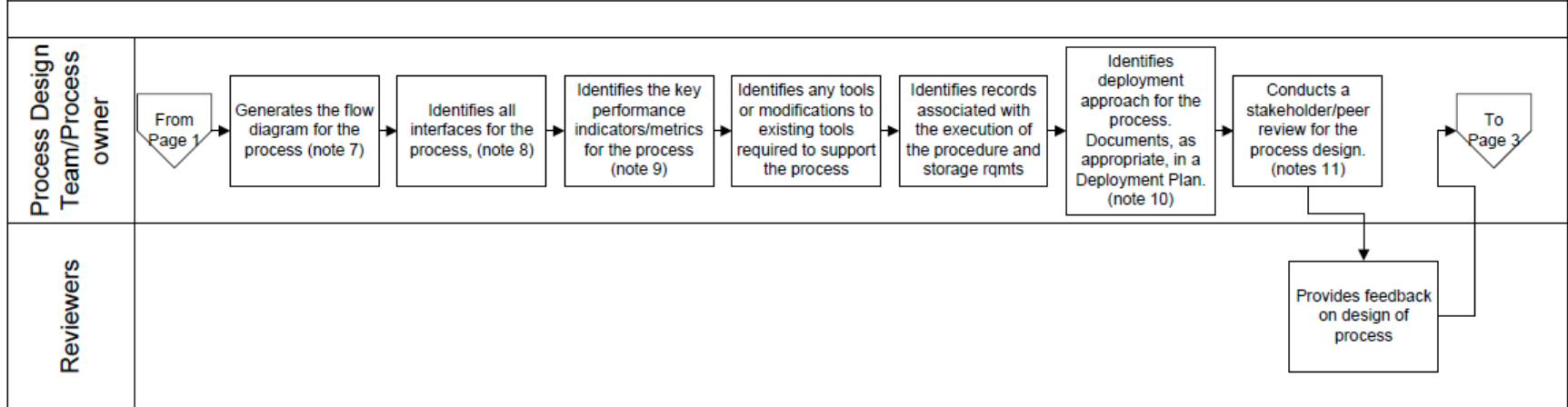
8 – Interfaces typically involve other processes, hardware, software, or human interactions.

9 – Metrics should be SMART – specific, measurable, actionable, relevant, and timely. The metrics should be consistent with and support the metrics and goals of the Laboratory or organization. Consider researching applicable metrics, perhaps via a web search. An appropriate source is APQC ([www.APQC.org](http://www.APQC.org)). Consider consultation with Best Practices or QA.

10 – Deployment includes who needs to be aware of and knowledgeable about the process and how to assure that they implement the process correctly. Techniques might include training, awareness, supervisory oversight, audits, and management/process owner assessments. The Deployment Plan should be documented, with an appropriate level of detail.

11 - The procedure itself and all the information associated with the peer review are considered records. If the procedure is a Labwide procedure, the records are stored in the Best Practices Office. Otherwise, the records are stored in the records system associated with organization that owns the procedure, e.g., QA for Q-005. See ENG-033 for the Lab process for peer reviews.

Design of new processes or complete redesign of existing processes (page 2)



**Notes**

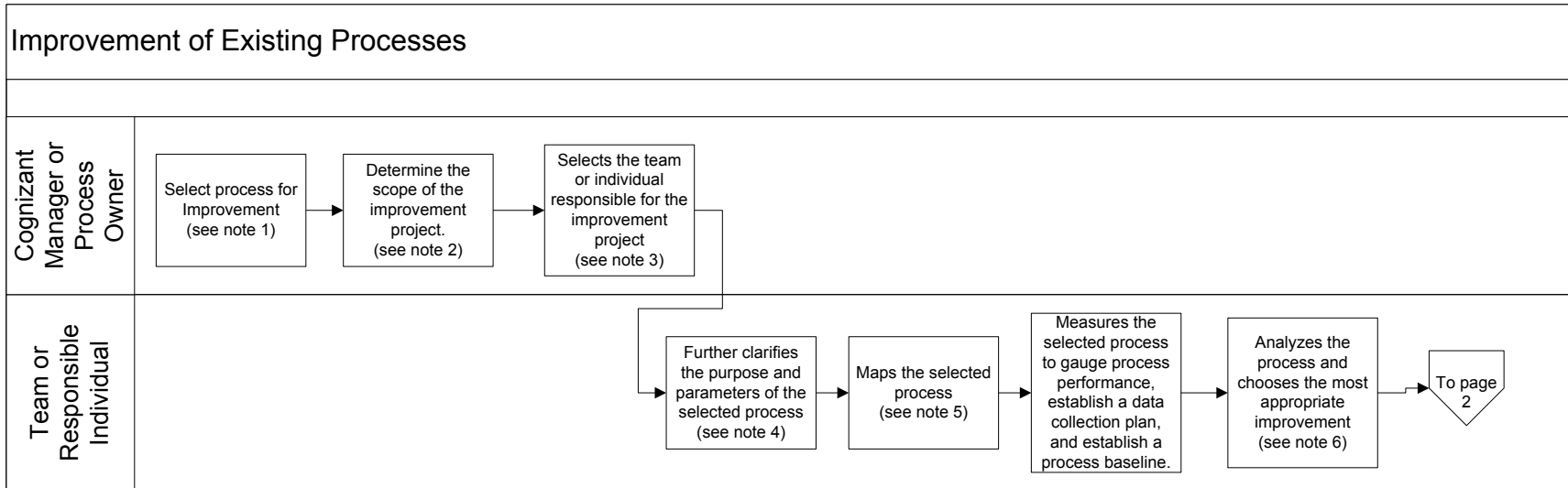
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Notes: 1 – Processes may be selected based on their criticality to the stakeholder or Laboratory strategic plans, goals or objectives, level of stakeholder satisfaction, the amount of effort required to implement them, known problems or weaknesses, deviation from desired level of performance, input from individuals involved in or effected by a process, or other criteria. Processes may also be selected based on the results of Quality Assurance Audits, Root Cause Analysis, or Failure Mode and Effects Analysis.

2 – The following items should be included, recognizing that the information provided at this early stage might be amended as the project proceeds: concise descriptive name for the project; brief narrative of project description, context, and background; statement describing the problem to be addressed and resolved; project scope identifying what will and will not be included in the project; project objectives describing the desired outcome, what will be delivered to the customer, and when it will be delivered; and delineation of the specific stakeholders for the project.

3 – A stakeholder representative for the process should be considered on the team. One member of the team should be trained in the methods of process improvement. Training may be obtained via outside courses or from Quality Assurance. Sources for assistance in implementing process improvement include Quality Assurance and Best Practices.

4 – Identifies the following: purpose of the process; whether the process is really needed, e.g., has a clearly defined purpose or requirements to satisfy, or can be eliminated; how the process is initiated, i.e., what are the initiating events; how the process is terminated, i.e., what events complete the process; the stakeholders of the process and their expected outputs; and the inputs for the process and their sources (suppliers).

5 - Identifies the following: process boundaries, when the process begins and ends; major activities of the process; inputs to the process; outputs of the process; sub-processes and flow paths; interactions with other processes, including redundancies or overlaps; and responsibilities within the process.

6 – Includes the following: analyzes the process to identify areas of improvement, e.g., bottlenecks, high error rate, repair or rework rates, long cycle times, unnecessary sub-processes or steps within processes, etc.; ranks improvement ideas based on cost, expected benefit, available resources, and risks. For both of these, it is helpful to consult the stakeholders.

