Document Control

Procedure

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Hart InterCivic	
Part Number: 1000538	REV: E.04
Part Name: Document Control Procedure	
File Name: Document Control Procedure - 1000538 E04.docx	Page 1 of 12

Change History

Version	Date	Author	Description
1	7/12/06	[redacted]	Initial Draft
2	9/05/06	[redacted]	Revision
3	9/19/06	[redacted]	Revision
A	10/6/06	[redacted]	Initial Release
B	3/15/07	[redacted]	Updated the “Proprietary and Confidential” statement
C	3/21/07	[redacted]	Updated to include ISMS
D	08/17/2012	[redacted]	Update to current processes
E.00	12/05/2012	[redacted]	Corrected description of page Header content Added Minor Revision Numbering definition Used Minor Revision Numbering Move Software Versioning reference Document Release
E.01.01	02/05/2013	[redacted]	Extended versioning by adding pre-release version definition, this benefits author during document creation Added Product Documentation Control reference
E.01	03/14/2013	Hart InterCivic	Document Release
E.02	11/13/2014	Hart InterCivic	TDP Discrepancy update
E.03	15Jan2015	Hart InterCivic	TDP Discrepancy update, added Product Branding section
E.04	10Feb2015	Hart InterCivic	TDP Discrepancy update, added Agile description section

Table of Contents

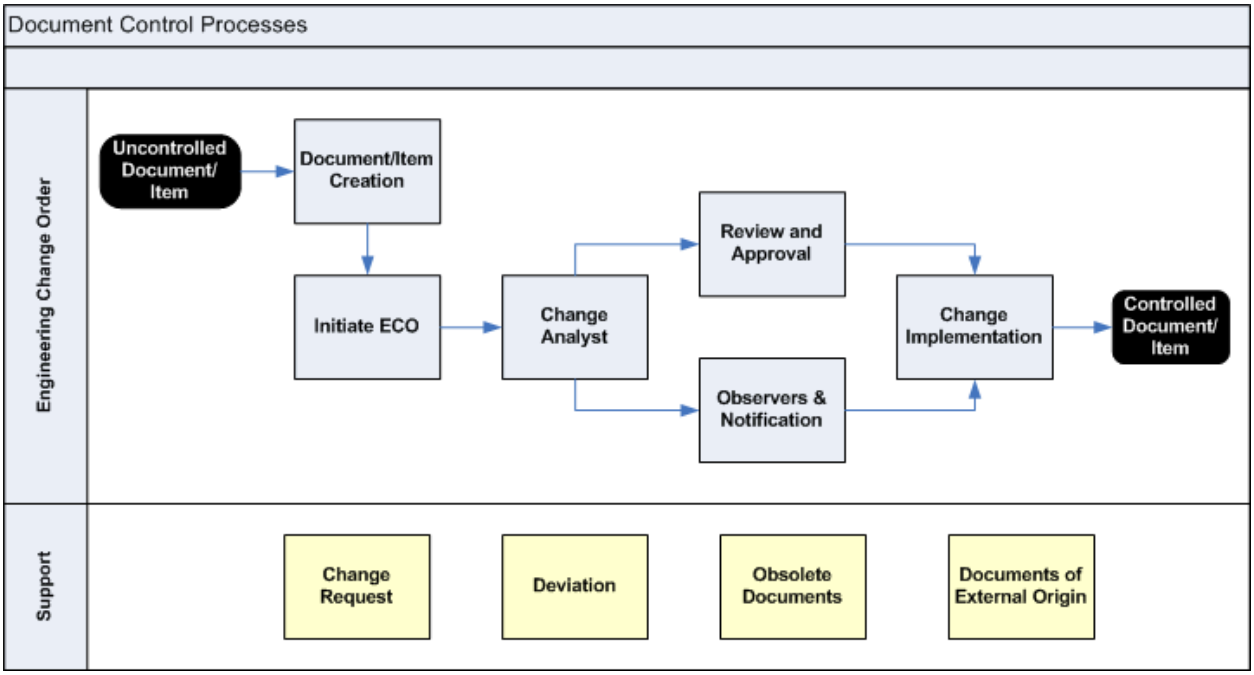
1 PURPOSE

Define the processes for Documentation Control and items that require reviews, approval, and revision control.

2 INFORMATIVE REFERENCES

- ISO9001:2000 4.2.3 Control of Documents
- ISO27001:2005 4.3.2 Control of Documents

3 DOCUMENTATION FLOW CHART



Processes with red background depict outsourced processes.

4 ENGINEERING CHANGE ORDER PROCESSES

Documents outlined in this process may describe hardware, software, licensed materials, user documentation, user manuals, and operating procedures.
Not all of Hart documentation is required to be versioned or released, this will depend on intended use and the need to formally control the document, many design documents are maintained in a revision control system and will not need versioning on the document itself due to the fact that the revision control system will provide this functionality.

4.1.1 Internal/Informal Design Documents

During the development process there will be many documents that are generated to capture ideas, concepts, and points of discussion; these documents are intended to bring clarity during the design phase of the development and are not necessarily formal in nature. These documents shall not be required to follow the formal document control process, but it is required that these documents are retained in a source control repository (SCR) such as SVN, GIT, or CVS. By using a SCR for these informal documents, all change history to a design document can be tracked. These informal documents shall not be required to have document numbers or revision numbers associated with them, in the manner that formal documents are required. It is suggested the document number be N/R and the revsion number be initials or name of the source control repository.

4.1.2 Product Life Cycle Management software

Hart has implemented Oracle's **Agile** Product Lifecycle Management to enable strategic management of the complete lifecycle of a product: from the ideation phase to recycling and retirement of a product.

Agile is a server based product that is licensed from Oracle, installed by Oracle, and maintained by Hart's IT Department.

Agile URL: http://agile.hartis.com/
Agile Version: AWS.2006.2.680.0
Agile Documentation: Hart IT Department

4.1.3 Product Branding

Product branding is a Product Management and Marketing function. There are no governing rules for the naming or branding of the product, but typically reflects the product's family and the products functionality.

When assigning documentation numbers associated with specific product brands, the correct product brand shall be selected (see 4.1.6.d).

4.1.4 Part Number & Revision

New documents/items are automatically assigned an item number or manually assigned an item number based (i.e. to allow for documents to be grouped by product line). When the document/item is added to the Document Control Application Software. The initial release of a document/item is revision A.00. Modified document/item requires an incremental rise in the major revision letter or the minor revision number depending on the modification, <Major>.<Minor>.

Major - modification to the document's design, structure, or adding/deleting functional descriptions described by the content.

Minor - modification to the document's description that does not change the functionality of the item being described by the document, but adds clarity/robustness to the existing description.

Pre-Release – prior to a <Major>.<Minor>.<PR> release of a document, the author should consider using a third number appended to the "to be released" version for tracking changes during document development. Pre-Release versions of the document can be used for document reviews, allowing the author to get feedback and integrating suggested changes prior to document release.

If the document being modified is currently released as version A.01 and the author is making a series minor modifications the author should use a numbering system to allow the tracking of the series of changes for the future release of A.02, thus modification tracking in the documents "change log" should look similar to this –

E.00	12/05/2012	TW Farley	Corrected description of page Header content Added Minor Revision Numbering definition Used Minor Revision Numbering Move Software Versioning reference Document Release
E.01.01	02/05/2013	TW Farley	Extended versioning by adding pre-release version definition, this benefits author during document creation Added Product Documentation Control reference
E.01	03/14/2013	Hart InterCivic	Document Release

At the time of release the "pre-release" numbers will be dropped from the document and it will be released as A.02 in this example.

4.1.5 Minimum Format Requirements

Minimum requirements for QMS and ISMS documents are:

a. Include a cover page that contains the:
   - Hart InterCivic Logo
   - Document Title
   - Confidentiality Statement
   - Current Copyright date

b. Include a header on each page that contains the:
    - Document Name in the upper left
    - Part number centered (alternative, Footer left side)
        a. Part numbers only need to be in one location Header or Footer
    - Revision letter in the upper right

c. Include a footer on each page that contains the:
    - Part number left (alternative, Header centered)
        a. Part numbers only need to be in one location Header or Footer
    - Document Security Classification (centered in Footer Section)
        a. Public
        b. Confidential & Proprietary
        c. Internal Only) centered
    - Page number out of the total number of pages

d. Documents, such as Quality Manual, Security Manual and Procedures shall also have a Change Table table with the following fields:
    - Date of change
    - Revision
    - Author
    - Description of change

e. Corresponding file is attached

Printed copies are considered uncontrolled and must be verified against the copy in Document Control before use. Typically, uncontrolled copies are provided to satisfy requests from third parties, such as a customer requesting a copy of the Quality Manual.

It is strongly suggested that document naming conventions include the title of the document as listed in the Title Block, Document (Agile Item) Number, and Revision (excluding any dot(period) from the revision number).

Example: Document Control Procedure – 1000538 D01
Document<*sp*>Control<*sp*>Procedure<*sp*>– <*sp*>1000538<*sp*>D01
Title: Document Control Procedure
Item Number: 1000538 (or 1000-538)
Revision: D.01 (shown as D01, no dot (period))
File name: Document Control Procedure 1000538 D01.doc

4.1.6 New Product Development (NPD) Pre-Release Documents

Pre-release documents developed during the NPD process are controlled with numeric revisions prior to formal release. The Project Manager maintains these documents in the SharePoint Project Repository

Pre-release software is controlled according to software versioning procedure.

4.1.7 Document/Item Control

Once the document/item has been reviewed by the appropriate team members, it can be transferred into Agile (or current Product Life-cycle Management (PLM) application).

The following steps are required:

a. Right click and select New from the pop-up window
b. Select type of object from the Object List
c. The Part Number may be automatically generated by clicking on the button "123" or the operator can manually enter a predefined number. This will assign the Part Number and open the form
d. Fill out the entire title block page of the form, including the type, category and the description of the item
e. Enter in all pertinent information on page two (if applicable)
f. On the BOM tab enter all corresponding items that fall under the assigned Part Number
g. Add Manufacturers (as applicable)
h. Attach the item details – include design documents and specifications
i. Click on Save
j. Initiate the Engineering Change Order Process

4.2 Engineering Change Order Initiation

Anyone in the organization with access to Agile (or the current Product Lifecycle Management tool) may request an Engineering Change Order (ECO). The ECO creator considers how the changes affect other documents and whether design, production or processes are affected. All potential impacts of the change should be thought through prior to assigning an ECO.

The following steps are required:

a. Open the item that will be revised
b. Right-click and select “new change” and determine the type of change
c. Click the “123” button to assign a number and open the form
d. Assign the Change Analyst
e. Assign the workflow
f. Define the Reason Code

g. Enter the Description of Change – A summary of the changes made to the original item that should include the specific product or processes affected by the change. If changes are too extensive to provide a brief summary, a “Read Me” file will be attached to the ECO to provide detailed account of the changes.
h. Enter the Reason for Change – An account of the purpose, objective and rationale for the change(s), as well as information on required timing for implementation.
i. Choose Signature Classification for the ECO based on the following Classification Matrix, refer to *I/N 1000418 – Classification Signature Matrix* for more detail

   A = Major changes, initial release of cross-functional controlled materials, visible to customer/external group

   B = Minor changes affecting cross-functional organization, not visible to customer

   C = Minor changes affecting product development or product implementation

   D = Documentation correction

j. Enter the description of the verification and validation steps that have been taken to determine that proposed changes are the proper solution.
   - Attach verification/validation documents, such as Review minutes and Test reports, to ECO attachment tab if appropriate.
k. Note any training that may need to occur – include details on who will require training, who should conduct training and when the training should occur.
l. Define Implementation: Lifecycle phase, effective date & material dispositions
   - Note: for most documentation with possible exception of end-user materials, such as product manuals, the dispositions will be NA.
m. Redline BOM, Manufacturers and attachments (if necessary)
n. Advance the ECO to next status and submit to Document Control Application Software Change Analyst

4.3 Change Analyst

The Change Analyst reviews the ECO and verifies the following:

a. all required fields are filled out per the above requirements
b. verification/validation is correctly entered
c. required supporting documentation is attached
d. attachments are located in the correct places
e. redlines are completed (if applicable)
f. correct signature classification has been assigned

Upon verification of the fields, the Change Analyst assigns Approvers according to the Classification Signature Matrix and routes the ECO for review and approval. The Change Analyst also assigns Observers and Notification persons according to the Classification Signature Matrix.

4.4 Change Control Board (CCB)

Employees assigned as Approvers are the Change Control Board required to review the ECO "package" before it can be released. This review is to ensure the ECO package completeness; it is not intended to be a review of the document content. The document content should be peer reviewed prior to ECO/MCO submission. There is not an order or sequence to the Approver list, each Approver can review the ECO/MCO submission at any time and provide approval or rejection.

All information relating to the change is included:

a. required documentation is attached
b. all attached documents have correct version
c. all attached documents, that require Review & Sign-off, are signed
d. ECO description of changes is correct

If necessary, comments can be made by approvers through Document Control Application Software to the originator. These comments become auditable records in Agile (or the current PLM) history tab. The Approvers have two options:

a. Accept: once the ECO is approved, the creator and Change Analyst are notified
b. Reject: A rejection by an approver will send the ECO back to the pending status. Notification is sent to the members of the CCB, originator and Change Analyst.

Designated Approvers may assign additional (ad hoc) approvers at anytime during the CCB process if the Approver deems broader review is necessary. Only a Change Analyst may remove ad hoc approvers after it has been confirmed that the approver is not required by the Classification Signature Matrix.

4.5 Observers and Notification Persons

Employees assigned as Observers and Notification are not required to approve the ECO, routing is for information only and the ECO cannot be rejected these persons. Comments can be made by Observers and Notification persons through Agile (or the current PLM) to the CCB. These comments become auditable records in Document Control Application Software history tab.

4.6 Document/Item Change Release

Once all Approvers have signed, Agile (or the current PLM) sends an email notification to the Change Analyst. The Change Analyst accepts redlines on documentation (if applicable) and incorporates (locks) attachments. The Change Analyst also notifies approvers, Observers and Notification persons regarding the release of the ECO.

4.6.1 Product Related Change Implementation

Supply Management is responsible for communicating and coordinating the implementation of product changes with the appropriate affected suppliers and/or manufacturers. Supply Management will work with Document Control to create a complete PDX package of ECO and affected items to be distributed to the appropriate parties (ITA, CM, Suppliers, etc.)

5 SUPPORT PROCESSES INSTRUCTIONS

5.1 Change Request

A Change Request differs from an ECO in that it is a formal suggestion. A Change Request is used when a potential change or improvement needs to be routed for approval. The Change Request is then routed through the appropriate department for approval. If the item is approved, an ECO will then be created. If the potential change or improvement was not accepted by the department representatives the Change Request is canceled.

5.2 Deviations

A Deviation differs from an ECO in that it has a limited effectiveness. When there is a need for a Deviation, it will include both an effective date and an expiration date. A Deviation may be used as a temporary fix for a line-down or emergency situation where product is not conforming. The revision is not changed; instead the Deviation number is marked on the product. With these exceptions, the Deviation procedure is the same as the ECO procedure.

5.3 Obsolete Documents

Obsolete documents and prior revision of documents are stored and maintained on the Agile (or the current PLM) or network. Obsolete documents are marked as such in a lifecycle phase in the Document Control Application Software. Some historical obsolete documents (prior to implementation of the new Document Control System) may also be stored the network. Access is Read-Only.

5.4 Documents of External Origin

External Documents are not controlled through the ECO process, but are retained by Document Control for reference. When possible, electronic versions of External Documents will be maintained on the network. Obsolete External Documents are retained within a separate file location and labeled “OBS” for “Obsolete” as part of the file name. Employees using External Documents must verify the currency of the document prior to use. External Documents are referenced in internal documents by control number, revision and description, if available.

Supplier and customer documents that form a part of the QMS documentation are maintained as External Documents and are typically named using the reference and revision letter of the supplier or customer document.

5.5 Software Package Release

Refer to the Software Versioning Procedure, Hart I/N 1001070.

After a software release candidate package has been validated and given the approval to is to be released to manufacturing, the RTM source, build process tools and instructions, and RTM compiled software shall be packaged and controlled documents created and released for this software build/release.

5.6 Product Documentation

Refer to the Professional Services documentation that provides guidance for product documentation and user documentation document control processes and naming conventions; these documents can be found in SharePoint:
http://intranet/engineering/Shared Documents/Tech Pubs

Reference Documents for User Documentation
Documentation Process Checklist
Training Product and File Naming Conventions