

Business Performance Associates (Company name & logo)	Document #: VAL005 Rev: 01 DRAFT Originator: Business Performance Associates	ECO #: p. 1 of 18	Effective Date:
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CHANGE CONTROL FOR VALIDATED SYSTEMS

1 PURPOSE

This document describes the procedure for making changes to validated systems.

2 SCOPE

This procedure applies to all components of a validated computer system. These items are identified either in the Validation Plan for the system or a separate controlled system description, such as a system specification.

A change control request is not needed for:

- Changes to hardware and/or software that host applications, or provide an infrastructure service, if those changes are made following a qualified operation and maintenance procedure, and configurations are not set which are outside of the acceptable range of configurations.
- Actions performed for the administration of an application that are described in an approved procedure as long as the performance of these actions has been included in the validation of the system.

3 REFERENCE DOCUMENTS

[Note to the purchaser of this document: The policy documents, procedures, and templates referenced here are available at www.BPAconsultants.com]

3.1 VAL0003 - Validation of Off-The-Shelf Computer Systems

4 DEFINITIONS

4.1 IT: Information Technology

4.2 QA: Quality Assurance

4.3 CSCC: Computer System Change Control

4.4 CSCR: Computer System Change Request

4.5 Computer System Change Control Board (The Board): The Board that reviews and approves changes to validated computer systems. The Board includes a representative from each of the following functions: QA, Validation, and IT. The head of each function appoints their representative.

4.6 Requester: The individual who is requesting the change to the system.

Business Performance Associates (Company name & logo)	Document #: VAL005 Rev: 01 DRAFT Originator: Business Performance Associates	ECO #: p. 2 of 18	Effective Date:
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CHANGE CONTROL FOR VALIDATED SYSTEMS

- 4.7 System Owner: The manager, or designee, of the department that is most impacted by, or is the primary user of, the system.
- 4.8 Change: Any modification made to a validated computer system or its technical documentation. Modifications include both changes to and enhancements of the system, for example:
 - 4.8.1 Changes to application source code.
 - 4.8.2 Deletion of code.
 - 4.8.3 Installation of patches to repair defects.
 - 4.8.4 Installation of new versions or upgrades of the software.
 - 4.8.5 Changes to configured values or default settings other than what is done following an approved operation/maintenance procedure (e.g., adjusting a database table size according to a database maintenance procedure).
 - 4.8.6 Addition, deletion, or changes to programs, macros, and other software added to a system.
 - 4.8.7 Enhancements to the system through the addition or modification of modules, programs or code.
 - 4.8.8 Changes to hardware components, other than the replacement of parts with identical parts as part of an approved maintenance procedure.
 - 4.8.9 Activating or beginning to use functionality in the system that had not been previously validated.
- 4.9 GxP: A generic designation for all FDA regulations, including GLP, GCP, and cGMP, as applicable to an industry

5 RESPONSIBILITIES

- 5.1 Requester
 - 5.1.1 Complete the "Request for Change" section of the CSCR form (Attachment 1) and submit the CSCR.
- 5.2 Computer System Change Control Board
 - 5.2.1 Review the CSCR for clarity, accuracy, and completeness. Ensure that the change complies with relevant regulations.

Business Performance Associates (Company name & logo)	Document #: VAL005 Rev: 01 DRAFT Originator: Business Performance Associates	ECO #: p. 5 of 18	Effective Date:
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CHANGE CONTROL FOR VALIDATED SYSTEMS

6.1.2 Changes that do not require the use of the change control procedure include:

6.1.2.1 Changes to hardware and/or software that host applications, or provide an infrastructure service, if those changes are made following a qualified operation and maintenance procedure, and configurations are not set which are outside of the acceptable range of configurations.

6.1.2.2 Actions performed for the administration of an application that are described in an approved procedure as long as the performance of these actions has been included in the validation of the system.

6.2 The Requester submits a Computer System Change Request (CSCR)

The Requester should provide the following information in the "Request for Change" section of the CSCR, as applicable:

6.2.1 Requester's name, department, and extension.

6.2.2 System(s) and subsystems affected.

6.2.3 Description of change. The description should be an adequately detailed outline of the proposed change, including the affected functionality.

6.2.4 Justification for the change.

6.2.5 Planned implementation steps.

6.2.6 Supporting attachments, as necessary.

6.2.6.1 If controlled documents need to be changed in conjunction with the computer system change, attach completed change request forms.

6.3 Initial Processing of the CSCR by the Head of the Board

6.3.1 The Requester submits the CSCR to the Computer System Change Control Board (The Board).

6.3.2 The Head of the Board performs an initial review of the CSCR for completeness, clarity, and accuracy.