

QUALITY SYSTEM DOCUMENT

TITLE: QUALITY SYSTEM DOCUMENTATION CONTROL

1.0 PURPOSE

- 1.1 This document is to ensure that quality system procedure; work instructions, SOPs, reference documents, forms, etc. have an easy to use and consistent format.
- 1.2 This document will outline the issuance control, define responsibilities for their maintenance and use, and correctly represent the quality system for all internal and external concerns.

2.0 REFERENCES

- 2.1 CWI-05-QAD-0001 Quality System Documentation Format
- 2.2 CWI-05-QAD-0002 Document Change Request (DCR)
- 2.3 CWI-05-QAD-0003 Document Distribution Form (DDF)
- 2.4 CWI-05-QAD-0004 Use of SOP's and Posted Materials
- 2.5 CWI-05-QAD-0005 Master Document Control List (MDCL)
- 2.6 CWI-16-QAD-0001 Quality Record Retention

3.0 RESPONSIBILITIES

- 3.1 The Plant Manager has responsibility for the overall site Quality System, to be overseen by the Quality Assurance Manager.
- 3.2 The ISO Coordinator has responsibility for the administration and maintenance of the site document control system.
- 3.3 Others as defined throughout this work procedure.

4.0 DOCUMENT CREATION, APPROVAL, AND CONTROL

- 4.1 All new or revised documents must pass through the document approval process known as the Document Change Request (DCR), CWI-05-QAD-0002.
- 4.2 The ISO Coordinator shall review all submitted documents for compliance to ISO standards, this procedure, CWI-05-QAD-0002, and CWI-05-QAD-0001, the Quality System Documentation Format.

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- 4.3 Final approved documents shall be formatted and assigned a number or revision per CWI-05-QAD-0001.
- 4.4 Original copies are to be retained in a master file by the ISO Coordinator.
- 4.5 Originals from the master file shall be used to make controlled copies for use by all GNB Columbus personnel.

5.0 WORK INSTRUCTION MANUALS

- 5.1 Reference manuals (relevant to specific department) will contain:
 - 5.1.1 Corporate Specification
 - 5.1.2 Plant Work Instructions
- 5.2 The Department Manager/Engineer will be considered the Manual Holder and be responsible for the maintenance of manuals in their area.
- 5.3 The ISO Coordinator shall maintain a current manual distribution list.
- 5.4 Each manual will be numbered for reference and include an index of all documents contained in it.
- 5.5 Manuals that require multiple binders to hold the contents of the manual are to be labeled "Book # of #". For example, if Manual 8.01 requires two binders; the binders are labeled 8.01 Book 1 of 2 and 8.02 Book 2 of 2.

6.0 DOCUMENT ISSUE

- 6.1 Controlled copies of Quality System documents are issued to Department Engineers, by referencing the Master Document Control List (MSDL), ensuring that each user has the latest of the document.
- 6.2 Distribution lists for official controlled copies of Quality System documents shall be determined by the Quality Assurance Manager and/or the ISO Coordinator.
- 6.3 These distribution lists shall be maintained using a document control database system so all relevant personnel can be properly notified of new or revised documents.
- 6.4 Distribution of controlled copies shall be by the ISO Coordinator and shall follow the Quality System Documentation Distribution, CWI-05-QAD-0003.

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7.0 CONTROLLED COPIES

- 7.1 Manual holders shall be responsible for incorporating new or revised documents, and keeping their manuals updated and accessible.
- 7.2 Manual holders shall ensure that all obsolete and uncontrolled documents are removed from points of use.
- 7.3 The ISO Coordinator may update any department manual in lieu of the department Engineer.

8.0 UNCONTROLLED COPIES

- 8.1 Company personnel may make uncontrolled copies of documents for training, short-term use (less than 30 days), audits, or proposed revisions.
- 8.2 These copies are to be discarded after use.
- 8.3 Uncontrolled copies of Quality System documents, including the Work Instruction Manuals, may be issued to organizations, customers, consultants, and suppliers at the discretion of the Plant Manager or Quality Assurance Manager.
 - 8.3.1 These copies are to be stamped "UNCONTROLLED COPY, CURRENT WHEN ISSUED". The recipient shall not receive subsequent revisions.

9.0 REVISIONS TO DOCUMENTS

- 9.1 All personnel are responsible for notifying the Supervisor, Engineer or Manager for their area if there is a need to update procedures whenever actual practices are permanently changed from documented procedures.
 - 9.1.1 The primary responsible Supervisor/Engineer or Manager for the department affected is responsible for initiating a document change request (DCR), in accordance with CWI-05-QAD-0002, to ensure document changes are made.
- 9.2 The ISO Coordinator shall be responsible for issuing a CF-Q-27, Document Distribution Form (DDF), in accordance with CWI-05-QAD-0003.
- 9.3 The nature of changes within revised documents shall be clearly indicated in the last section "REVISION CONTROL" of each Work Instruction.

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9.3.1 Details of the three latest revisions will be maintained in the current document.

9.4 Actual documents shall be maintained by retaining electronic copies of all old revisions.

10.0 WITHDRAWAL OF DOCUMENTS

10.1 It is the responsibility of all employees to destroy obsolete documents found in their work areas.

10.2 Current and approved documents shall appear by number on the index found in the front of each Manual and on the Master Document Control List (MDCL).

10.3 Removal of a document from the MDCL shall constitute permanent withdrawal of that document.

10.4 These documents shall be considered obsolete and removed from all work areas. Any obsolete document not destroyed shall be clearly stamped in red, "OBSOLETE DOCUMENT".

11.0 MASTER DOCUMENT CONTROL LIST

11.1 Follow procedure outlined in CWI-05-QAD-0005 to assist in the control and identification of current Columbus Quality System documents.

12.0 RECORD RETENTION

12.1 The Plant shall retain quality records for an appropriate time as determined by the QA Manager.

12.2 Record retention schedules and procedures are documented in the Record Retention Procedure, CWI-16-QAD-0001.

13.0 BACK UP OF ELECTRONICALLY STORED DOCUMENTATION

13.1 Documentation electronically stored by the Network Management Group shall be backed up using a tape backup process.

13.2 The monthly tape drive back-up shall be retained for 3 years.

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14.0 USE OF SOP's and REFERENCE MATERIALS

- 14.1 SOP's are controlled summaries or highlights of work instructions, procedures, drawings, product specifications, or best process parameters.
- 14.2 The use of SOP's as posted material is authorized in accordance with CWI-05-QAD-0004.
- 14.3 A SOP log shall be maintained to assist in the control of all posted materials.
- 14.4 This log shall contain a document number, revision level, reference to parent document, and department location of document.

15.0 USE OF FORMS

- 15.1 Forms referencing or recording product data or process specifications, work practices, SOP's, etc...are to be controlled as part of the document control system.
- 15.2 The ISO Coordinator will maintain a form log assist in the control of forms requiring document control.
- 15.3 The form log shall consist of a form number, form title/description, revision level and revision date.
- 15.4 Supervisor/Engineer is responsible for reviewing forms when adding, removing or modifying process equipment.
 - 15.4.1 As part of the PM system, a semi-annual review is required.
- 15.5 Initiating or revision forms shall be done by:
 - 15.5.1 Drafting or marking up current revision and turning it in to the ISO Coordinator
 - 15.5.2 ISO Coordinator will create/edit the file and issues the form.

16.0 REVISION CONTROL

- 16.1 Revision C – Format changes. Redefine responsibilities and all sections of this work instruction.
- 16.2 Revision D – Remove sections 5.1.3 Plant SOPs, 5.1.4 Plant Forms and 5.1.5 Labels. Remove “and revision” from section 10.2. Clarify section 15.4

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- 16.3 Revision E – remove “and initialed by the authorizing manager, the Plant Manager, or the QA Manager” from 4.3. Delete 4.4 “The authorizing manager is the manager of the department responsible for the procedure, see CWI-05-QAD-0001.” And 4.7 “The QA Manager and the ISO Coordinator are the only personnel authorized to store the controlled copy paper.”
- 16.4 Revision F – Changed 1.1 from “This document is to ensure that quality system procedure documents, forms, etc. have an easy to use and consistent format.” Removed section 4.7. Changed 6.1 was “Controlled copies of Quality System documents are issued to Department Engineers, by referencing the Master Document Control List (MSDL), as required to maintain the standards of quality, ensuring that each user has the latest issue and has received adequate training for use of the document.”. Added 7.3 “The ISO Coordinator may update any department manual in lieu of the department Engineer.” Added “(less than 30 days),” to 8.1. Added 9.1.1. Add new sections 15.4 and 15.4.1.