Document Control Procedure

1.0 PURPOSE AND SCOPE

1.1 Purpose

1.1.1 The purpose of this procedure is to define methods for Document Control at our Company.

1.2 Scope

1.2.1 This procedure is applicable to all programs at our Company

2.0 APPLICABLE DOCUMENTS

The following documents are applicable as specified herein:

Industrial/Commercial/Government Documents

ISO 9001	Quality Management System - Requirements

Internal

Document(s)

ATS-QAP-1004	Quality Records
ATS-QAP-1008	Internal Audits

Form(s)

None

3.0 RESPONSIBILITIES

3.1 General

3.1.1 **Quality Assurance** – is responsible for maintaining procedure and enforcing the document control methods defined in the procedure.

3.1.2 **Document Control/Configuration Management** - is responsible for Document Control activities as specified in this procedure.

3.1.3 **Other Functions** – are responsible for following the document control methods defined in the procedure.

4.0 REQUIREMENTS

4.1 DocumentNumbering

4.1.1 Documentitems that required document control are assigned a unique number or alpha numeric identifier for control purposes. No two or more items shall be assigned the same number or identifier.

4.1.1.1 Our Document Control function is used for ISO 9001 QMS Documentation.

4.1.2 **Our Document Control function for ISO 9001 QMS Documentation** - is performed by our Quality Assurance Department who responsible for assigning ISO 9001 QMS manual, procedures, instructions and form numbers. Project Managers or Operations Department is responsible for working with Document Control/Quality Assurance for assigning project specific documentation numbers. See paragraphs 4.2, 4.3, 4.4, 4.5 and 4.6 for specific information related to the methods used for Document Control of ISO 9001 QMS Documentation.

4.2 ISO 9001 QMS;Document Review and Release

4.2.1 Documents shall be reviewed for completeness and accuracy prior to release by Quality Assurance/Document Control per paragraphs 4.3, Initial Release and Revision Control and 4.4, Change Release and Revision Control. Prior to releasing a Document (i.e. manual, policy, procedure, instruction, form, etc.) that affects other department(s), Quality Assurance management ensures that an informal review or discussion that includes getting input from effective departments is performed prior to electronically approving the new item or change for release.

4.2.2 Each new Document shall be assigned a Revision Letter starting with Revision "- or A". When authorized by Quality Assurance/Document Control, the Document maybe assigned another Revision Letter (i.e. D, F, H, etc.) as deemed necessary (i.e. a major release of prior used Documentation being released for the first time, etc.). Revision Numbers (i.e. 1, 2, etc.) may be used for pre-production releases to indicate that the item is under pre-production control.

4.2.3 Document Control/Quality Assurance shall retain an electronic copy of the document for Document Control purposes; this includes retaining old revision electronic copies. Document items shall have the item's unique part number and revision on the front page and in the electronic file name (i.e. ATS-QAM9001A, or QAM9001A, FORMATS10-1234A or FM1234A).

4.2.3.1 The electronic files that are retained on the Internet Web; ISO 9001 QMS Documentation folder shall be segregated as "Current" and "Old Revision/Obsolete" to prevent improper use.

4.2.4 Document Control/Quality Assurance, as requested, shall make copies or make the document available electronically (i.e. Intranet web, etc.) to the user departments.

4.2.5 Document Control/Quality Assurance maintains a master file of approved Documents (i.e. manuals, policies, procedures, instructions, and forms) and Software using our Internet Web; ISO 9001 QMS Documentation folder.

4.2.5.1 Our document control process ensures that:

a) the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed
b) invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;
c) any obsolete documents retained for legal and/or knowledge-preservations purposes are suitably identified

4.2.6 Document Control/Quality Assurance ensures the timely review, distribution, implementation and maintenance of all authorized and released drawings, standards, specifications, planning and changes. Document Control maintains an electronic record of change incorporation and, when required, coordinates these incorporations with the customer and/or regulatory authority.

4.3 <u>ISO 9001 QMS Initial Release and Revision Control</u>

4.3.1 When a Document item is to be initially released, the functional department who prepared the item ensures that it has been assigned the following information on the first page minimum:

- Document No.:
- Revision: X
- Date: MM/DD/YY (not required for forms)
- Sheet X of X

4.3.1.1 The electronic file name for the Document shall include the item's assigned number (as much as needed to ensure correct item during use) and revision (i.e. ATS-QAM9001A, or QAM9001A, FORMATS10-1234A or FM1234A).

4.3.2 The item is then submitted to Quality Assurance for review and approval. This review includes:

- Verification that the changed item(s) meet ISO 9001 QMS requirements, and Customer order requirements,
- Ensuring electronic file name includes unique identifier, revision and sheet X of X information

4.3.2.1 Where needed, Quality Assurance ensures other affected departments have an opportunity to a timely review the new or changed items prior to final release approval. A record of this participation is not required.

4.3.3 **Release Approval** - Quality Assurance has sole responsibility for approval and uploading Document item(s) to the Internet Web; ISO 9001 QMS Documentation folder. This QA approval is recorded electronically (Password Protected) when the item is uploaded to the Internet Web; ISO 9001 QMS Documentation folder. The Internet Web; ISO 9001 QMS Documentation folder is password protected where IT management, Quality Assurance/Document Control and our President has access.

4.3.3.1 Each Document released on the Internet Web; ISO 9001 QMS Documentation folder includes the item's unique number and revision, and other information (i.e. description) as required by Quality Assurance.

4.4 ISO 9001 QMS Change Release and Revision Control

4.4.1 When a Document item is changed after initial release per paragraph 4.3, the functional department who changed the item ensures that it has been assigned the following information on a minimum the first page and updates the revision letter (i.e. A to B, B to C, etc.):

- Document No.:
- Revision: X
- Date: MM/DD/YY (not required for forms)
- Sheet X of X

4.4.1.1 The electronic file name for the Document shall include the item's assigned number (as much as needed to ensure correct item during use) and revision (i.e. ATS-QAM9001B, or QAM9001B, FORMATS10-1234B or FM1234B).

4.4.2 The person(s) making the changes, shall ensure the reviewer knows the scope of change (i.e. add, delete or change) by highlighting "text font" changed area using a unique color (i.e. red, etc.) and saving it for use during the release process. Using Mircosoft Word edit tracking may be used, but not recommended. It is preferred just to change the "Text Font" to another color (i.e. red) besides black. For each new proceeding revision (i.e. Revision B to C, etc.), make sure you select all (Control A) and turn the last unique (i.e. red) color Font Text to black, then highlight new changes to another color (i.e. red) besides black.

4.4.3 The item is then submitted to Quality Assurance for review and approval. This review includes:

- Verification that the changed item(s) meet ISO 9001 QMS requirements, and Customer order requirements,
- Ensuring the revision level has been updated
- Ensuring electronic file name includes unique identifier with new revision

4.4.3.1 Where needed, Quality Assurance ensures other affected departments have an opportunity to a timely review the new or changed items prior to final release approval. A record of this participation is not required.

4.4.4 **Release Approval** - Quality Assurance has sole responsibility for approval and uploading Documents to the Internet Web; ISO 9001 QMS Documentation folder. This QA approval is recorded electronically (unique login signature captured) when the item is uploaded to the Internet Web; ISO 9001 QMS Documentation folder. The Internet Web; ISO 9001 QMS Documentation folder is password protected where IT management, Quality Assurance/Document Control and our President has access.

4.4.4.1 Each Document released on the Internet Web; ISO 9001 QMS Documentation folder includes the item's unique number and revision, and other information (i.e. description) as required by Quality Assurance. The old revision item is saved in the "Old Revision" folder to maintain a history of change and prevent un-authorized use.

4.5 Records Control

4.5.1 Document Control/Quality Assurance shall store, maintain and control the master (original) Document items using the Internet Web for ISO 9001 QMS Documentation and Subversion Software for Custom Software Products.

4.6 Obsolete Documentation/Software

4.6.1 When new Documents or Software are released, Document Control/Quality Assurance is responsible for gathering and removing obsolete items from usage. Manuals shall be gathered and updated at the same time to ensure manuals are updated with accuracy, completeness and performed in a timely manner. In addition, electronic documentation on the Internet Web for ISO 9001 QMS Documentation and Subversion Software for Custom Software Products shall be updated by Document Control/Quality Assurance.

4.6.2 Area supervisor(s) or leader(s) are responsible for obsolete documentation or software if exposed to the work area.

4.6.2.1 All obsolete documents or software shall be disposed of as directed by Document Control/Configuration Management/Quality Assurance.

4.6.3 Obsolete or earlier revision documents or software shall be clearly marked or stamped with “Old Revision” or “Obsolete” to suitably identify for users that the item is not the most current revision. Personnel shall not use obsolete or earlier revision documentation unless required by Customer order, or when specified by Document Control/Configuration Management/Quality Assurance.

4.6.3.1 It is acceptable for Document Control/Configuration Management/Quality Assurance to retain Obsolete or Old Revision Documentation or Software as long as it is clearly marked or stamped with "Old Revision" or "Obsolete".

4.6.4 When it is necessary to issue manuals, procedures, and instructions to personnel, the documentation shall be issued in a controlled manner for recall and maintenance. Each item copy shall be assigned a Control Number:____ and the Master Copy of the controlled item shall be labeled as Master Copy for the Control Number and retained in the Document Control/Configuration Management/Quality Assurance area.

4.6.4.1 Document Control/Configuration Management/Quality Assurance is responsible for promptly recalling/gathering the Controlled Copies and removing/updating as changes occur.

4.6.5 When controlled copies are provided to employees via an intranet, update of the master copy and controlled copy are conducted.

4.7 Software Product Design; Document and Software Review and Release

4.7.1 The Project Manager for each Software Design Project working with Configuration Management is responsible for ensuring his/her project Software Product Design documentation and software item are assigned a unique number using the Subversion Software or other project specific software for tracking purposes. Each item is assigned a unique identification (i.e. number) and revision for tracking.

4.7.2 The Project Manager working with Configuration Management is assigned the responsibility for reviewing and approving Software Product Design documentation and/or software prior to release. This approval is electronically recorded via Subversion Software or other project specific software.

4.7.3 Changes - All changes are require a change to the items revision and shall be approved in the same manner as an initial released Software Product Design. The scope of change is tracked using the Internet Web Software or other project specific software.

5.0 QUALITY ASSURANCE

5.1 Audits

5.1.1 QA shall audit this process as scheduled per ATS-QAP-1008, Internal Audits.