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A&DM – Quality Systems

Master Quality Manual

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Abstract:

This is the quality systems manual for A&DM

Document Status:

Working Revision

Revision History

Revision History for this document. This section only notes major contributions by the editors. Further information may be found in VSS.

Revision	*Author*	*Notes*
1.4	LJG	Major updates.
1.3	LJG	Major additions to all facets of quality manual as per quality review. These changes include additions to supplier performance measures and updates that reflect changes in technologies used at A&DM.
1.2	LJG	Adjusted serial numbering format to suit Radiation Source Holders and Code of Practice Requirements.
1.1	LJG	Added extra detail for use of Autodesk Inventor.
1.0	LJG	Initial Revision

Table 1: Document Revision History

Control History

Controlled Document

DO NOT make copies of this document. The latest version of this document (Master_Quality_Manual) may be obtained from the following location(s):

Location	*Path*
1 - VSS	\admwork\documents\Quality_Systems
2 - Server	\\eqss-server-01\\admwork\documents\Quality_Systems
3 - Web	http://admeasure.com.au

This document has been issued to the following parties:

Issue	*Party*	*Reason*
1	ARPANSA	Model 1860 Radiation Transport Cask, Approval Submission
2		
3		
4		
5		

Table 2: Issue Control History

Documentation Conventions

The list below highlights important documentation conventions.

Text presented in this manner is intended to provide the user with some general information. The user should ensure information presented in this manner is clearly understood.

Text presented in this manner provides the user with information to assist in completion of the current procedure being explained.

Text presented in this manner indicates that further actions are required by the user.

Text presented in this manner indicates that a failure to follow directions could result in damage to equipment, loss of information, bodily harm, or loss of life.

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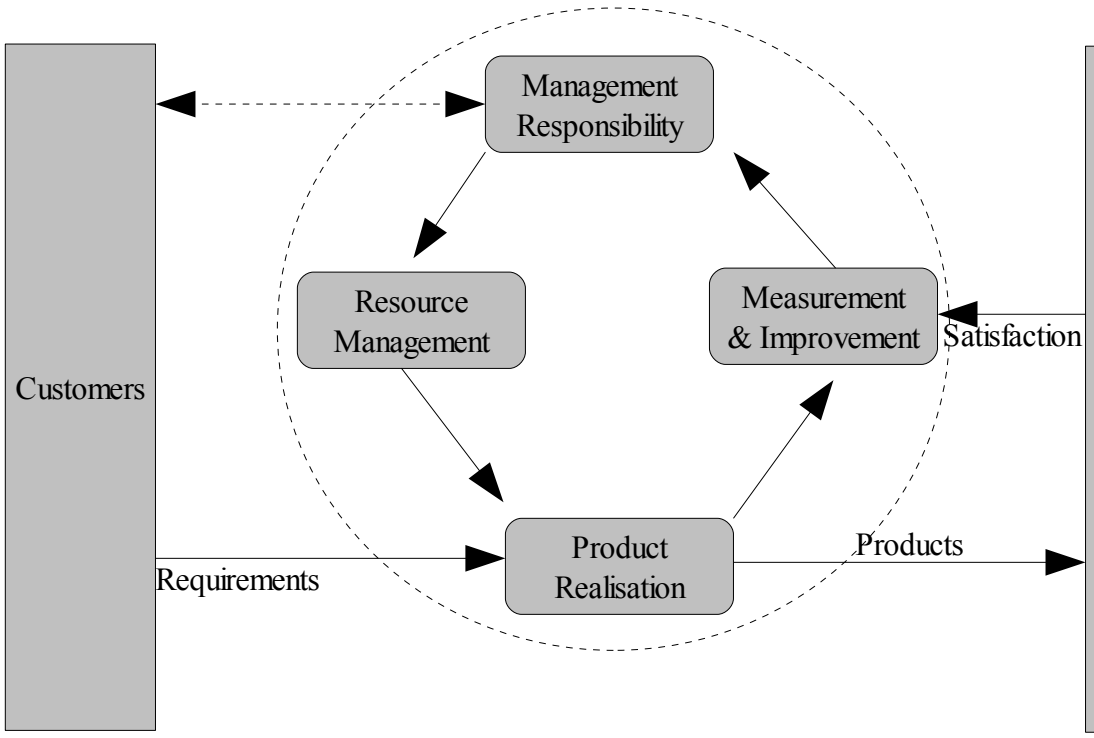
Table of Contents

Quality Management System

This adoption and development of this quality management system has been a strategic decision by Analogue & Digital Measurements Pty. Ltd. ("A&DM"). The design and implementation of this Quality Management System ("QMS") has been influenced by a large array of needs, objectives products and processes.



Text 1: Quality management System Overview

Requirements

General[1]

Item	*Requirement*
1.	The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this document.
2.	The organization shall 1. identify the processes needed for the quality management system and their application throughout the organization 2. determine the sequence and interaction of these processes, 3. determine criteria and methods needed to ensure that both the operation and control of these processes are effective, 4. ensure the availability of resources and information necessary to support the operation and monitoring of these processes, 5. monitor, measure and analyse these processes, and 6. implement actions necessary to achieve planned results and continual improvement of these processes.
3.	These processes shall be managed by the organization in accordance with the requirements of this document.
4.	Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system. NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

Table 3: QMS - General Requirements

The Quality Policy Statement

The purpose of this quality policy statement is to define the intentions and direction of the quality management system. It demonstrates A&DM's commitment to quality with clear leadership by top management.

All employees are stake holders in the companies success, and as such are empowered and committed to delivering flawless products and technology. Everyone

1 Referenced Directly From AS9001:2000

who works with us is expected to ensure ownership for quality.

To provide the highest quality products and services to its customers A&DM commits to.

1. Meet all customer's requirements; applicable regulatory, statutory and contractual requirements; and relevant national / international standards.
2. Evaluate and continually improve the effectiveness of its services
3. Ensure that this quality policy is communicated and understood by all employees.
4. Provide a process for establishment, review and modification of quality objectives
5. Review and modify this policy, regularly, for continued suitability.

Accessing the Quality Manual

The quality manual can be accessed by all staff members and outside contractors in several ways.

Item	*Access Method*
1.	Direct access to the latest addition of the quality manual in PDF format: \\eqss-server-02\admwork\quality_systems\master_quality_manual\master_quality_manual.pdf
2.	Access from the companies internal web site http://companyweb/  *Illustration 1: Web Site Image*
3.	Via our web site (Please note you will be required to contact lockie@eqss.com.au to obtain access) http://admeasure.com.au/

Documentation Requirements

Overview

The quality manual and any documents covered by the A&DM Quality System (See General Consideration on Page 24), are required to conform to the documentation requirements covered in this section.

Requirements

These requirements have been referenced from AS9001:2000.

General[2]

Item	*Requirement*
1.	The quality management system documentation shall include 1. Documented statements of a quality policy and quality objectives, 2. A quality manual, 3. Documented procedures required by AS9001:2000 4. Documents needed by the organization to ensure the effective planning, operation and control of its processes 5. Records required by this International Standard (See Table 4: General Requirements Item 1 on page 22).
2.	Where the term “documented procedure” appears within this Quality Manual, this means that the procedure is established, documented, implemented and maintained
3.	The extent of the quality management system documentation can differ from one organization to another due to 1. the size of organization and type of activities, 2. the complexity of processes and their interactions, and 3. the competence of personnel.
4.	The documentation can be in any form or type of medium.

Table 4: General Requirements

2 Referenced directly from AS9001:2000

Quality Manual[3]

Item	*Requirement*
1.	The organization shall establish and maintain a quality manual that includes the scope of the quality management system, including details of and justification for any exclusions.
2.	The organization shall establish and maintain a quality manual that includes the documented procedures established for the quality management system, or reference to them.
3.	The organization shall establish and maintain a quality manual that includes a description of the interaction between the processes of the quality management system.

Table 5: Quality Manual Requirements

3 Referenced Directly From AS9001:2000

Document Control[4]

Please see Document Control on page 23

Item	*Requirement*
1.	Documents required by the quality management system shall be controlled. (See Document Control on Page 23)
2.	Records are a special type of document and shall be controlled according to the requirements given in Table 4: General Requirements, on Page 19
3.	A documented procedure shall be established to define the controls needed 1. to approve documents for adequacy prior to issue, (See Document Approvals on Page 27) 2. to review and update as necessary and re-approve documents, (See Document Review on Page 29) 3. to ensure that changes and the current revision status of documents are identified, (See Changes and Revision Control on Page 30) 4. to ensure that relevant versions of applicable documents are available at points of use, 5. to ensure that documents remain legible and readily identifiable, 6. to ensure that documents of external origin are identified and their distribution controlled, and 7. to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose

Table 6: Control Of Documents - Requirements

4 Referenced Directly From AS9001:2000

Control Of Records[5]

Item	*Requirement*
1.	Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.
2.	Records shall remain legible, readily identifiable and retrievable.
3.	A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

Table 7: Control Of Records - Requirements

5 Referenced Directly From AS9001:2000

Quality Manual

This document forms the quality manual for Analogue and Digital Measurements.

Document Control

This section details how A&DM handles document control.

Document Awareness

The quality officer is responsible for ensuring that communication is maintained between parties to ensure that all parties are aware when a controlled document changes. All staff members are also mode aware of how to check if they have the latest revision of a document before commencing any work.

Open Standard Policy

Where practical all documents will be stored in an open standard document type. A&DM relies on the OASIS (www.oasis-open.org). Where practical if an open format application exists it will be used in place of a proprietary format application.

A&DM makes extensive use of the OpenOffice.org suite of applications which support the OASIS XML file format allowing interoperability between almost any office application.

General Consideration

Consideration must be placed when deciding the type of document being developed and if it will need to meet the requirements of the A&DM Quality System. In general any document which forms part of a final product must meet the control requirements for documentation.

To assist the rapid development and compliance with this required of AS9001:2000 many templates have been developed and are available to assist in this process.

All documents and files used in a project must be stored appropriately. The following document types are examples of what will be applicable to this quality system.

Item	*Type*
1.	Mechanical Drawings 1. Autodesk Inventor™ 2. Autodesk AutoCAD™
2.	Electronic Design 1. Altium Designer™
3.	Firmware 1. C/C++ Source Code 2. VHDL (Including Test Scripts) 3. Assembly Language
4.	Documentation 1. Specifications 2. User Manuals 3. Factory Manuals 4. Quality Assurance Related Documents 5. Product Brochures, Data sheets, Etc. 6. Engineering Change Notifications (ECN's) 7. Project Management
5.	Public Electronic Information 1. Web Sites(s) 2. Marketing 3. Flyers & Brochures

Table 8: General Considerations - Document Types

File Locations

The storage of our electronic data during project development is of utmost importance to the management of any project. As a result a standard folder name conventions will be adhered to.

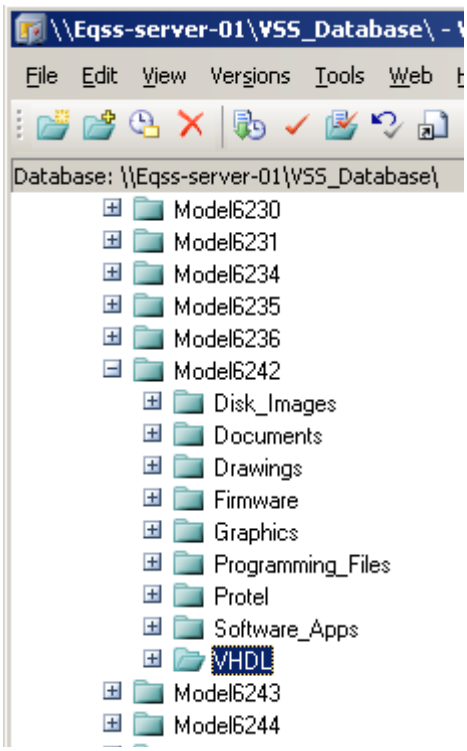


Illustration 2: Standard Directory Structure

Visual Source Safe ("VSS") will contain a standard directory structure for each project and this will be mirrored on the server. It is up to the individuals with some guidance from this document to decide if their files should be placed in version control. See Visual Source Safe on Page 30 for more information about VSS.

Standard directory structure

The standard directory structure will allow everyone to become familiar with the locations of particular documents, and so in the future it will be easy to go back to a previous project and quickly find the relevant documents. The directory structure must be explicit enough to ensure that there is only one logical place to store a particular document, whilst not over policing and therefore confusing the structure.

Distribution Control

The control of distribution of documents ensures that all parties have the correct and up to date information for the task they are completing. As a result a heavy emphasis is placed on ensuring that documents are stored in electronic format and that the electronic copies are controlled for:

Item	*Requirement*
1.	Unauthorised Access
2.	Unauthorised Modifications
3.	Incorrect Revision Information.

Table 9: Distribution Control - Requirements

Control Mechanisms

Visual Source Safe (See: Visual Source Safe on page 30) will be used as the control mechanism. It can control each user's rights, as well as global project rights.

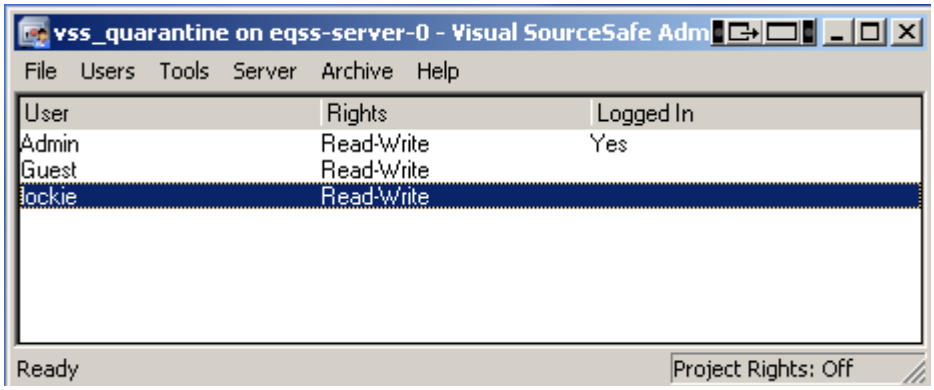


Illustration 3: Visual Source Safe Administration

Document Approvals

All documents that are used in the production, sale or replication of any product will require approval by an appropriately qualified person (such as the QA Officer) prior to release.

A list of these document types may be found in Table 8: General Considerations - Document Types on page 24.

Document Approval Requirements

Each document must carry an approval mark stating that the document has been approved for release. The approval mark can is to contain the following information:

Item	*Requirement*
1	QA Mark (i.e. “QA Approved”)
2	Name of Authorised Person
3	Date of Authorisation

Table 10: Document Approval Requirements

Approval Example

An example of an approval mark on a PDF file is shown below.

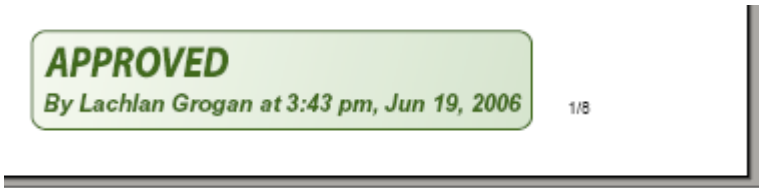


Illustration 4: Example Approval Mark

Approval Check List

The following items should be checked prior to submitting a document to the QA Officer for final checking.

Item	*Requirement*
1.	The document is in electronic format.
2.	The document is stored in Visual Source Safe if it meets the requirements as set out in Table 5: Quality Manual Requirements on Page 20
3.	The document's accessibility is controlled to prevent unauthorised changes.
4.	The document is complete and is accurate
5.	The document meets the documentation standards as set out in the section Documentation Standards on Page 52

Table 11: Approval Check List

Document Review

It is policy that any document required by this quality system be reviewed for its accuracy and completeness. Table 5: Quality Manual Requirements On Page 20, lists the types of documents that are applicable to review.

Review Procedures

A&DM will review its documents on a per use basis. Changes to documents are made as a result of many factors and as such documents must be reviewed before they are used.

Changes and Revision Control

Visual Source Safe

Visual Source Safe ("VSS") is a revision control system running on our servers. VSS consists of a database stored on the server, a shadow folder stored on the server and a client application run on your local computer.

Theory

VSS is like a huge library containing all of your files. They are stored on the server and each file, as it is changed is given a new version number. When you wish to edit a file you will need to “check out” the file from VSS. This process is similar to borrowing a book from a library. Once you have the file on your local computer it is yours and no-one else can edit it, but everyone can view it. Once you are finished making changes you can check the file back in (return the book) and VSS automatically catalogues it and gives it a new version number.

As projects are completed the entire project can be labelled (example “Revision1”).

Example:

Lets just say a project was complete and went to manufacture, 100 units were produced, and the project was labelled “Revision1” in VSS. Through field testing we need to make some changes to a auto cad drawing. The engineer responsible would check the CAD drawing out of VSS to their local machine, make the necessary changes and check it back in. As a result some documentation was updated and checked back in also. The project manager could then label the entire project “Revision2” as the necessary components were manufactured and the product sold. In 6 month time a customer rings up and asks for a user manual for Revision1. Using VSS we can find the user manual (even though it was changed in revision 2) and get a copy of the manual as at revision 1, this can then be sent to the customer without any fear of damaging the revision 2 manual.

Connecting to a database

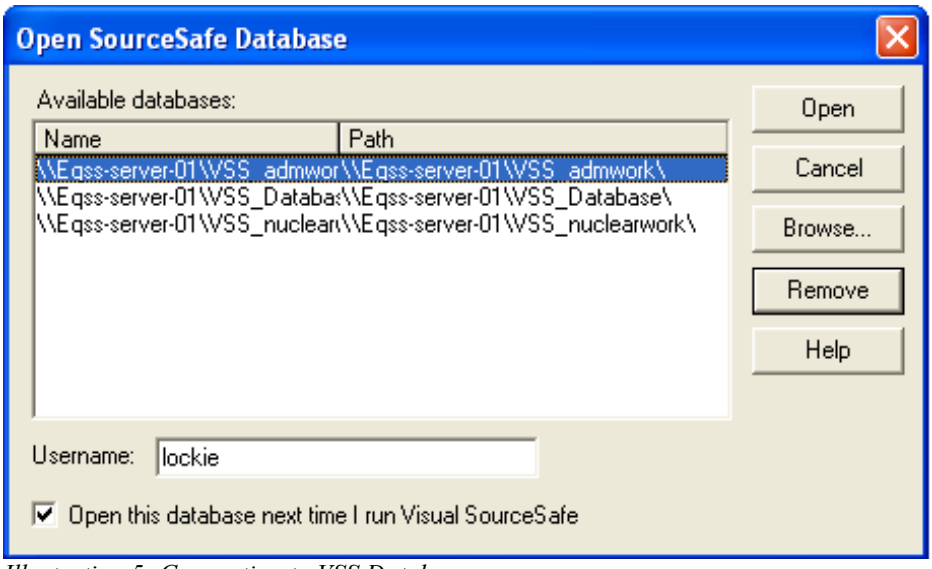


Illustration 5: Connecting to VSS Database

As a user you will need to connect to a database which is located on the server. Depending on what involvement you have in a project may depend on what rights you have to change information within a project. You can only have one database open at a time.

From the file menu in VSS choose “Open”.

You might need to browse to the server to find the srcsafe.ini file located in a source safe database. (See Below)

Databases

There are 3 databases in existence, you should connect to a database dependant on what project you are currently working on

Company Category	*Database Path*
EQSS	\\eqss-server-01\VSS_Database\
ADM	\\eqss-server-01\VSS_admwork\
NS	\\eqss-server-01\VSS_nuclearwork\

Table 12: VSS Databases

Setting Working Directory

It is very important to ensure that your working directory is always set correctly.

You should only need to do this once for each database. When your using VSS, the copies of the work your editing are stored on your local machine. Example:

Database	*Local Path*
EQSS	C:\eqsswork\
ADM	C:\admwork\
NS	C:\nuclearwork\

Table 13: VSS Working Directories

And as such you will need to ensure that the root directory of a project ($/) is set to the correct directory. You will only ever need to do this once.

For Example in the ADM Database:

Illustration 6: Set Working Directory - Step 1

Select The ($/) folder from the top of the tree and right click with your mouse.

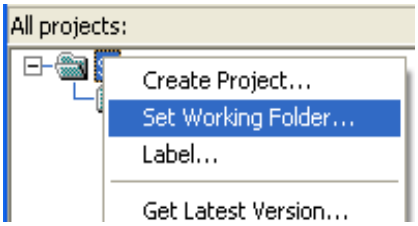


Illustration 7: Set Working Directory - Step 2

The select “Set Working Folder”

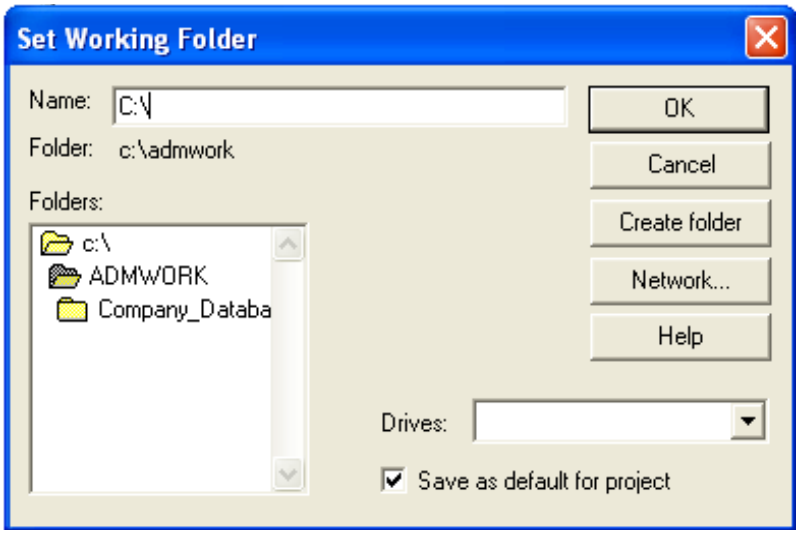


Illustration 8: Set Working Directory - Step 3

Enter C:\

Press OK to continue.

Your working folder is now set, you should not need to do this ever again for this database.

Shadow Folders

As files are checked in to VSS, the files are made read-only and shadowed on our server.

Category	*Shadow Folder*
EQSS	\\eqss-server-02\eqsswork\
ADM	\\eqss-server-02\admwork\
NS	\\eqss-server-02\nuclearwork\

Table 14: VSS Shadow Folders

This ensures that all project information is available to everyone in the company at any time, even if they are not a user of VSS. All information in the shadow folders is read only and MUST NOT be changed.

Creating A Project

Under the root directory of a VSS database ($/) are a list of the projects.

Example of the eQSS Database:

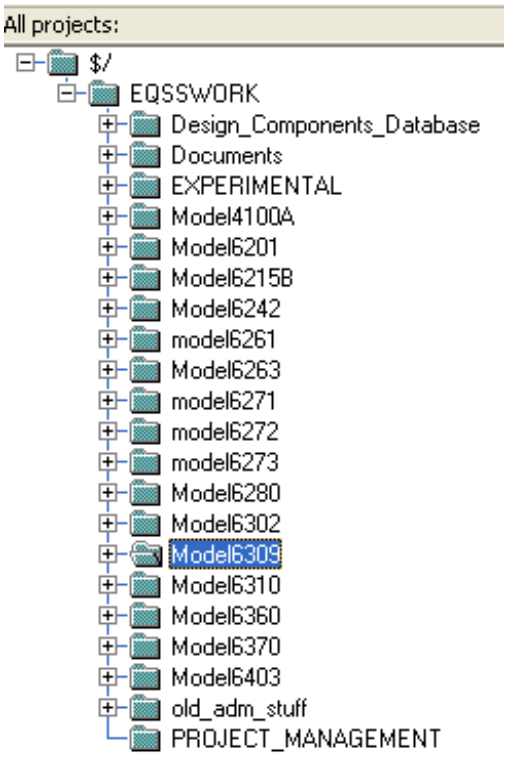


Illustration 9: Create Project - Step 1

Please note the folder structure.

To create a project of your own:

(I will use the ADM database to demonstrate)

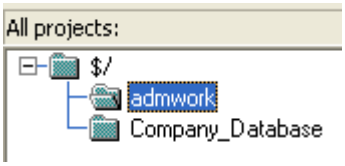


Illustration 10: Create Project - Step 2

Select the ADM Work Database from ($/)

Right Click on “admwork” and select Create Project

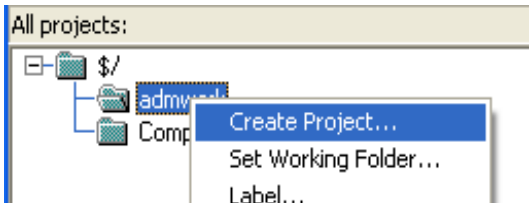


Illustration 11: Create Project - Step 3

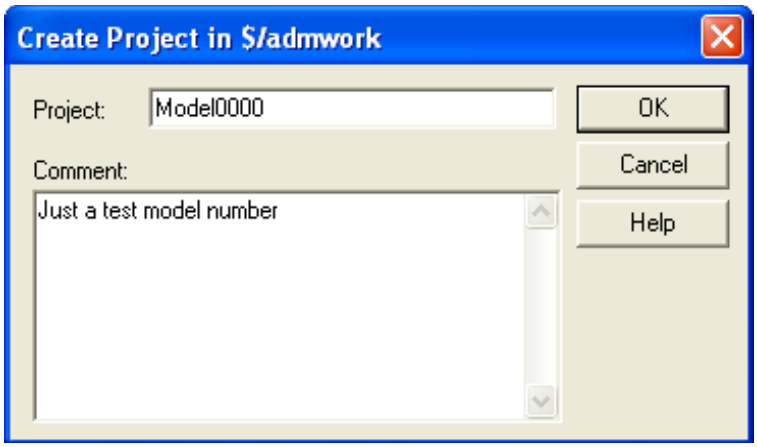


Illustration 12: Create Project - Step 4

In the dialogue box, type in your project name, and a comment for the project. Then select “OK”.

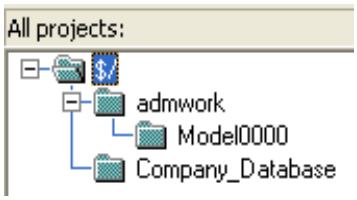


Illustration 13: Create Project - Step 5

You will then see the new model number project created under ADM work.

Directory Structure

In keeping with standards each project will have a standard directory structure, this may vary slightly between projects.

A Project should contain the following directories

Name	*Description*
Documents	All documents, stored in appropriate folders related to the project
Drawings	All auto cad, or inventor drawings, scans of hand drawings, etc.
Graphics	All graphics, including photographs, line drawings, mock images, etc.
Protel	Altium Designer (Protel) projects
VHDL	VHDL files and test benches
Firmware	Firmware source files
Experiments	Experimental data, test applications, etc.

Table 15: VSS - Example Directory Structure

Please note that all directories should start with a capital letter, and should NEVER contain any spaces. If you need to use a space, please insert an "_" underscore.

Creating the directory structure

The easiest way to create a directory structure under a project is to follow the same procedure to create a project:

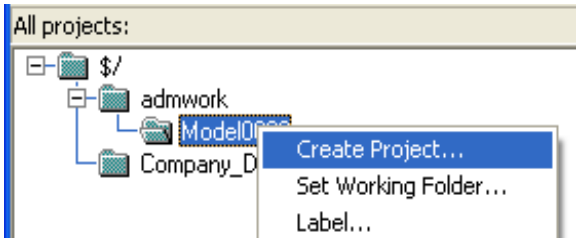


Illustration 14: Create Directory - Step 1

Select the project you wish use, right click and select "Create Project" For this example I am going to create the Documents directory

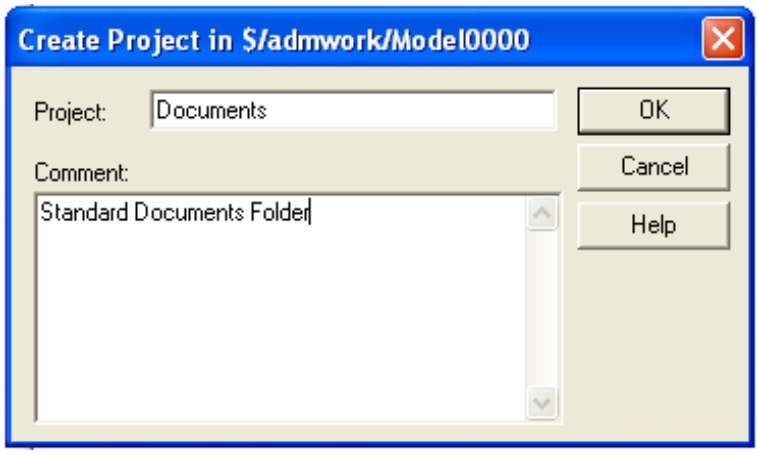


Illustration 15: Create Directory - Step 2

Enter the name of your Project (“Documents”) and a brief description. Press OK

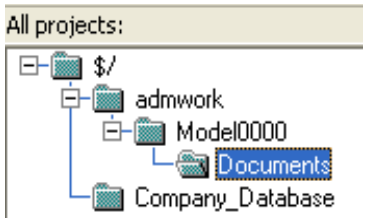


Illustration 16: Create Directory - Step 3

You will then see the documents folder appear in the project.

Adding A Folder

So you've got this far and have created a documents folder in the VSS database. But how do you get the folder on your computer so as you can add files to it. The easiest way is to use “Get Latest Version”. Only do this if you have just created a project or directory and no files exist.

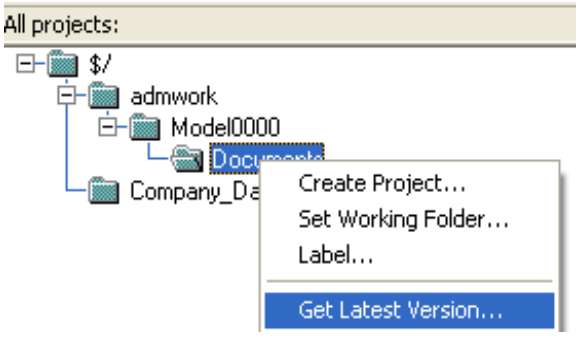


Illustration 17: Adding Folder - Step 1

Browse to the folder you've just created and select “Get Latest Version”.

Always ensure that “Recursive” check box is checked, and select OK. You will not need to fill in any other information.

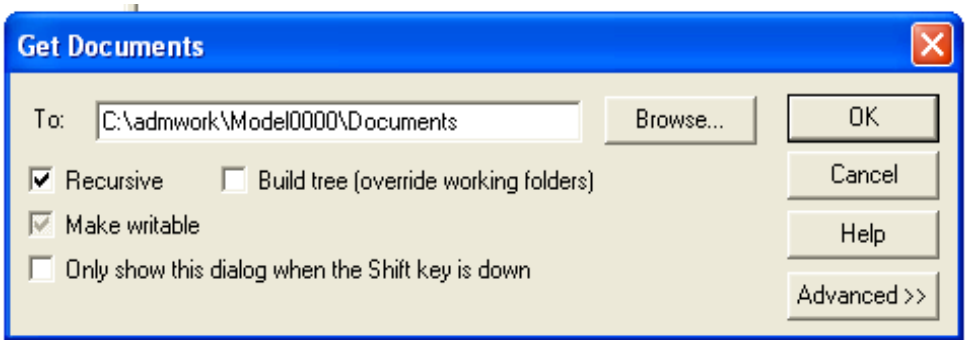


Illustration 18: Adding Folder - Step 2

You will then be prompted with a dialogue box to create the folder. If the folder name or path is incorrect, call for assistance immediately. It should say “C:\....” and never “\\eqss-server-01\...”

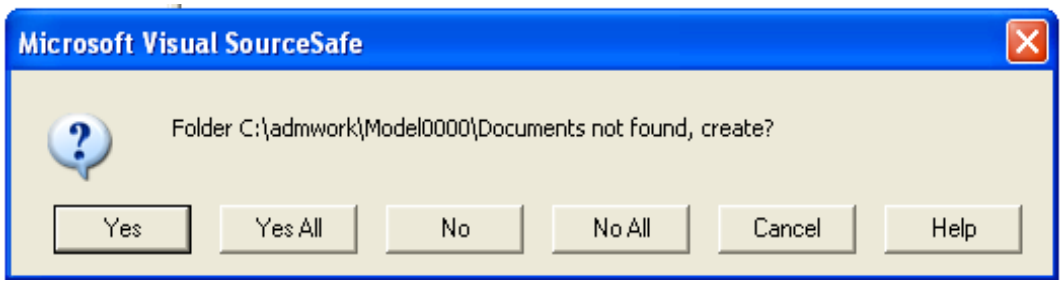


Illustration 19: Adding Folder - Step 3

Press Yes to create the folder on your computer.

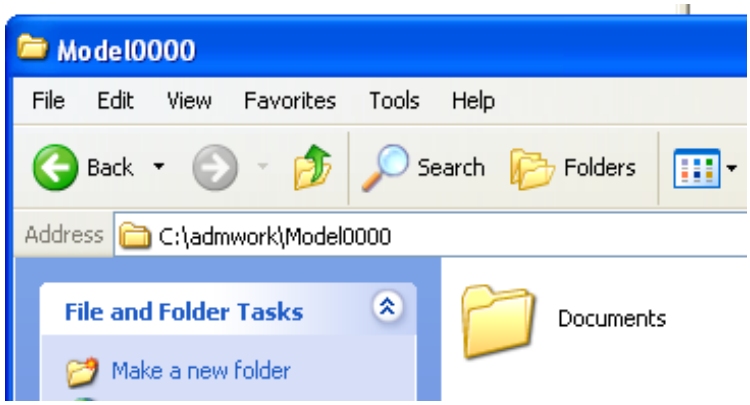


Illustration 20: Adding Folder - Step 4

Using windows explorer you can verify that the folder was created correctly.

To add a file

Suppose I have a text document called example.txt and I create / place the file in the documents folder:

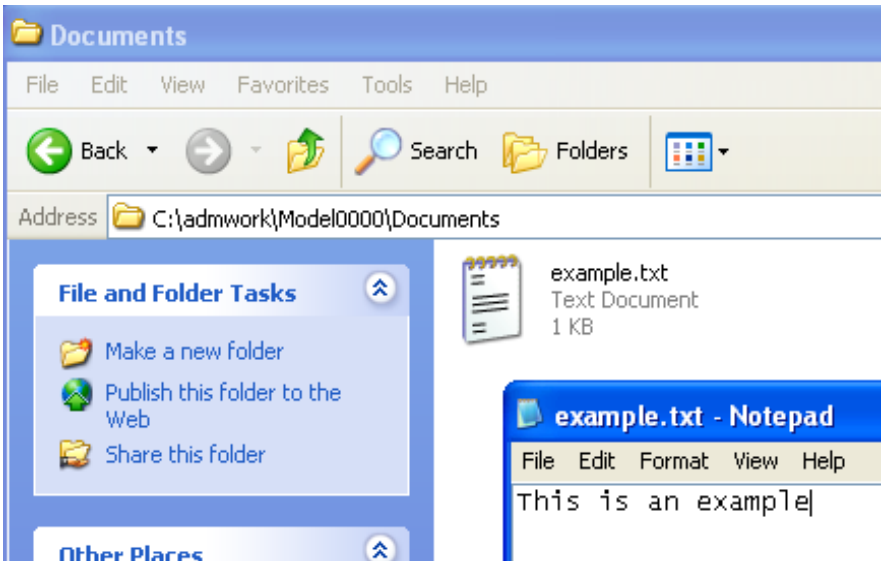


Illustration 21: Add File - Step 1

The file contains some text. “This is an example”

Now to add the file to VSS:

Make sure the file is closed, and you are not currently editing it.

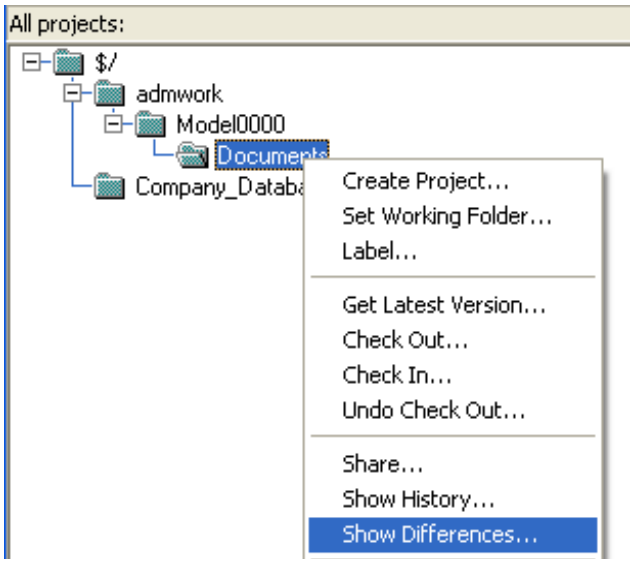


Illustration 22: Add File - Step 2

Right click on the documents folder in VSS and select, “Show Differences”

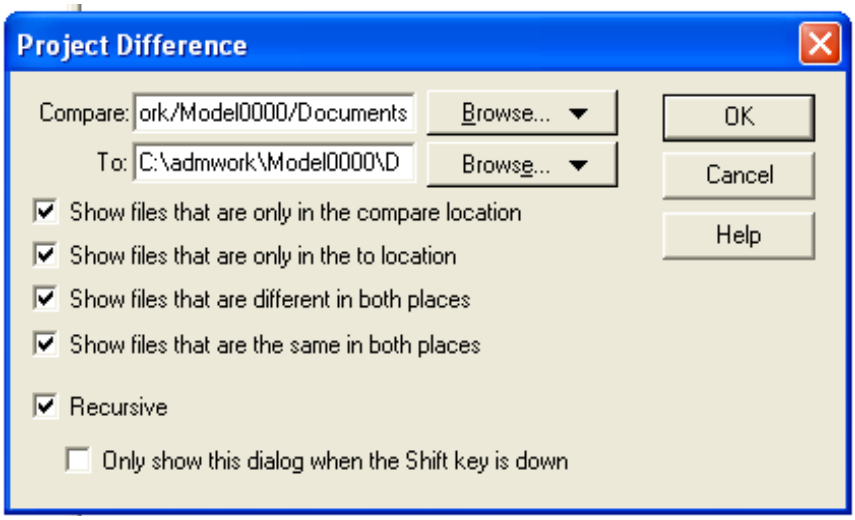


Illustration 23: Add File - Step 3

Ensure that the “Recursive” check box is ticked and select OK.

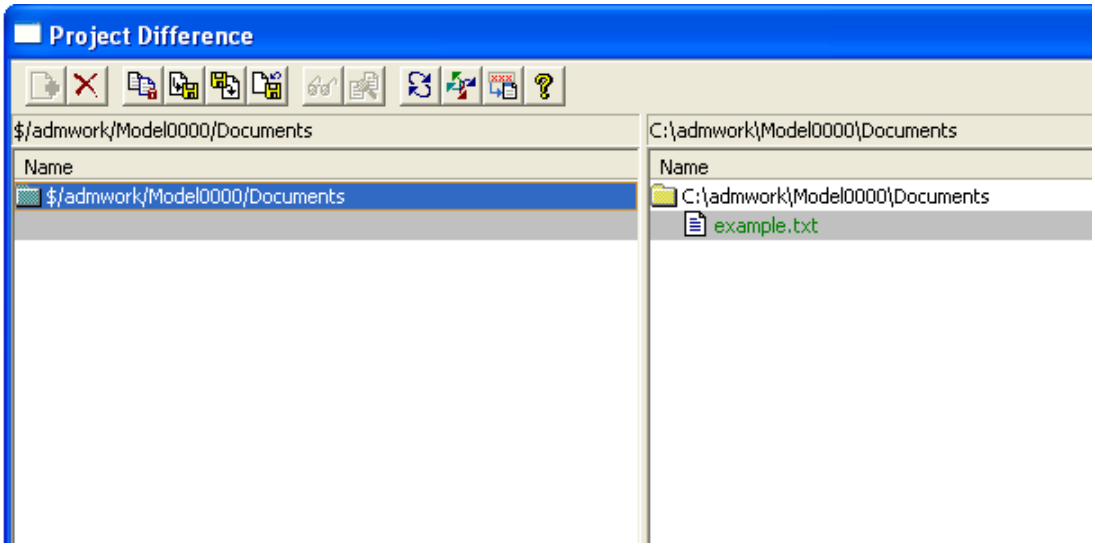


Illustration 24: Add File - Step 4

You will be presented with a dialogue box. The items that appear on the right hand side and are highlighted in green are not in VSS.

Right click on the file you wish to add and select “Add Files”

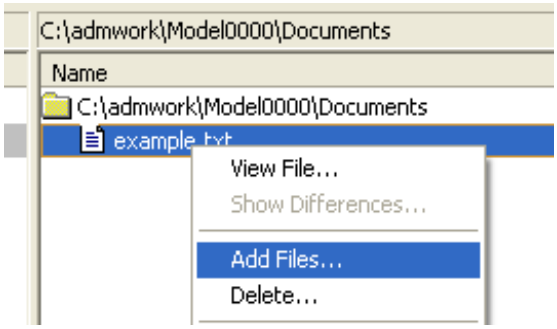


Illustration 25: Add File - Step 5

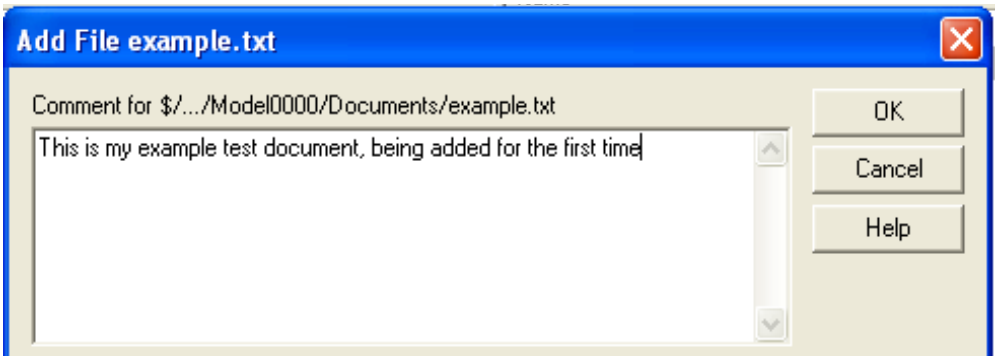


Illustration 26: Add File - Step 6

You will need to add a comment to the file, every file should have a comment.

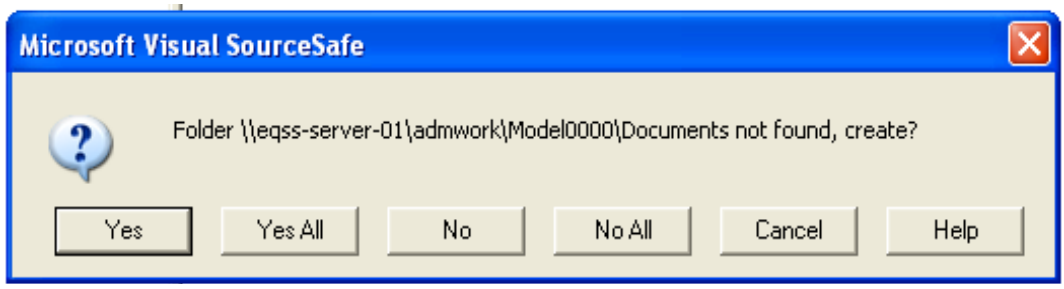


Illustration 27: Add File - Step 7

You will most likely be presented with another dialogue box. This is for the shadow copy of the database on the server.

Select YES.

Close the “Project Difference” dialogue.

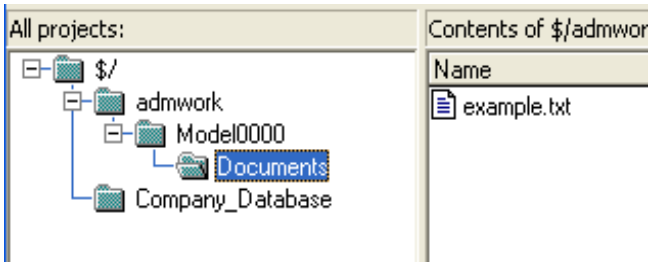


Illustration 28: Add File - Step 8

In the documents folder in VSS you will see the example text file.

Checking Out

You've just added your document to the document folder in the project you've created in VSS. You would like to make a change to the document. Currently because you have the file checked in, it is read-only on your computer and you can not edit it.

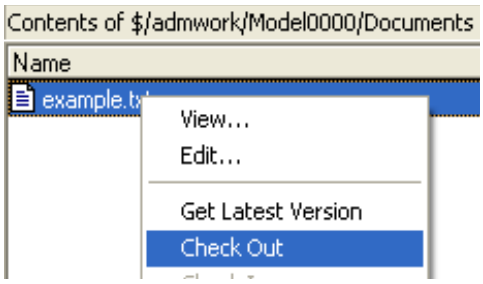


Illustration 29: Check Out - Step 1

Select the file, right click and then select “Check Out”

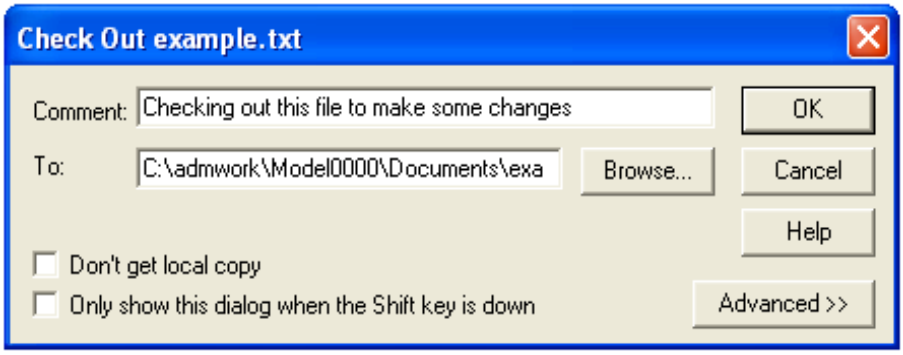


Illustration 30: Check Out - Step 2

You may add a comment if you wish and then select OK.

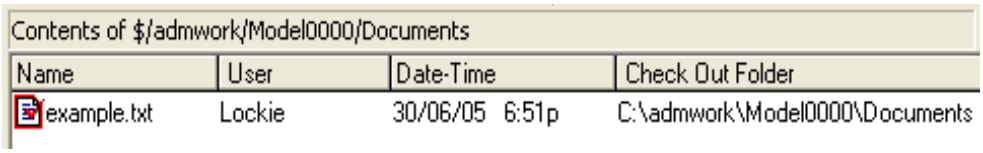


Illustration 31: Check Out - Step 3

You will then see the document has changed to red, the user of the document is "lockie" and it is checked out to a folder on my local machine. I am now free to edit the file, and no-one else can edit the file as it is read-only on their machines.

Checking Back In

I have just edited the file using my favourite editor. The file now looks like:

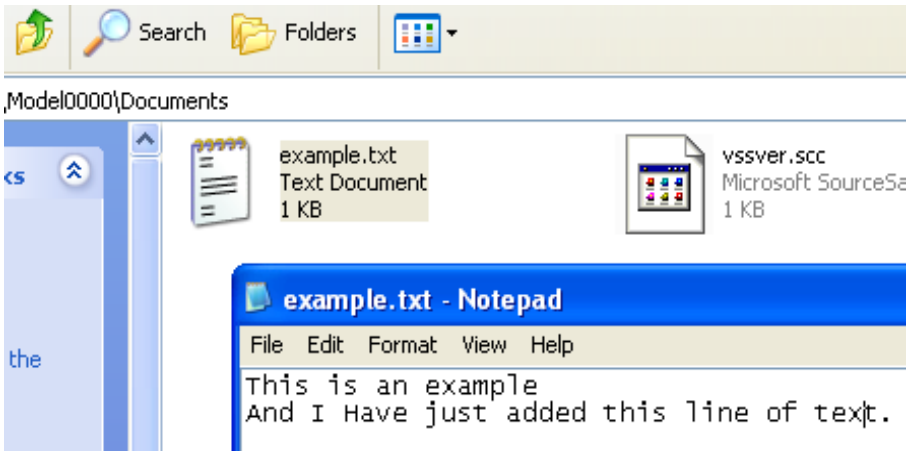


Illustration 32: Check In - Step 1

I have finished editing the file and I wish to check the file back in, so it can become part of the project. I may never need to edit the file again.

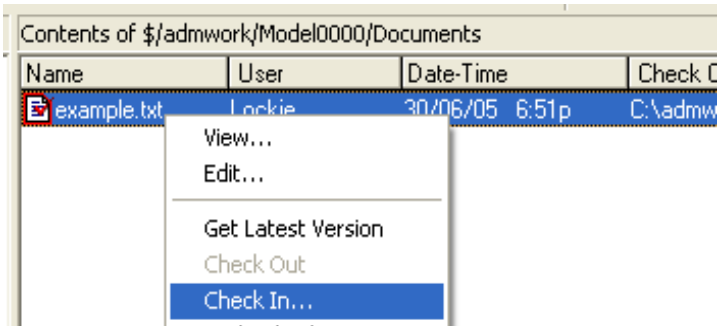


Illustration 33: Check In - Step 2

Select the file, right click and select “Check In”

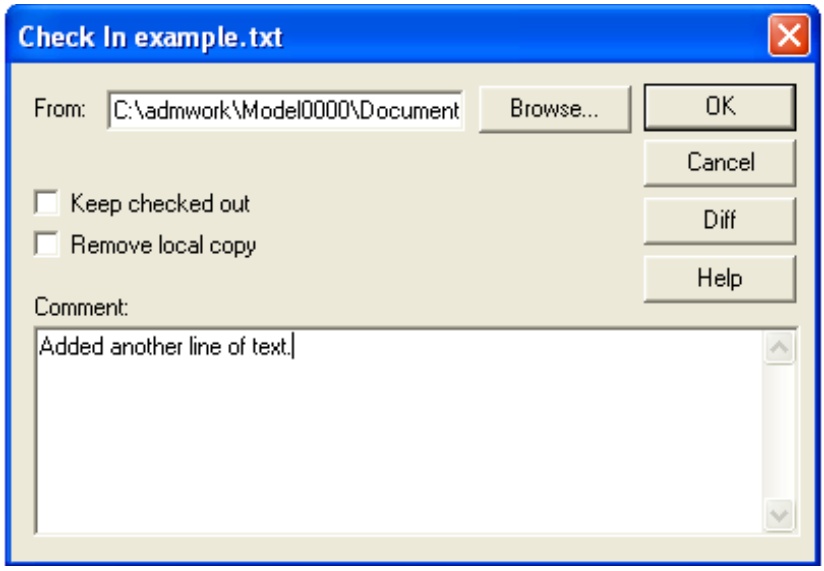


Illustration 34: Check In - Step 3

You must add a comment stating what you have changed. Select OK when you are done. The file is now checked into VSS and is safe.

Version History

You can view the version history of a file by selecting the file and showing its history.

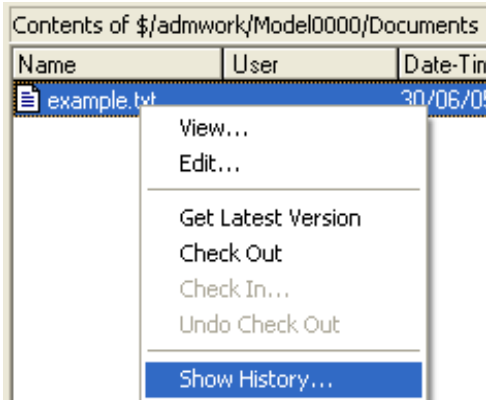


Illustration 35: Version History - Step 1

Click on “Show History

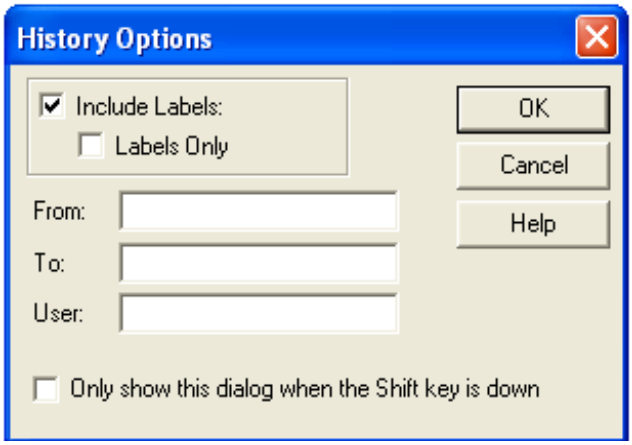


Illustration 36: Version History - Step 2

Just click on OK in the dialogue box. You will then be presented with the history of the file, including what was changed, and who changed it.

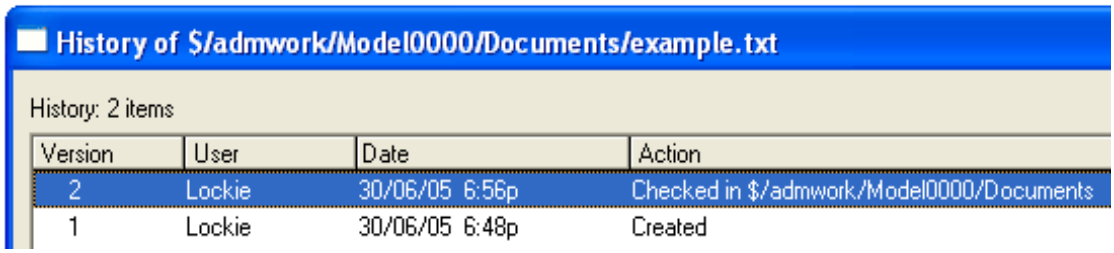


Illustration 37: Version History - Step 3

You can see that version 1 of the file was created at 6:48, and version 2 of the file was checked back in at 6:56pm. You can view more advanced information about what occurred to a file by selecting the file and choosing “Details”

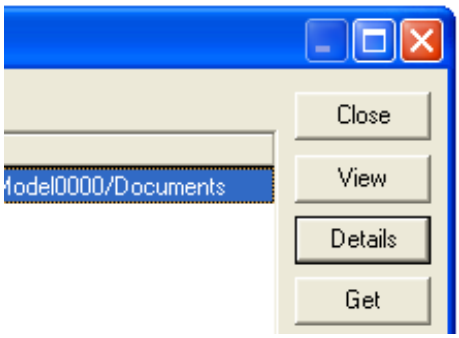


Illustration 38: Version History - Step 4

Choose “Details”

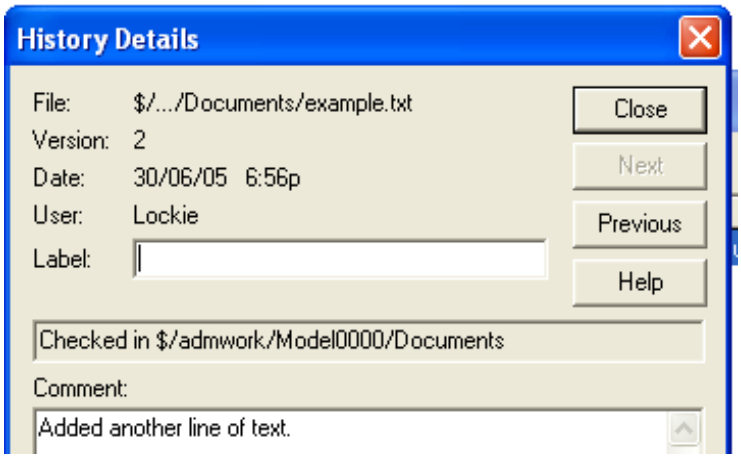


Illustration 39: Version History - Step 5

You can see that file version 2 was checked in at 6:56pm by Lockie and the comment I made was “Added another line of text.”

Labels

Labels are the most important aspect of VSS. An entire project can be given a label. VSS automatically labels every file in the project with the same label, making it very easy to step back to a particular point in the project.

Label Format

The suggested format for labels is:

model_number.discipline.number

Where:

Model_Number = The current model number you are working on.

Discipline =

- HW – Hardware
- SW – Software
- MEC – Mechanical
- VHDL – VHDL
- FW – Firmware
- DOC – Documentation.

Number = An incrementing number.

ECN Process

Proper documenting of Engineering Change Notices (ECN's) is essential to ensure that the contract manufacturer (CM) and ADM are on the exact same page on what is being built. Not only does an ECN need to be produced as a formal request for change, but it also has to be tracked and stored with the appropriate project and parts which are affected. An ECN also needs appropriate company wide approval before being implemented to ensure that there are no issues which may be created by the change in the product.

Relevant parties that may be needed to seek approval are:

- R&D Hardware Manager
- R&D Software Manager
- Manufacturing Manager
- Support Manger
- Marketing Manager
- Regulatory Manager
- Finance Manager[6]
- CEO/ Managing Director[7]

An ECN may be triggered because of a query from the CM i.e. They have found an equivalent material for a cheaper price; from a supplier i.e. A particular component is being replaced with another one; or by the R&D team i.e. Interfacing with support it has been discovered that the most common fault with the system is 'x' and therefore a slight modification to this area would alleviate the problem.

An ECN will be created for **ANY** change that happens to **ANY** part of the product or manufacturing process.

There is a standard ADM ECN template document which must be used when an ECN is being produced. This helps ensure that all relevant information is being collected, and also helps for traceability in the future.

There are two options for an ECN a 'hard roll' or a 'soft roll'. A hard roll may occur when the change must go into manufacturing immediately and therefore any components that were used previously will be scrapped. This may occur for example if it was realized that a electronic component used actually had a fault associated with it and therefore it was decided to move to another brand of component. A soft

6 Usually only in the case when the ECN will bring about either a large cost increase, or scrapping of a large amount of components (and thus wasting a large amount of money)

7 Usually only in the case when the ECN will bring about either a large cost increase, or scrapping of a large amount of components (and thus wasting a large amount of money)

roll might occur if it was found that another manufacturer of the same component could supply it to us cheaper, and therefore all the components already bought should be used up before switching to the new component.

Once the ECN is issued to the CM they need to acknowledge it and state when it is planned to be implemented. When it does get implemented they need to report back the last serial number before the change, and the first serial number after the change so that this information can be recorded against the ECN.

Document Distribution

Work In Progress.

Document Legibility

Work In Progress.

External Documents

Work In Progress.

Obsolete Documents

Control of Records

A very critical component in the Quality System is the control of records.

In general records (evidence) of activities relating to the requirements of the Quality Management System must be kept and in easily accessible and maintainable format.

To assist in this task, many templates and electronic services have been implemented to ensure that all employees (where applicable) have access and the ability to control their records.

VSS Database

To assist in the storage and management of the records, a Visual Source Safe database has been implemented.

Database Location

The database can be found in:

\\eqss-server-01\vss_records

Database Folders

Documentation Standards

Introduction

This section details the necessary information to produce and manage a document. Any document used in; or related to, a final product must follow these documentation standards. Upon completion of a document, the nominated QA officer will check the documents compliance with this set of standards. In general all documents will be produced using the OpenOffice suite of tools.

Requirements

This section details the specific requirements for each document as per the guidelines set out in AS9001:2000

Structure Requirements

The table above lists the structural requirements for each document. The overall structure of each document will differ slightly based on the content of the document, however in general, all documents must include this information.

Item	*Requirement*
1.	Front Page 1. Must contain the company letter head at the top of the page. This must include the companies ABN. 2. Must contain the major category heading using the style “heading” 3. Must contain the minor category heading using the style “sub_heading” 4. May contain a graphic of the product or process being described.

Item	*Requirement*
2.	Second Page 1. Must contain the document identifier (document file name) 2. Must contain the location of the document as per the users local working folder from VSS 3. Must contain the contributors and details of how to contact them 4. Must contain a brief abstract of the document which must be set as a section for linking outside of the document. 5. Must contain the documents revision status. 6. Must contain the warning notice about controlled documents, together with information about obtaining the latest version.
3.	Third Page 1. Must contain a revision history table. The table entries must be in reverse chronological order. This table must be manually updated.
4.	Fourth Page 1. Must contain a list of the documentation conventions, this includes graphical symbols, text, etc. This list must be linked to the companies documentation conventions document and must not be manually entered.
5.	Fifth Page 1. May contain any legal notices
6.	Sixth Page 1. Must contain the table of contents. This table of contents must be automatically generated and must not be manually entered.
7.	Last Page 1. Must contain an index of illustrations (if used) 2. Must contain an index of tables (if used) 3. Must contain an alphabetical index (if used) 4. Must contain a table of references (if used) 5. All indexes must be automatically generated (except for references) and must not be manually entered.
8.	Document Header / Footer 1. Generally the header must remain blank 2. The footer must contain the current page, page count and a confidentiality notice in red if necessary.

Table 16: Document Structural Requirements

Document Headings

Document headings are used in documents to clearly differentiate major and minor headings.

The table above describes the table headings used in a document.

Item	*Requirement*
1.	Heading Level 1 1. Must use style “heading 1” 2. Must not be numbered 3. Must be Arial, 26, Bold, Blue 4. All Level 1 headings must be on a new page designated by a manual page break.
2.	Heading Level 2 1. Must use style “heading 2” 2. Must not be numbered 3. Must be Arial, 20, Bold, Blue 4. Must be indented 5mm 5. Where Practical all level 2 headings must be on a new page designated by a manual page break.
3.	Heading Level 3 1. Must use style “heading 3” 2. Must not be numbered 3. Must be Arial, 16, Bold, Blue 4. Must be indented 10mm
4.	Heading Level 4 5. Must use style “heading 4” 6. Must not be numbered 7. Must be Arial, 14, Bold, Blue 8. Must be indented 15mm
5.	Subsequent Headings 1. Generally must be avoided, re-work the document if you have too many levels deep.

Table 17: Document Headings

Captions

Captions are used for identifying resources within a document. These resources include tables, illustrations and graphics.

The table above lists the requirements for captions.

Item	*Requirement*
1.	All Tables, Illustrations, Graphics, Pictures, Notes, etc. must contain a caption.
2.	Captions must be placed at the bottom of the item and must be left justified.
3.	Captions must be used to generate the indexes as per item 7 in Structure Requirements

Table 18: Structure Requirements - Captions

Cross References

Cross references are used for referencing objects in a document to in-line text. References are required to maintain documents that can be easily maintained.

Item	*Requirement*
1.	1. Cross References must be used when referring to any item in a document. 2. Cross References must be set in the document for each and every item that requires referencing within the documents text. 3. Cross References must not be manually entered

Table 19: Structure Requirements - Cross References

Equations

Equations such as $y = mx + c$ or symbolic numbers such as ^{137}Cs must be formatted in equation writer. Equation writer ensures that all text of a mathematical nature is presented in the same format and ensures consistency across our documents.

Document Templates

In general all documents should be based on a template. Various templates exist for both the styles and layout of a document exist. Templates are to be used for all documents to ensure conformity with the above listed requirements. A change in the template will result in a change in all documents based on that template.

List Of Templates

To be Revised.

Indexes and Tables

Indexes and tables are designed to automatically collate and tabulate the information contained in the headings, captions and bibliography.

The following requirements relate to the use of indexes and tables.

Item	*Requirement*
1.	Table Of Contents 1. Must appear in the first few pages of a document 2. Must show all heading levels
2.	Table of Illustrations 1. All illustrations must be automatically tabulated in a table of illustrations
3.	Table of Tables 1. All tables in a document must be automatically tabulated in a table of tables
4.	Bibliography 1. Any text in a document where a reference to an external source is made must be added to a bibliography. 2. The bibliography must be stored in a database for the current project.

Table 20: Bibliography's

Alphabetical Index

Where practical an alphabetical index must be maintained for all documents.

Images

Any images placed in documents must be linked into the documents, and not inserted. The link must point back to the path of the image (say from an model rendering).

Management Responsibility

This section describes the responsibility of upper management with respect to maintaining the integrity of the Quality Management System.

Requirements

These requirements have been extracted from the AS9001:2000 document, and referenced accordingly.

Management Commitment[8]

Please see Management Commitment on page 63

Item	*Requirement*
1.	Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements.
2.	Top management shall provide evidence of its commitment to establishing the quality policy
3.	Top management shall provide evidence of its commitment to ensuring that quality objectives are established
4.	Top management shall provide evidence of its commitment to conducting management reviews
5.	Top management shall provide evidence of its commitment to ensuring the availability of resources

Table 21: Management Commitment - Requirements

Customer Focus[9]

Please See Customer Focus on page 66

Item	*Requirement*
1.	Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction

Table 22: Customer Focus - Requirements

8 Referenced Directly From AS9001:2000
9 Referenced Directly From AS9001:2000

Quality Policy[10]

Item	*Requirement*
1.	Top management shall ensure that the quality policy is appropriate to the purpose of the organization
2.	Top management shall ensure that the quality policy includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system
3.	Top management shall ensure that the quality policy provides a framework for establishing and reviewing quality objectives
4.	Top management shall ensure that the quality policy is communicated and understood within the organization
5.	Top management shall ensure that the quality policy is reviewed for continuing suitability

Table 23: Quality Policy – Requirements

Planning Quality Objectives[11]

Item	*Requirement*
1.	Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization.
2.	The quality objectives shall be measurable and consistent with the quality policy.

Table 24: Planning - Quality Objectives

Quality Management System Planning[12]

Item	*Requirement*
1.	Top management shall ensure that the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives
2.	Top management shall ensure that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented

Table 25: Planning - Quality Management System Planning

10 Referenced Directly From AS9001:2000
11 Referenced Directly From AS9001:2000
12 Referenced Directly From AS9001:2000

Responsibility & Authority[13]

Please see Responsibility, Authority and Communication on page 67

Item	*Requirement*
1.	Top management shall ensure that responsibilities and authorities are defined and communicated within the organization

Table 26: Responsibility, Authority & Communication - Responsibility & Authority Requirements

Management Representative[14]

Please see Management Representative on page 67

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes

Item	*Requirement*
1.	Ensuring that processes needed for the quality management system are established, implemented and maintained.
2.	Reporting to top management on the performance of the quality management system and any need for improvement
3.	Ensuring the promotion of awareness of customer requirements throughout the organization.
4.	The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

Table 27: Responsibility, Authority & Communication - Management Representative Requirements

Internal Communication[15]

Item	*Requirement*
1.	Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

Table 28: Responsibility, Authority & Communication - Internal Communication Requirements

13 Referenced Directly From AS9001:2000
14 Referenced Directly From AS9001:2000
15 Referenced Directly From AS9001:2000

Management Review Requirements

General[16]

See Management Review on page 68

Item	*Requirement*
1.	Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.
2.	Records from management reviews shall be maintained (see 4.2.4).

Table 29: Management Review - General Requirements

Review Input[17]

The input to management review shall include

Item	*Requirement*
1.	Results of audits
2.	Customer feedback
3.	Process performance and product conformity
4.	Status of preventive and corrective actions
5.	Follow-up actions from previous management
6.	Changes that could affect the quality management
7.	Recommendations for improvement

Table 30: Management Review - Review Input Requirements

16 Directly Referenced From AS9001:2000
17 Directly Referenced From AS9001:2000

Review Output[18]

The output from the management review shall include any decisions and actions related to

Item	*Requirement*
1.	Improvement of the effectiveness of the quality management system and its processes
2.	Improvement of product related to customer requirements
3.	Resource needs

Table 31: Management Review - Review Output Requirements

18 Directly Referenced From AS9001:2000

Management Commitment

Introduction

This section describes and documents the commitment management has to its Quality Policy in the following areas.

1. Improving the quality of its management system
2. Establishment of the quality policy
3. Ensuring quality objectives are being met
4. Ensuring management reviews are conducted
5. Ensuring that management makes the necessary resources available.

QMS Development & Implementation

The quality management system has been developed and implemented within A&DM. A&DM recognises the importance of a Quality Management System and as such, has put the infrastructure and resources in place to ensure that everyone covered by the scope of the QMS has access to the necessary resources.

These include:

- Electronic web access to parts database, assembly lists, customers and supplier databases, materials, etc.
- Electronic access to a revision control system which ensures the correct documentation is delivered to the correct parties.
- Electronic web access to an always “up to date” copy of the Quality System Manual which can be accessed by all staff.
- An assigned person to maintain the quality management systems, including infrastructure and training.

Quality Policy Establishment

The quality policy has been established within the guidelines of AS9001:2000.

Management Reviews

Management reviews are scheduled to take placed every 6 – 12 months to ensure that the quality management system is functioning correctly and to ensure it gets updated accordingly.

Resource Availability

A&DM makes available a dedicated staff member to control and maintain the Quality Management System. Please see Management Representative on page 67 for further details.

Customer Focus

Privacy Policy

Collection and Storage – Personal Information

In the course of our business, personal information such as names, addresses, may be collected and held, for use in fulfilling the primary purposes intended. This includes information required to provide customers and others with products and services. Information retained on our database is also used to inform stakeholders and customers of relevant developments in procedures or products which we believe is either necessary or will assist in the use of the product or service we offer.

Unless we are informed otherwise, we will continue to use the information collected in this manner. Accuracy of information is important to us and changes or corrections to information held will be welcomed at any time.

Normally we collect information from the persons concerned and they are under no obligation to provide it. However without certain information we may be unable to provide the products and services, or facilitate the preferred payment method. Most personal information is stored in-house.

All reasonable steps are taken to protect the security of the personal information held, be it stored in electronic or hard copy form.

Customer Satisfaction

Customer satisfaction is important in ensuring the product or service being delivered meets the requirements it was designed for. As a result A&DM has procedures in place to ensure customer satisfaction data can be gathered and added into the next revision of the product.

The following items are measured:

- Direct communication with the customer to gain feedback
- Feedback via warranty and returns
- Feedback from service department
- Feedback via technical help desk
- Feedback from advertising material, such as web site hits and magazine response forms.
- Feedback via performance data systems in embedded software / hardware.

Responsibility, Authority and Communication

Introduction

This section describes who is responsible person for the quality management system, who has authority and the functional position requirements.

Management Representative

Lachlan Grogan has been appointed the management representative for A&DM for the purposes of Quality Assurance. Lachlan Grogan has been appointed this position due to his vast experience and knowledge gained through upper management positions.

Please see position descriptions for details of QA officers requirements.

The following duties are required of the management representative:

QMS General

This requirement sees the management representative ensure that the quality system is established, implemented and maintained and reviewed on a regular basis.

Throughout A&DM the management representative has to meet the following requirements.

Item	*Requirement*
1.	Ensuring that the quality system is established and meets the requirements of this manual.
2.	Ensuring that throughout the company that the quality system is implement and all staff are aware of the quality requirements.
3.	Ensure that the quality manual is maintained.

Table 32: Management Representative - QMS Requirements

Reporting

This requirement ensures that the management representative reports to top management the performance and quality of the management system and what improvements need to be maintained.

QMS Awareness

This requirement ensures that the management representative ensures that everyone throughout the organisation is aware of the Quality System.

Management Review

This section discusses the requirements by senior management to review A&DM's quality management system.

General

The management review of the quality system shall:

1. Be conducted at regular intervals no greater than 6 months apart.
2. Be conducted when ever there is a contention or lack of information in the quality manual
3. Be conducted as a result of changing project demands.
4. Be conducted as a result of a large rate of change in business activity.

Review Input

In general the inputs to a management review shall include

1. Results of any previous audits on the quality system, including any outside audits.
2. Customer Feedback
3. Process performance and product conformity,
4. Status of preventive and corrective actions,
5. Follow-up actions from previous management reviews,
6. Changes that could affect the quality management system
7. Recommendations for improvement.

Review Output

The output from the management review shall include any decisions and actions related to:

1. Improvement of the effectiveness of the quality management system and its processes
2. Improvement of product related to customer requirements
3. Resource needs.

Resource Management

Requirements

Provision Of Resources[19]

Item	*Requirement*
1.	The organization shall determine and provide the resources needed to implement and maintain the quality management system and continually improve its effectiveness
2.	The organization shall determine and provide the resources needed to enhance customer satisfaction by meeting customer requirements.

Table 33: Provision of Resources – Requirements

Human Resources[20]

Item	*Requirement*
1.	Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

Table 34: Human Resources - General Requirements

19 Referenced Directly From AS9001:2000
20 Referenced Directly From AS9001:2000

Competence, Awareness & Training[21]

Item	*Requirement*
1.	Determine the necessary competence for personnel performing work affecting product quality
2.	Provide training or take other actions to satisfy these needs,
3.	Evaluate the effectiveness of the actions taken
4.	Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives
5.	Maintain appropriate records of education, training, skills and experience (see 4.2.4).

Table 35: Human Resources - Competence, Awareness & Training Requirements

21 Referenced Directly From AS9001:2000

Company Structure & Authority

Organizational Information

Responsibility

Analogue and Digital Measurements Pty. Ltd (A&DM) implements its quality assurance programme as normal operation in the following areas:

Area	*Description*
1 – Design	Ensuring that all design work is carried out in a controlled manner, using proven tools and methodologies by competent engineers.
2 - Manufacture	Ensuring that all design information is conveyed to the parties responsible for manufacturing, and that each party ensure adherence to the manufacturing requirements.
3 – Testing	Ensuring that the design, and any subsequent designs are tested in accordance with the competent authorities regulations.
4 - Documentation	Ensuring that all documentation related to the items listed in this table is written and maintained to a strict set of standards.
5 - Use	Ensuring that the use of any product or service covered by this quality system is documented correctly as per the guidelines covered in this quality system.
6 - Maintenance	To ensure that any maintenance work performed on critical components is performed to a set of documented standards.
7 - Inspection	

Table 36: QA Programme - Target Areas

The management of A&DM is responsible for the continued implementation of this programme on all current and future projects.

Authority

A&DM has an established organisational structure with procedures which ensures that in all areas of quality assurance, the assignment and responsibility for each area, is:

Item	*Details*
1.	Achieved and maintained by appropriately qualified and trained personnel
2.	The the conformance of Item 1 (above) is verified by individuals or groups not directly responsible for work performed
3.	That quality verification and reporting to management heir achy precludes conflict of interest (i.e. Independent from costing and scheduling), in management areas of responsibility.
4.	All personnel involved with Quality Assurance have the authority and responsibility, in writing, to stop at any time, the further process of any non conformal material, work, shipment, delivery or installation with direct recourse to upper management.
5.	QA managers have the further responsibility, in writing, to supervise further processing after corrections, for any procedural reason, have been made.

Table 37: QA Programme - Authority

Structure

The current organisational structure of A&DM is detailed below. This includes both direct and indirect lines of communication.

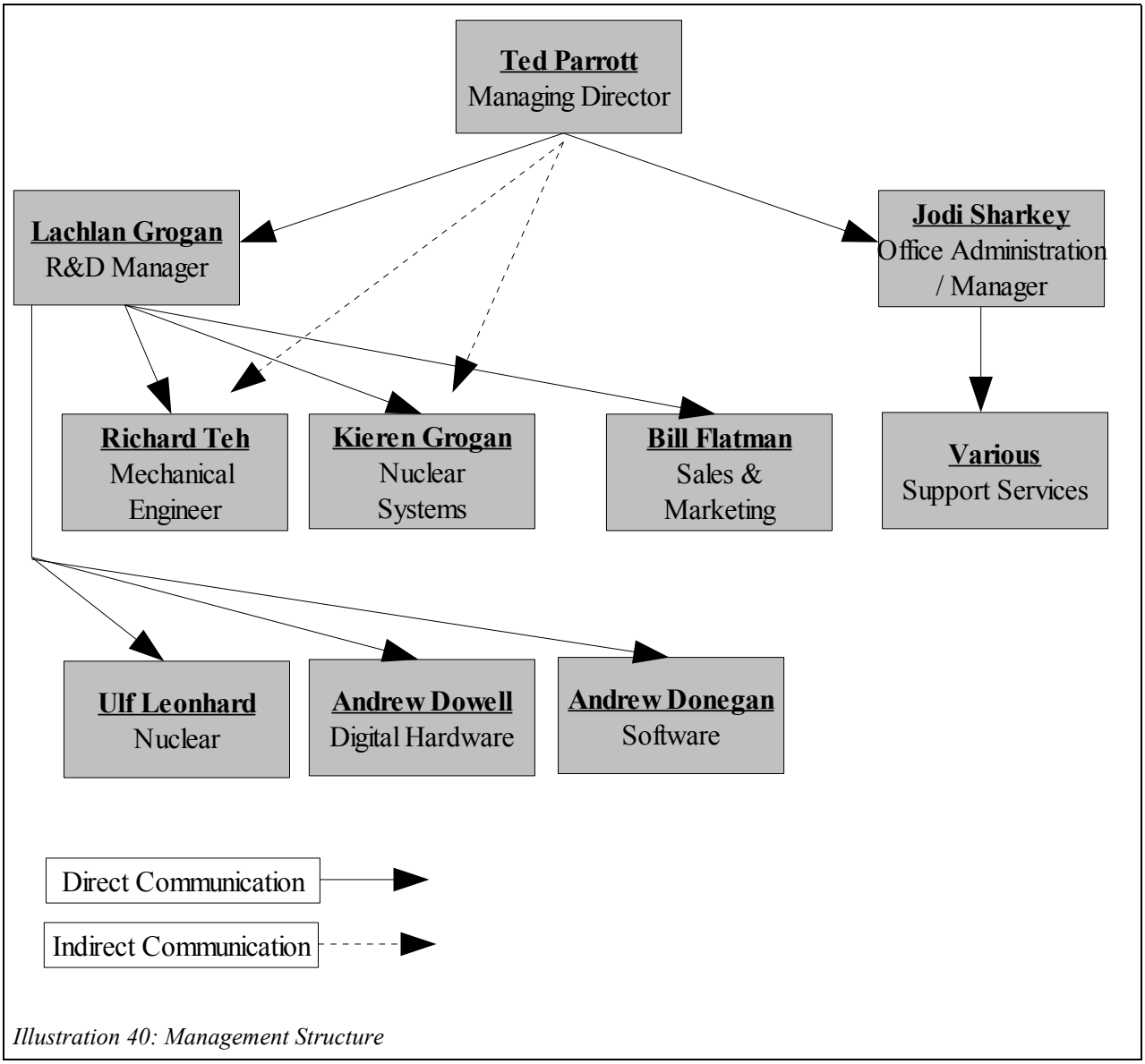


Illustration 40: Management Structure

Position Descriptions

Each employee in A&DM has a position description which clearly describes their roles, responsibilities and rights within the organisation.

Ted Parrott – Managing Director

As the sole owner, is responsible for the financial status of the company

CHARACTERISTICS OF POSITION

Key Responsibilities

The Managing Director will manage and lead the company managers to design, develop and maintain the Companies software and hardware systems.

- Ensure there is sufficient resources to carry out the day to day activities of the company.
- Carry out all legal responsibilities for the operation of the company as set down by ASIC.
- Interface with the Australian Tax Office.
- Ensure company and company staff licensing meet the state regulator requirements.
- Maintain both local and international contacts for sales and purchasing
- Interface with regulators for equipment approvals and supervise perpetration of submission documents.
- Back up support for the engineering staff.
- Sales for both ADM Nuclear and eQss. Preparation of quotations and contracts.
- Design of Industrial Source Holders.
- Design of Type A transport packages.
- Design of Type B(U) transport packages.
- Design of storage casks.
- Make final decisions for the commitment and continued investigation of development issues as outlined by the R&D manager and his support staff.

Skills

- 45 Years experience with radiation measurement and isotopes.
- 50 years experience with load cells and associated technologies.
- 30 year experience with operating a business.
- 40 years experience with the design and manufacture of electronic. measuring equipment.

Decision Making Authority

- the Managing director has ultimate authority in all aspects of the company operation.

Lachlan Grogan – R&D Manager

CHARACTERISTICS OF POSITION

Key Responsibilities

The Research & Development Manager will manage and lead the team to design, develop and maintain the Companies software and hardware systems.

A key participant in the company for innovation, excellence and quality, the individual will help identify and document customers requirements and perform any other duties as required by the Managing Director.

- Responsible for determining Company direction, product development and sales strategies for the eQSS product range.
- Coordinates technical support, development and construction
- Responsible for billing technical support related activities to customers
- Overall responsibility in the absence of Managing Director
- Responsible for all aspects of employees directly under his control.
- Assist when necessary in meeting our commitments with our Nuclear Division

Key Relationships

- Reports internally to the Managing Director
- The individual will need to interact directly and responsibly with other employees, suppliers and customers

Decision Making Authority

- Right to hire personnel authorised by the M.D
- Right to dismiss personnel that do not meet the program requirements
- Lead employees to develop sales and technical strategies
- Provide management, leadership and direction in technical design and implementation decisions
- Authorised for the purchase of hardware, software and components related to Development and Manufacturing.

- Authorized to give instructions to all A&DM employees
- Authorized to bill customers for technical support and other support activities

Problem Solving Responsibilities

- Work through employee problems and relationship issues with employees
- Identify key issues from a variety of information
- Propose and develop alternate solutions for customer requirements that are based on logical assumptions and factual information that take in to consideration constraints, business drivers, technology available, etc.
- Work through challenging technical issues

MINIMUM COMPETENCIES REQUIRED

Experience

- At least 5 years experience developing intelligent hardware systems
- Experience managing and leading other employees

Skills

- Project Management and leadership skills
- Hardware analysis and design
- Software Systems Design
- Excellent communication and interpersonal skills
- Quality Systems Awareness

Education

- Bachelor of Electrical/Computer Systems Engineering

Kieren Grogan – Nuclear Systems Engineer

Characteristics Of Position

Key Responsibilities

The Product Support Engineer (Radiation) is a key participant in the company for innovation, excellence and quality. The individual will help identify and document customers requirements, provide technical support, service, training, development and perform any other duties as required by the Managing Director. Your key responsibilities are outlined below, however you are to provide a backup for the development and ongoing support to the eqss program, at which time you will be on loan to eQSS and Responsible to the R&D Manager.

- Product installation, testing and maintenance
- Servicing customers equipment (particularly equipment with Isotopes)
- Development of Radiation Transport Container & Source Holder Products
- Promotion & Implementation of our Wipe Test Service
- Promotion & Implementation of Radiation Management Plans
- Develop equipment to enhance the operation of Blood Product Irradiators
- Develop an Instrument to measure & categorise Isotopes that may be evident in or on persons entering a building.
- Build & Promote a Calibration Rig for Calibration of Survey Meters
- Coordinate technical support and customer service
- Technical documentation including product manuals, installation procedures, test information and service reports
- Responsible for smooth running of downstairs Workshop
- Wherever possible handle the repairs & maintenance that require you, to go on site
- Transport of Radioactive Materials, to the Code of Practice.

eQSS

- When on loan to eqss you will be required to assist in the design and testing of both hardware and software for the crane computer as directed by the R&D Manager.

Key Relationships

- Reports directly to the Managing Director
- When on loan to eQSS reports to the R&D Manager.
- The individual will need to interact directly and responsibly with other employees, suppliers and customers

Decision Making Authority

- Identify and implement the best possible outcomes, taking into consideration occupational health and safety, constraints, technology available etc.
- Interact with and supervise sub contractors building equipment for both Radiation and eQSS divisions.
- Initiate orders to procure the parts or Services necessary to meet your commitments
- Balance the needs & allocate time between the two divisions.

Problem Solving Responsibilities

- Identify key issues from a variety of information
- Work through challenging technical issues

Skills

- Hardware and software design and analysis
- Excellent communication and interpersonal skills

Education

- Bachelor of Electrical/Computer Systems Engineering (or similar).
- Radiation Safety Management.

Bill Flatman – Sales and Marketing

CHARACTERISTICS OF POSITION

Key Responsibilities

The Sales & Marketing Engineer will be responsible for handling the sales and marketing requirements of the 3 company categories being:

- Nuclear Products and Services
- Equipment Safety Products and Services
- Instrumentation

You are key participant in the company for customer interfacing, quality and business development. You will help identify and document company procedures, develop customer relationships and perform any other duties as required by the R&D Manager.

Your specific responsibilities include:

- *Business Development:* You are responsible for further developing the business of A&DM by liaising with potential principle companies, identifying target markets, identifying new products, procedures and technologies. You are expected to spend a minimum of 0.5 days a week exploring new business avenues for the company.

- Documentation: You are required to ensure that all your work is documented as per our quality systems requirements and that no deficits exist in your documentation, database's or activity diaries.

- Company Databases: You are responsible for maintaining the company database lists of customers, suppliers, etc., that relate to your job function. The database's will need you to identify any related target markets and follow up on these markets by way of mail outs (either in electronic or paper format) or by way of phone conversations.

- Document Preparation: From time to time you will be required to review documentation relating to our products and correct the documents for formatting, presentation, etc. You will be responsible to prepare customer documents (printing, binding, etc.) and to ensure

that these documents are presented to the customer in a professional manor.

- *Customer Interface:* You are responsible for interfacing with the customers in a professional manor. When you are required on a customers site you need to ensure that all relevant health and safety regulations are met.

- Inquiry Handling: You are responsible for responding to the majority of customer enquiries for products or services. You must make yourself aware of the products and services that the company has to enable you to respond to any inquiry in a timely and professional manner.

- Marketing: You will need to devote a large amount of your time to marketing the companies products and services. The marketing process starts by entering the target customer in the company database and then preparing the necessary information pack to send out. You will need to make verbal communication with almost every customer before sending marketing information.

- Planning: You will need to maintain a working plan of your sales and marketing strategies and ensure that this plan is visible to the company at all times. You should seek input from other employees for continual enhancement to this plan.

- Quality Systems: The company has a comprehensive set of quality systems which are continually being developed, you will be required to use your skills and experience to add to this quality documentation from time to time.

Key Relationships

- Reports internally to the R&D Manager.
- The individual will need to interact directly and responsibly with other employees, suppliers and customers

Decision Making Authority

- Provide management, leadership and direction in the areas of sales and marketing.
- Authorized to give instructions to A&DM employees on issues related

to your position description.

Problem Solving Responsibilities

- Identify key issues from a variety of information
- Work through any technical or non technical issues that may arise.

MINIMUM COMPETENCIES REQUIRED

Experience

- At least 5 years experience in sales, marketing and quality systems.
- Electronics, Mechanical and management skills.
- Experience communicating with employees and suppliers.

Skills

- Software skills including, MS Office products and CAD Tools.
- Excellent communication and interpersonal skills.

Andrew Dowell – Digital Hardware Engineer

CHARACTERISTICS OF POSITION

Key Responsibilities

The Digital Hardware Engineer will be responsible for the day to day requirements of our electronics activities including design, development, testing, repairs & maintenance, documentation and safety. A key participant in the company for safety, quality and technology, the individual will help identify and document company procedures, develop customer relationships and perform any other duties as required by the R&D Manager.

Your specific responsibilities include:

- *Business Development:* You are responsible for further developing the business of A&DM by liaising with potential principle companies, identifying target markets, identifying new products, procedures and technologies. You are expected to spend a minimum of 0.5 days a week exploring new business avenues for the company.
- Documentation: You are required to ensure that all your work is documented as per our quality systems requirements and that no deficits exist in your documentation or database's for our nuclear based activities. This also means that a complete paper trail must be kept for every nuclear activity.
- Production: You are required to assist where possible in the production of the companies products and services. This may require you to lean new skills or procedures to enable you to complete this requirement.
- Company Databases: Responsible for maintaining the company database lists of customers, suppliers, etc. The database's will need you to identify any related target markets and follow up on these markets by way of mail outs (either in electronic or paper format).
- Document Preparation: From time to time you will be required to review documentation relating to our products and correct the documents for formatting, presentation, etc. You will be responsible to prepare customer documents (printing, binding, etc.) and to ensure that these documents are presented to the customer in a professional manor.
- *Customer Interface:* You are responsible for interfacing with the customers in a professional manor. When you are required on a customers site you need to ensure that all relevant health and safety regulations are met.
- Reporting: Responsible for the generation of reports based on current jobs or activities when required by your manager.

Key Relationships

- Reports internally to the R&D Manager.
- The individual will need to interact directly and responsibly with other employees, suppliers and customers

Decision Making Authority

- Provide management, leadership and direction in the areas of nuclear activities and related systems.
- Authorized to give instructions to A&DM employees on issues related to your position description.

Problem Solving Responsibilities

- Work through employee problems and relationship issues with employees
- Identify key issues from a variety of information
- Work through any non technical issues that may arise.

MINIMUM COMPETENCIES REQUIRED

Experience

- At least 10 years experience in digital electronics design.
- Radiation and health safety training.
- Experience communicating with employees and suppliers.

Skills

- Software skills including, MS Office products and CAD Tools.
- Excellent communication and interpersonal skills.

Ulf Leonhard – Nuclear

CHARACTERISTICS OF POSITION

Key Responsibilities

The Nuclear Systems Engineer will be responsible for the day to day requirements of our nuclear activities including source handling, repairs & maintenance, documentation, safety and design. A key participant in the company for safety, quality and technology, the individual will help identify and document company procedures, develop customer relationships and perform any other duties as required by the R&D Manager.

Your specific responsibilities include:

- *Business Development:* You are responsible for further developing the business of A&DM by liaising with potential principle companies, identifying target markets, identifying new products, procedures and technologies. You are expected to spend a minimum of 0.5 days a week exploring new business avenues for the company.
- Documentation: You are required to ensure that all your work is documented as per our quality systems requirements and that no deficits exist in your documentation or database's for our nuclear based activities. This also means that a complete paper trail must be kept for every nuclear activity.
- Production: You are required to assist where possible in the production of the companies products and services. This may require you to lean new skills or procedures to enable you to complete this requirement.
- Company Databases: Responsible for maintaining the company database lists of customers, suppliers, etc. The database's will need you to identify any related target markets and follow up on these markets by way of mail outs (either in electronic or paper format).
- Document Preparation: From time to time you will be required to review documentation relating to our products and correct the documents for formatting, presentation, etc. You will be responsible to prepare customer documents (printing, binding, etc.) and to ensure that these documents are presented to the customer in a professional manor.
- *Customer Interface:* You are responsible for interfacing with the customers in a professional manor. When you are required on a customers site you need to ensure that all relevant health and safety regulations are met.
- Reporting: Responsible for the generation of reports based on current

jobs or activities when required by your manager.

Key Relationships

- Reports internally to the R&D Manager.
- The individual will need to interact directly and responsibly with other employees, suppliers and customers

Decision Making Authority

- Provide management, leadership and direction in the areas of nuclear activities and related systems.
- Authorized to give instructions to A&DM employees on issues related to your position description.

Problem Solving Responsibilities

- Work through employee problems and relationship issues with employees
- Identify key issues from a variety of information
- Work through any non technical issues that may arise.

MINIMUM COMPETENCIES REQUIRED

Experience

- At least 10 years experience in the Nuclear Industry
- Radiation and health safety training.
- Experience communicating with employees and suppliers.

Skills

- Software skills including, MS Office products and CAD Tools.
- Excellent communication and interpersonal skills.

Jodi Sharkey – Office Management

CHARACTERISTICS OF POSITION

Key Responsibilities

The Office Administration individual will manage the day to day operations of the companies office. A key participant in the company for management, organization and quality, the individual will help identify and document company procedures, develop customer relationships and perform any other duties as required by the R&D Manager.

Your specific responsibilities include:

- *Office Communications:* Responsible for ensuring that all incoming phone calls are answered and, if necessary, directed to the relevant parties. Responsible to ensure that all fax and email communications are collected and followed up by any relevant parties.

- MYOB: Responsible to ensure that that the day to day MYOB tasks are handled correctly and diligently. This includes purchasing, invoicing and following up on monies owed. You are also to ensure that as you develop (or change) any office procedures that they are documented and added to our procedures manual. You may also be required to handle the payroll requirements of the company.

- Purchasing: Responsible for purchasing parts and materials as required by our engineering teams, and ensuring that the records of such purchases are maintained as per our quality systems. You will also be required to handle any overseas orders, including follow up's and general communication with principles.

- Company Databases: Responsible for maintaining the company database lists of customers, suppliers, etc. The database's will need you to identify any related target markets and follow up on these markets by way of mail outs (either in electronic or paper format).

- Document Preparation: From time to time you will be required to review documentation relating to our products and correct the documents for formatting, presentation, etc. You will be responsible to prepare customer documents (printing, binding, etc.) and to ensure that these documents are presented to the customer in a professional manor.

- *Jobs:* Responsible to ensure that current jobs are managed from initial communication with the customer through to billing, and to ensure that our internal job lists (including reporting) and procedures are maintained and enforced.

- Reporting: Responsible for the generation of reports based on current jobs, profits / losses, stock on hand, monies owing, etc.

- Responsible for all aspects of employees directly under your control, including those that are contracted (i.e. Building maintenance, etc.).

Key Relationships

- Reports internally to the R&D Manager.
- The individual will need to interact directly and responsibly with other employees, suppliers and customers

Decision Making Authority

- Provide management, leadership and direction in the areas of office administration and its related systems.
- Authorised for the purchase of hardware, software, components and services as required by other employees within the company procedures guidelines.
- Authorized to give instructions to A&DM employees on issues related to your position description.

Problem Solving Responsibilities

- Work through employee problems and relationship issues with employees
- Identify key issues from a variety of information
- Work through any non technical issues that may arise.

MINIMUM COMPETENCIES REQUIRED

Experience

- At least 5 years experience in an office environment.
- Experience managing an office and communicating with employees and suppliers.

Skills

- Software skills including, MS Office products and MYOB.
- Excellent communication and interpersonal skills.

Richard Teh – Mechanical Engineer

CHARACTERISTICS OF POSITION

Key Responsibilities

- To Support both ADM nuclear and eQss with the design and manufacture of mechanical assemblies or parts that make up the company products.
- To report directly to the managing director

Decision Making Authority

- Preparation of construction programme for radiation holders and other sundry parts.
- Supervision of sub contractors
- Coordinates QA programmes with subcontractors
- Purchase of materials and services
- Maintenance of QA records

Skills

- Efficient use of computer programs and design tools as required by the R&D manager

Education

- Bachelor of engineering (Mechanical)

Andrew Donegan – Software Engineer

Key Responsibilities

The Software Engineer will be responsible for the day to day requirements of our software activities including design, development, testing, repairs & maintenance, documentation and safety. A key participant in the company for safety, quality and technology, the individual will help identify and document company procedures, develop customer relationships and perform any other duties as required by the R&D Manager.

Your specific responsibilities include:

- *Business Development:* You are responsible for further developing the business of A&DM by liaising with potential principle companies, identifying target markets, identifying new products, procedures and technologies. You are expected to spend a minimum of 0.5 days a week exploring new business avenues for the company.
- Documentation: You are required to ensure that all your work is documented as per our quality systems requirements and that no deficits exist in your documentation or database's for our nuclear based activities. This also means that a complete paper trail must be kept for every nuclear activity.
- Production: You are required to assist where possible in the production of the companies products and services. This may require you to lean new skills or procedures to enable you to complete this requirement.
- Company Databases: Responsible for maintaining the company database lists of customers, suppliers, etc. The database's will need you to identify any related target markets and follow up on these markets by way of mail outs (either in electronic or paper format).
- Document Preparation: From time to time you will be required to review documentation relating to our products and correct the documents for formatting, presentation, etc. You will be responsible to prepare customer documents (printing, binding, etc.) and to ensure that these documents are presented to the customer in a professional manor.
- *Customer Interface:* You are responsible for interfacing with the customers in a professional manor. When you are required on a customers site you need to ensure that all relevant health and safety regulations are met.
- Reporting: Responsible for the generation of reports based on current jobs or activities when required by your manager.

Key Relationships

- Reports internally to the R&D Manager.
- The individual will need to interact directly and responsibly with other employees, suppliers and customers

Decision Making Authority

- Provide management, leadership and direction in the areas of nuclear activities and related systems.
- Authorized to give instructions to A&DM employees on issues related to your position description.

Problem Solving Responsibilities

- Work through employee problems and relationship issues with employees
- Identify key issues from a variety of information
- Work through any non technical issues that may arise.

MINIMUM COMPETENCIES REQUIRED

Experience

- At least 2 years experience in software design.
- Radiation and health safety training.
- Experience communicating with employees and suppliers.

Skills

- Software skills including, MS Office products and CAD Tools.
- Excellent communication and interpersonal skills.

Minimum Job Qualifications

From time to time A&DM is required to increase its staffing levels on a demand basis. A set of minimum job qualifications have been detailed to ensure that any staff, including temporary staff have enough qualifications to safely and accurately carry out their job function.

Minimum job qualifications are posted with each position description.

Product Realization

Introduction

This section covers the necessary requirements and processes to produce a product or service. This section discusses the necessary life cycles for product planning, design & development as well as meeting the needs of the customer.

Requirements

The requirements for this section can be found in the individual sections below.

Product Planning

This section discusses the requirements for planning a product.

Planning

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system.

Item	*Requirement*
1.	quality objectives and requirements for the product
2.	the need to establish processes, documents, and provide resources specific to the product
3.	required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance
4.	records needed to provide evidence that the realization processes and resulting product meet requirements
5.	The output of this planning shall be in a form suitable for the organization's method of operations.
6.	A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

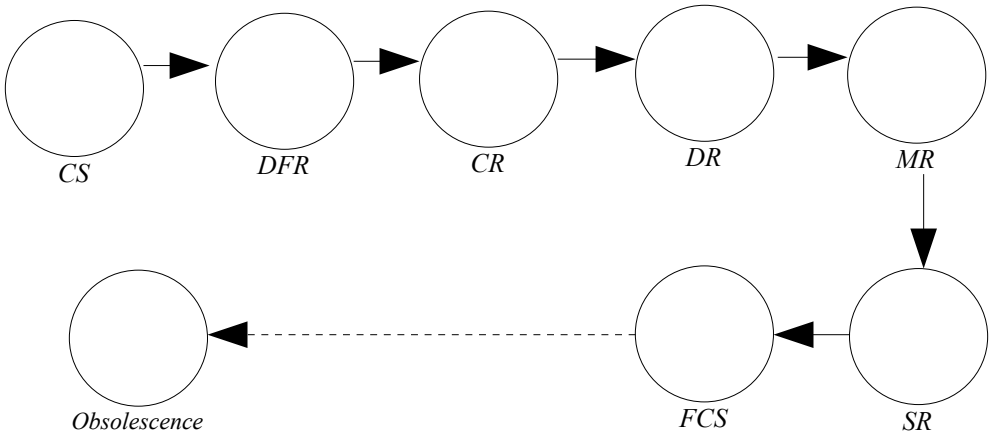
Table 38: Product Planning Requirements

Introduction

This section describes the compulsory product planning procedures which covers the project life-cycle from concept right through to customer supply.

Project Life Cycle

Every project should follow the correct project life cycle procedure as documented below:



Text 2: Project Life Cycle Diagram

CS

A candidate project will go through a 'Concept Selection' where it is chosen above all other possible projects that the company has in its funnel, based on what is the best fit for the companies roadmap, customer requests, and companies resources. There are key actions that need to be completed before a candidate project passes though this milestone.

DFR

When moving into the Definition Release milestone the project is formally recognised throughout the company. R&D resources are quickly brought into the project to scope the technical aspects and attempt to de-risk any questionable areas and Marketing start defining the market potential. Key functional blocks and components are identified and checked for availability (when sourcing them from another company). Marketing objectives are set, sketches, mock drawings, mock models, mock brochures are constructed defining the products and its operation. A project plan is created to allow visibility in what needs to be done to get to the Commitment Release (CR) milestone.

CR

This is the commitment release of the project, and it defines when the company commits to put all necessary resources behind the project to get it to DR. At this point:

- Product Requirements are finalized
- R&D engineering specifications are completed
- project plan is in place
- high level architecture has been fleshed out
- time lines are completed
- project test specification and plan has been developed
- product launch plan is specified
- project financial viability plan has been created
- project manufacturing plan has been created
- project manufacturing test plan has been created
- regulatory requirements plan has been created
- support product plan has been created
- documentation plan has been created

Dollar estimates and resource estimates for the project are completed and management has signed off and agreed to spend the money.

DR

Design release occurs when all new components in the project have been developed and integrated in. It does not mean that development has finished, rather that R&D are in a consolidation phase rather than an exploration phase. System QA is now run over the system and non optimal workings, functional blocks which haven't had all their functionality developed yet and bugs are worked on and fixed. There is a clear path in what the project has to achieve to get to MR i.e. All bugs fixed, functionality as per the R&D specification.

MR

When all of the CR plans have been executed i.e. Documents have been created, support is ready to go, the product meets the R&D specification, the prototype product has been reviewed against any regulatory requirements, and where necessary a first pass has occurred to ensure that there is high confidence in passing regulatory requirements when the real product is built, manufacturing are ready to receive the product, the company has the necessary resources in place to

launch, the Manufacturing Release can be declared. This is a formal handover of the project from R&D to Manufacturing. No development is expected to be necessary from now on, unless issues are found in the field. Manufacturing are expected to be able to build the product to a consistent standard due to the design now being solidified, and ensure that it meets the quality standards by executing the manufacturing test plan.

A project review should happen at this point to work out what went well, what went wrong, what could be improved etc. Also a review on any IP that has been developed in the project, and strategies that should be undertaken to protect it i.e. Patents.

SR

Depending on how ready manufacturing are, and how well R&D handed over the product Shipment Release can happen almost immediately after Manufacturing Release. Shipment Release is declared when manufacturing are able to build the product in the necessary volumes demanded by customers. A pre production run has been completed, and appropriate testing and checking has occurred.

FCS

The First Customer Shipment milestone can occur when the product is fully certified against any regulatory requirements. This may have happened back at MR if the prototype was being built in the same way as the now finished product, and there has not been any changes. FCS occurs when the first product is shipped to the customer.

Discontinuance and Obsolescence

Discontinuance is generally a plan of how to get to obsolescence. Referring to the companies roadmap it can be decided that a product is no longer necessary for a variety of reasons. Before this milestone occurs customer and market requirements need to be fully understood, and any 'fallout' due to removing this product from the market need to be deemed acceptable. An understanding of warranties and servicing for products that are already out in the field has to be undertaken.

Model Number Allocation

Every project, regardless of weather it is a minor test tool or a product in mass production, must have a model number if you wish to sell it to a customer.

Company Categories

There are three main company categories for products, Crane Related, Measurement Related and Nuclear Related. We have 3 trading names to suit.

Company Category	*Trading Name*
Crane Related Products	EQSS (eQuipment Safety Systems)
Measurement Related Products	ADM (Analogue And Digital Measurements)
Nuclear Related Products	NS (Nuclear Stuff)

Table 39: Company_Categories

Series Numbers

All products belong to a series of products. The Series numbers are in increments of 100. For Example:

Series	*Description*
Series 6200	Processor based crane measurement
Series 6300	Crane Sensors

Table 40: Example Series Numbers

Each company category will have a different set of series, therefore regardless of the company category, each product will be uniquely identifiable.

Model Numbers

A model number in a series starts at 00 and continues on until 99 at which point a new series must be started (its unlikely we will reach 99 products in a series) For Example:

Model Number	*Description*
6201	Pipe Layer Computer
6242	Crane Safety Appliance.

Table 41: Model Numbers - Example

A spread sheet of model numbers exists for each company category. The Visual Source Safe Databases have been created for each category; For Example:

Category	*Path To Model Number Spreadsheet*
EQSS	\eqsswork\Documents\Model_Number_Allocation\
ADM	\admwork\Documents\Model_Number_Allocation\
NS	\nuclearwork\Documents\Model_Number_Allocation\

Table 42: VSS databases

Please note that \eqsswork\, \admwork\ and \nuclearwork\ are all VSS databases.

Serial Numbers

All products leaving our doors that we manufacture must carry our standard serial number in the format listed below.

Format

The format for a serial number is as follows:

MODEL_NUMBER–S**BN**-DATE_CODE–SEQUENCE_NUMBER

Model Number

The model number is the model number of the product, for example Model 4100 – GM Switch would be written as 4100-X1.

Date Code

The date code is in ISO standard format: YYMM

Marker	*Description*
YY	2 Digit Year Code
MM	2 Digit Month Code

Table 43: Date Code Table

Sequence Number

The sequence number starts at 000 and goes through to 999. It is unlikely that we will produce more that 999 of a particular model of product.

Example

The Third Model 6215 Windicator, built in March 2005 would be numbered **6215-0503-003**

The second Model 6242 CSA built in April 2005, but has been adapted to a specific customers requirements (SBN) will be: **6242-R1-0504-002**

Serial Number Spreadsheet

For every product that is sold the following information must be maintained in a spreadsheet, located in the documents directory of the EQSS, ADM or NS VSS databases:

Item	*Requirement*
1.	Serial Number
2.	VSS version label (product version)
3.	Customer Job Number
4.	Any relevant notes.

Table 44: Serial Number Spreadsheet Requirements

The spreadsheets have been created and are available for you to edit.

You will need to check the spreadsheet out of VSS to edit it. For details on VSS please see Changes and Revision Control on Page 30

Special Cases

There are special cases where the recommended serial number format can not be used. One such example is the data plates fitted to source holders.

The format of radiation source holders data plate format is specified in the code of practice. Therefore the serial number format must be broken up.

Example:

Product is an ASHF2-A1, with sequence number 045, built in march 06

Our serial number would be ASHF2-A1-0603-045

The marking on the data plate would be:

Model = ASHF2-A1

Serial Number = 045

Date of Manufacture = Mar. 06

Terminology

Item	*Name*	*Description*
1.	Product	The physical end product that will be manufactured from a range of materials and assemblies containing components
2.	Assembly	An assembly is a collection of components or other assemblies.
3.	Component	A component is the smallest entity in an assembly.

Table 45: Product Number Allocation Terminology

Product Number Allocation

A product number is a descriptive number assigned to each product. Generally speaking product numbers fall into categories; series numbers and physical names. It is open as to what format you would use.

For Example:

Product number 6242 is the crane computer display.

Likewise ASHF2 is also a product number, from the ASHF series.

Product numbers also carry a configuration and revision identifier. Please see below.

Configuration And Revision Identifier

Each product number will also have a configuration and revision identifier as part of the product number. The configuration identifier is generally a character in the range of A – W, while the revision identifier is a number in the range 1-9.

Products that do not have different configurations, or that carry generic components or assemblies shall use an “X” as the configuration.

Products that are of prototype nature must carry a ZERO as the revision identifier.

For Example:

The product number is ASHF2

The configuration is “E”

The revision is 2

Therefore the product number is ASHF2-E2

Assembly & Component Numbering

As mentioned previously, groups of components form assemblies and assemblies form products. Each component and assembly in a product must carry a unique number to identify it in the current product, and also in the case of future revisions.

All assembly numbers start from 000 and range through to 099

All component numbers start from 100 and range through to 999.

The Product Number – Revision & Configuration Identifier is appended to the start of each assembly of component number.

For Example:

The top level assembly in the ASHF2-E2 product would have the number:

ASHF2-E2-000

While the first component in the product (regardless of where it sits in an assembly) will have the number:

ASHF2-E2-100

Logging Spreadsheet

It is a basic requirement of this standard that a spreadsheet be kept which details what components and assemblies have been created for a particular product. The spreadsheet should be kept in the same folder as the product.

The format of the spreadsheet is open.

Drawing Numbering

All drawings must carry the product number, configuration / revision identifier, the component or assembly number for the component being described together with a sequential number starting at 00.

An example drawing number would be:

ASHF2-E1-023-00

Autodesk® Inventor™ Specific Requirements

This section details the specific requirements for developing products using Inventor™.

Document Storage

Storage and retrieval of documents created in Inventor™ is of utmost importance to the success of the product. Generally speaking simple products[22] will be stored in a folder labelled with the product number and configuration & revision identifier.

Advanced products[23] will need to have their common component and assemblies stored in a common folder, while the different configuration options reside in sub folders.

Suggested Directory Structure

It is suggested that a common directory structure be created for each project to facilitate the efficient storage of documents for each product.

A folder called “Autodesk_Inventor” should be created under the product folder.

A further set of directories under the “Autodesk_Inventor” folder should be created to detail the various configurations and revisions of the particular product.

Each configuration should have directories for “Components”, “Assemblies”, “Drawings”, “Presentations”, etc.

22 Simple products are defined as products that have fewer than 20 components and only one configuration.
23 Advanced products contain many components, and have multiple different configurations and revisions

Example Storage System (Simple Product)

Product AXYZ is produced and does not have any variants. The product is sent into manufacture immediately after being checked and no prototype version was built.

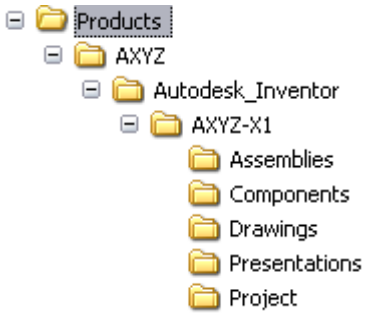


Illustration 41: Example Storage System (Simple)

As can be seen from Illustration 41 (above) a folder called “Autodesk_Inventor” is created under the main folder for our example product.

A folder is then created under “Autodesk_Inventor” with the name that matches the current product number and configuration / revision identifier.

Further folders are created, their contents are documented below.

Item	*Folder Name*	*Contents*
1.	Assemblies	This folder contains assemblies with the “.iam” file extension.
2.	Components	This folder contains only components used for the current configuration. All components in this directory carry the “.ipt” file name extension.
3.	Drawings	This folder contains only drawing files for the current product configuration. All drawings in this folder must contain the “.idw” extension. It is permissible to have another folder under this directory called “PDF” which contains the exported files in Adobe Acrobat format.
4.	Presentations	This folder contains presentations of any component or assembly for the current product configuration. This directory should only contain “.ipn” files. Do not confuse presentations with drawings. A presentation is not a drawing until you create a drawing with the presentation embedded in the drawing.

Item	*Folder Name*	*Contents*
5.	Project	This folder contains the project file for the current configuration. This folder is optional, however it is highly recommended that a project file be created correctly for each product configuration.

Table 46: Product Folders

Example Storage System (Advanced Product)

Product BCDE has a range of common components and assemblies, it also has various configurations. The image below details the expected directory structure.

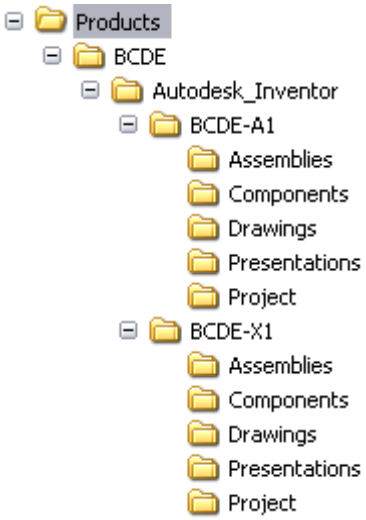


Illustration 42: Example Storage System (Advanced Product)

Customer Processes

Requirements

Determination of Customer Requirements[24]

Item	*Requirement*
1.	Determine the requirements specified by the customer, including requirements for delivery and post delivery activities
2.	Determine requirements not stated by the customer by necessary for the specified or intended use, where known.
3.	Determine the statutory and regulatory requirements related to the product.
4.	Determine any additional requirements required by the organisation.

Table 47: Determination Of Customer Requirements

Review of Customer Requirements

Customer Communication

24 Referenced Directly From AS9001:2000

Design and Development

This section describes the design and development processes related to product realization.

Requirements

Design & Development Planning[25]

Item	*Requirement*
1.	The organization shall plan and control the design and development of product
2.	During the design and development planning, the organization shall determine 1. the design and development stages 2. the review, verification and validation that are appropriate to each design and development stage 3. the responsibilities and authorities for design and development.
3.	The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.
4.	Planning output shall be updated, as appropriate, as the design and development progresses.

Table 48: Design & Development Planning Requirements

25 Referenced Directly From AS9001:2000

Design & Development Inputs[26]

Item	*Requirement*
1.	Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include 1. functional and performance requirements 2. applicable statutory and regulatory requirements 3. where applicable, information derived from previous similar designs 4. other requirements essential for design and development.
2.	These inputs shall be reviewed for adequacy.
3.	Requirements shall be complete, unambiguous and not in conflict with each other.

Table 49: Design & Development Inputs - Requirements

Design & Development Outputs[27]

Item	*Requirement*
1.	The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.
2.	Design and development outputs shall 1. meet the input requirements for design and development 2. provide appropriate information for purchasing, production and for service provision 3. contain or reference product acceptance criteria 4. specify the characteristics of the product that are essential for its safe and proper use.

Table 50: Design & Development Outputs – Requirements

26 Referenced Directly From AS9001:2000
27 Referenced Directly From AS9001:2000

Design & Development Review[28]

Item	*Requirements*
1.	At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)
2.	Evaluate the ability of the results of design and development to meet requirements
3.	Identify any problems and propose necessary actions.
4.	Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

Table 51: Design & Development Review - Requirements

Design & Development Verification[29]

Item	*Requirement*
1.	Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements.
2.	Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

Table 52: Design & Development Verification - Requirements

28 Referenced Directly From AS9001:2000
29 Referenced Directly From AS9001:2000

Design & Development Validation[30]

Item	*Requirement*
1.	Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known.
2.	Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

Table 53: Design & Development Validation - Requirements

Control of Design & Development Changes[31]

Item	*Requirement*
1.	Design and development changes shall be identified and records maintained.
2.	The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation.
3.	The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.
4.	Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

Table 54: Control of D & D Changes - Requirements

30 Referenced Directly From AS9001:2000
31 Referenced Directly From AS9001:2000

Development Planning

This section describes the planning requirements for a project. The planning stage can only be commenced based on the requirements stated in Project Life Cycle on page 97

Document Storage

Consideration must be given to the types of documents (files) that will need to be stored during the life of the project.

Generally speaking, all documents storage locations should be developed as per the guide lines in General Consideration on page 24

Project Planning

In general every project must be started with a basic project plan, which evolves during phases of the project to eventually be able to track manufacturing and shipment.

The project plan contains:

1. Resources required for the project
2. List of phases
3. List of activities
4. Any relevant mile stones.

As a general guide, A&DM uses Open Workbench (as opposed to Microsoft Project) for maintaining its project plans.

Project Task Websites

A&DM's intranet has a series of sites set up to track each project, its tasks and resources. Once a new project is started the QA officer is required to set up a new task site.

Development Inputs

The development inputs are defined as per the commitment release phase of the project life cycle. Details can be found in CR on page 98.

Evidence that the criteria has been met must be documented and stored in the projects documents folder.

Further Inputs

Further inputs to the project may be in the form of:

- Regulatory Requirements
- Reference Designs
- Prototype Platforms
- Australian or ISO standards
- Drawings
- Specifications
- Competing Products

Where practical documentation must be produced for these inputs and stored in the project's folder.

Qualitative Acceptance

Each input into the design should be accepted based on several criteria, including

- Past performance
- Acceptable To the application(s)
- Cost

The project's description and time line may be changed based on the acceptance of various inputs, even if the quality of such inputs is not immediately realised.

Development Outputs

This section describes the outputs that are to be created during development of a product.

Revision Control

All development outputs must be controlled as per Changes and Revision Control on page 30

Autodesk® Inventor™ Specific Outputs

Drawing Layout

The layout for an Inventor drawing must contain at least 2 pages.

Page 1 must contain:

Item	Description
1	Revision Table
2	Isometric View Of the Component Or Assembly Being Described

Page 2 onwards must contain:

Drawing Requirements

All drawings produced for development / production use must conform to the prescribed company standard. The standard is in place to ensure all drawings carry the minimum amount of detail necessary for someone to re-produce the component or assembly. Drawings that carry the correct information will help expedite manufacture.

The table below details the specific requirements for a drawing.

Item	*Detail*	*Description*
1.	File Name	A drawing must be named correctly as per the file name specification.
2.	Template	A drawing must be produced from the supplied drawing template. Only A3 drawings are acceptable, except in the case of requirements of a competent authority
3.	Parts List[32]	A drawing must contain a list of components / assemblies that are present in the drawing The parts list must contain material information where applicable.
4.	Drawing Revision History Table	Each drawing must contain a revision history table detailing what has been modified on every edit of the drawing. The first revision is revision is revision 1 and should be described as “Initial Revision”
5.	Revision Number	The drawing revision number must be modified to reflect the most current revision entry in the revision table.

Table 55: Drawing Specific Requirements

Drawing Specifics

Autodesk Inventor Drawing templates exist to ensure that all drawing outputs produced in this software package are of an acceptable standard.

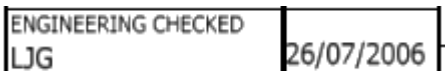
The user editable information is to be configured so as the title block contains relevant and accurate information about the component or assembly being displayed.

DRAWN LJG	26/07/2006	**eQuipment Safety Systems Pty. Ltd.** http://eqss.com.au			
ENGINEERING CHECKED LJG	26/07/2006	Project / Model	**6242R1.2**		
DRAWING QA CHECK LJG	26/07/2006	Component Number	**6242R12-DISP1-105**		
TOLERANCE (UNLESS SPECIFIED)	0.2mm	Component Description	Front Insert		
		Drawing Description	Layout For Acetal Insert		
		SIZE A3	SCALE N.T.S	DWG NO	SHEET 1 OF 1	REV 1

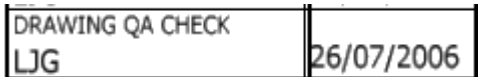
The title block contains the relevant information for a drawing to meet the QA requirements.

32 Parts list describes a generic list which could describe components, assemblies or library components.

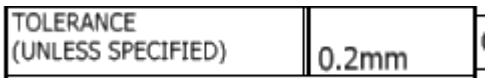
The “Drawn” box contains the initials of who initially drew the document, and the date in which it was drawn. This is automatically entered by Inventor and generally should not be changed.



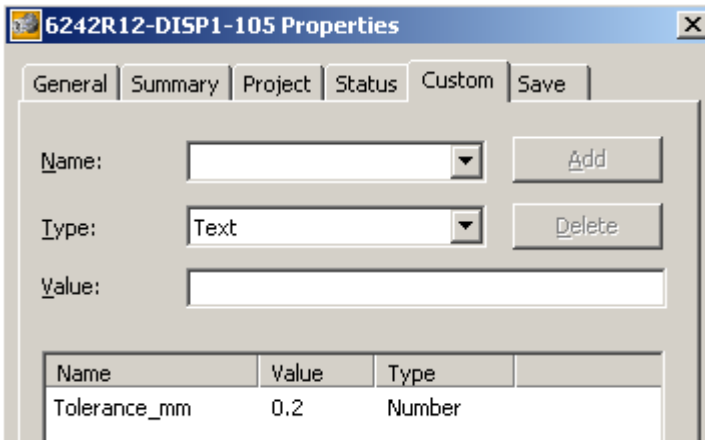
The “Engineering Checked” box contains the initials of the competent person whom checked the drawing (component & assembly) for technical accuracy and completeness. Once approved, this information may be entered into the iProperties of Inventor.



The drawing QA check is to be completed by the QA officer prior to converting the document to PDF and then stamping.



The tolerance statement is set up with the template, this must be added to old drawings via the drawings iProperties.



Development Review

The development review is critical in ensuring the project remains on track and the design outputs (as they progress) will converge towards the final design goal.

Review Frequency

Generally formal design reviews happen once a week, or more frequently during critical phases of the design and development.

Design reviews may be conducted via email which aids in the tracking of vital information.

Review Outputs

In general, each design review should be documented and its outcomes posted to all relevant team members. This can be achieved by means of meeting minutes, or via electronic means, such as email.

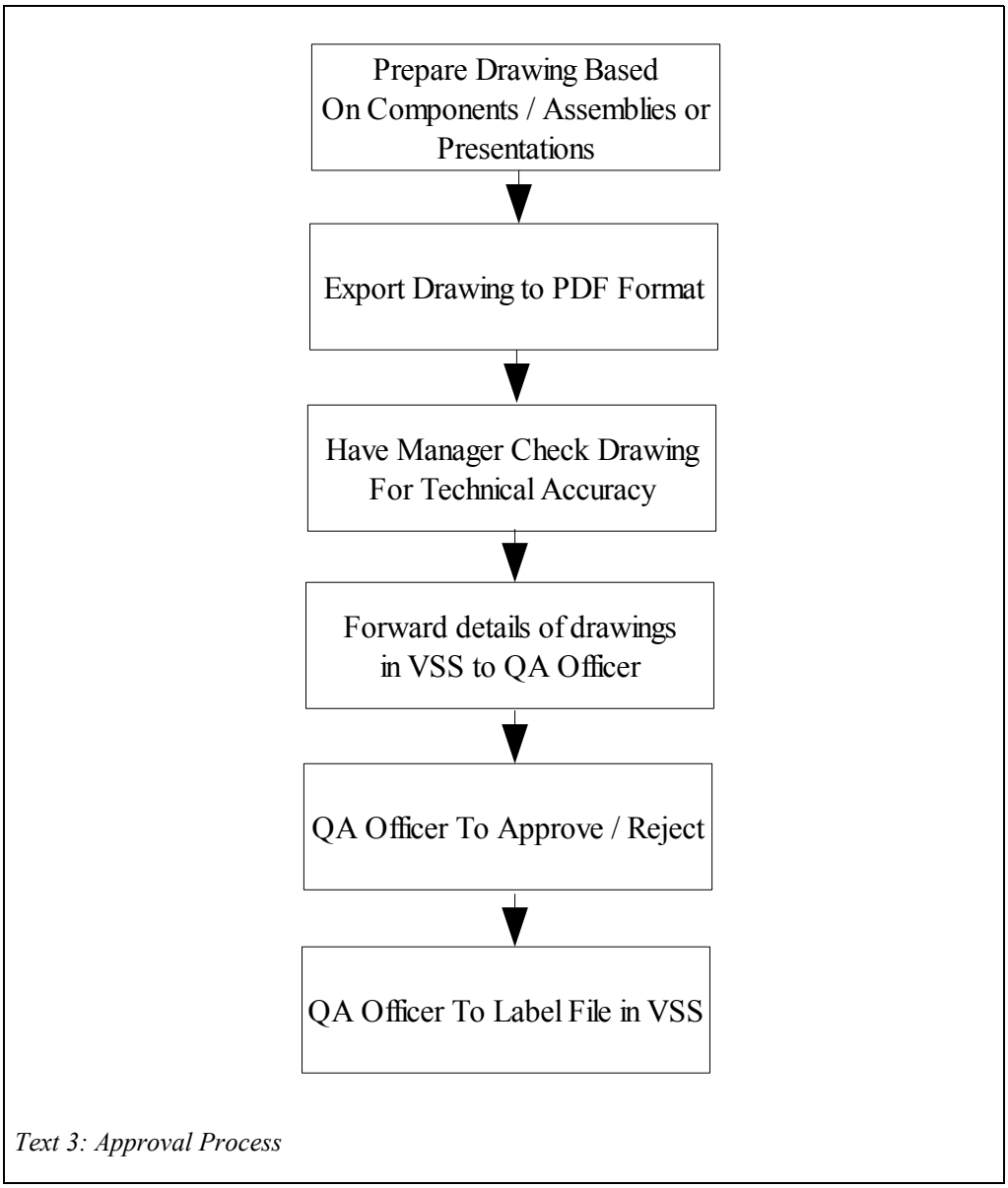
Development Verification

Once the development outputs are in progress, several stages of verification occur to ensure the outputs will function in the greater scheme of things.

Approval of Drawings

Drawings that are produced must be approved before they are release for manufacture. Generally speaking the Quality Assurance officer is responsible for approving drawings.

The approval process is as follows:



Text 3: Approval Process

Control of Development Changes

Development changes are controlled via several means, these include:

- Software, hardware and document / drawing revision numbers
- Version control software
- Reflections in model numbering.

Purchasing

This section describes the requirements and procedures for the purchasing of products, materials or services.

Requirements

Purchasing Process Requirements[33]

Item	*Requirement*
1.	The organization shall ensure that purchased product conforms to specified purchase requirements. See: Verification of Purchased Product on page 131
2.	The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.
3.	The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements.
4.	Criteria for selection, evaluation and re-evaluation shall be established.
5.	Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

Table 56: Purchasing Process - Requirements

33 Referenced Directly From AS9001:2000

Purchasing Information[34]

Item	*Requirements*
1.	Purchasing information shall describe the product to be purchased, including where appropriate 1. requirements for approval of product, procedures, processes and equipment, 2. requirements for qualification of personnel, and 3. quality management system requirements. See: Purchasing Process on page 127
2.	The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

Table 57: Purchasing Information - Requirements

Verification Of Purchased Product[35]

Item	*Requirements*
1.	The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.
2.	Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

Table 58: Verification of Purchased Product - Requirements

34 Referenced Directly From AS9001:2000
35 Referenced Directly From AS9001:2000

Supplier Selection Criteria

Supplier Selection will be based on the following parameters

Item	*Parameter*
1.	Past Trading History
2.	Relative Geographical Distance From Our Offices
3.	Past Quality Performance
4.	Documented Standards / Quality Certification
5.	Ability to perform the required task
6.	Ability to deliver the required task in a timely manor

Table 59: Supplier Selection Criteria

Performance Records

A record of each suppliers performance must be kept and reviewed as necessary. Generally a review will take place when the QMS is reviewed, or if a QA problem is found with the supplier.

Performance records will exist for each supplier and are stored in Visual Source Safe under vss:\\records\suppliers\performance_records\

A template for performance records exists under vss:\\records\templates\performance_records\

An example of a performance record entry is shown below:

Company Name	Name Here	
Date		**01/01/06**
Measure		
	Past Trading History	0
	Geographical Distance	0
	Quality Performance	0
	Documented Standards	0
	Ability To Perform Work	0
	Ability To Deliver Work	0
	SCORE / 10	**0**

Purchasing Process

This section describes the processes for the purchase of a product, service or material.

Material Purchase

Materials that are purchased (such as Stainless Steel Plate used in Transport Casks) must be correctly identified and records of the purchase must be kept. To simplify this process two procedures are in place.

The first procedure relates to a material ID for components designed in Autodesk Inventor. (See: Materials on page 136).

The second procedure related to actually purchasing the material and the check list's that must be adhered to. The steps described below will assist in purchasing a material and controlling the records of that purchase.

Step 1 – Material Description

The description of the material(s) to be purchased can only come from a Autodesk Inventor drawing[36]. The drawing must meet the following requirements:

Item	*Requirement*
1.	The drawing is provided to the purchasing officer in electronic format.
2.	The engineer requesting the purchase of the material has provided a written request for the materials to be purchased. The description of the material must exactly match the description of the material as stated on the drawing.
3.	The electronic format of that document is PDF format.
4.	The PDF document contains a “Green Stamp” stating that it has been approved for manufacture
5.	The PDF document has not expired, and does not contain any corrections.

Table 60: Material Description

Once the drawing is provided to the purchasing officer, it is up to the purchasing officer to generate a written purchase order in the companies format and to ensure that the details of the material being purchased is exactly that as stated on the supplied documents.

36 In some situations it may be a requirement of the supplier that they reproduce a drawing in their own format which is a representation of the supplied drawing. In such a case, both our original drawing and the suppliers reproduced drawing must be provided.

Example

The example below shows an email written to the purchasing officer stating a request for materials, and an accompanying drawing.

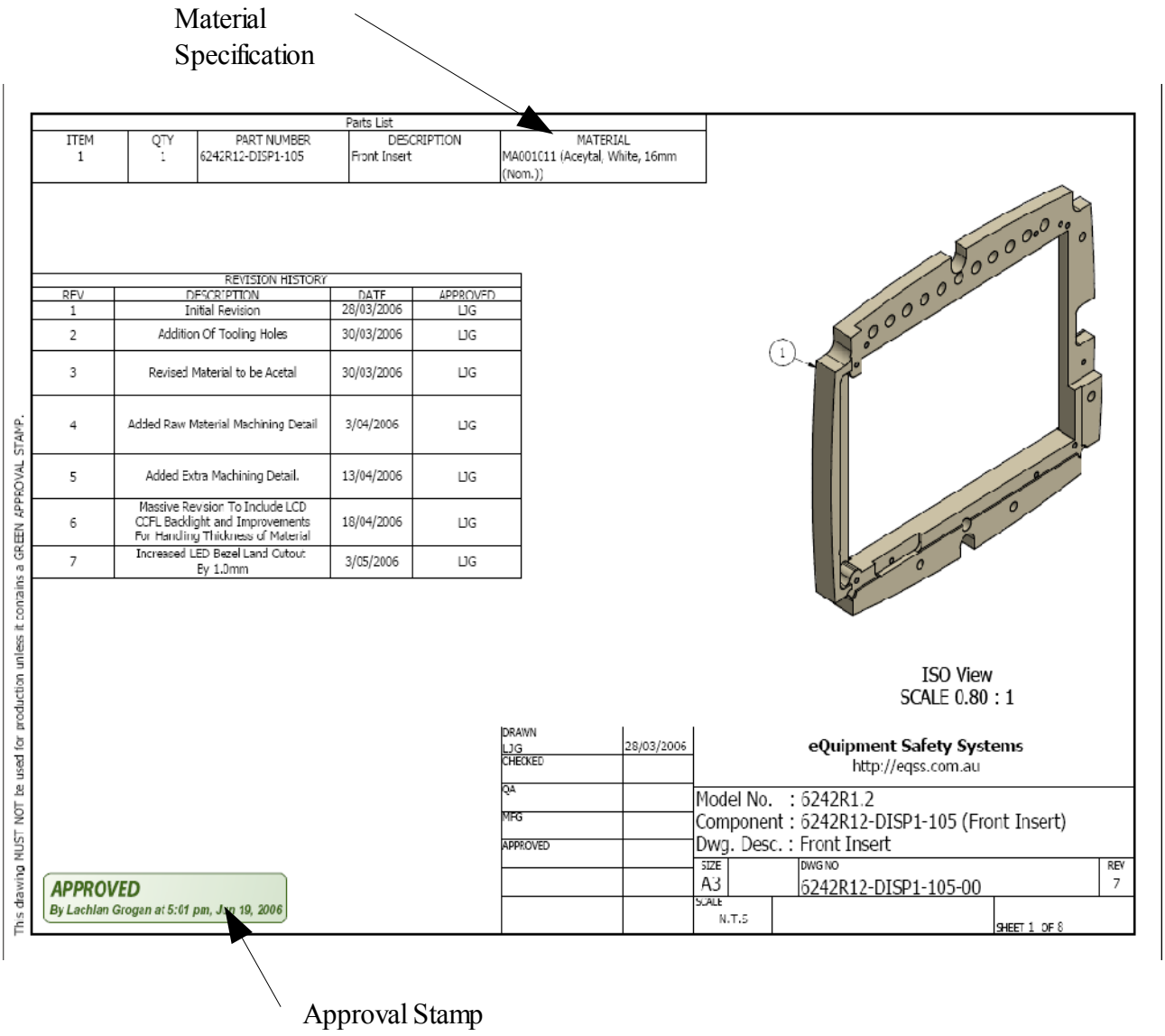


Illustration 43: Example Drawing Format

Step 2 – Purchase Order

Once the purchase order has been completed it must be re-produced in electronic PDF format. The purchase order, along with the electronic copies of the documents must be forwarded to the QA officer at which point if the documentation is correct, the QA officer will issue a green stamp on the purchase order. At this point the purchase order may be sent to the supplier.

The line numbers on a purchase order must reflect the PR number as detailed below.

An example purchase order is shown below that meets the requirements.

PURCHASE ORDER # 00004607

A Noble & Sons
135 South Gippsland Highway

SHIP TO:

Analogue & Digital Measurements Pty Ltd
27 Cumberland Drive
Seaford, 3198
Victoria Australia

SALESPERSON	YOUR NO.	SHIP VIA	SHIP DATE	TERMS	DATE
	----------			Net 30th after EOM	20/06/20

LINE NUMBER	QTY	DESCRIPTION	UNIT PRICE	DISC %	PRICE
PR001	1	STAINLESS STEEL POCKET	$500.00		$500.00
PR002	5	STUDS	$12.50		$62.50
PR003	10	SWITCH BODIES	$25.00		$250.00
PR004	2	STICKERS	$60.00		$120.00

Text 4: Example Purchase Order

Step 3 – Storage Of Records

Once the QA officer has issued a green stamp on the purchase order, the details of each item in each purchase must be stored in an appropriate folder from within Visual Source Safe.

The next step is to allocate a unique purchase record number to each line item in the purchase order. A spreadsheet has been set up for this purpose and can be found under vss:\\vss_records\purchasing\number_allocation\

An example line entry for the records spread sheet is located below.

PR Number	P.O Number	Line Number	Date	Supplier Name	Description
PR000	1234	1	19/06/06	Lachlan Grogan	Test Entry

Once the Purchase Record number has been allocated in the spread sheet, a folder must be created using the format Prxxx, where xxx is the sequence number.

Copies of the purchase order, along with the files that were used to generate the purchase order must be placed in this folder and checked into Visual Source Safe.

Verification of Purchased Product

Once a product, material or service has been purchased, it is important to verify that the purchased product meets the requirements as stated in the purchase order and that records are kept as evidence.

There are two methods for verification:

1. When the material from a supplier is delivered directly to another supplier (i.e. Plate steel delivered to the laser cutter).
2. When material is delivered directly to our premises.

Verification Records

Records for the verification of purchased products must be kept.

Templates exist for record keeping, and a template MUST be used at all times. When a template does not exist, it is the policy of this quality manual that a review takes place and a new template is created.

Once the Quality Record Template is filled in (either by us, or the supplier), the information must be returned, scanned, and stored in Visual Source Safe in the purchase record number (PR) folder for which the verified product was ordered.

Verification Of Materials

A Quality Record Template (QRT) exists for verification of materials. The details of the QRT Are:

Item	*Description*
QRT Number	QRT001
Location	VSS:\\records\\templates\quality_record\templates\

Identification

Purchased materials must be labelled in a manor where the label can not inadvertently be destroyed.

Internal Part Number Allocation

When a product, service or material is brought in from the outside it is allocated an internal Brought In Part number.

This number allows us to use a product, service or material in a product and not only ensure continuity with the supplier but to ensure that the purchased product meets the requirements of the engineering department.

Part Number Database

A record of the internal part number allocations is recording in a database which can be accessed via the Company Web internal website

Access The Database

To access the database open up a web browser and go to the company web, by typing “company web” into the address bar.

Illustration 44: Access Company Web

From the Links column on the right of the page select “Parts Database”

Illustration 45: Access Parts Database

This will open the parts database interface.

Add a Part

To add a new part to the database select “Add Part” from the left column.

The main window will open with a new part record.

Enter a part number as described below in Number Format.

Fill in the remaining details and click Update to store the new part to the database.

Find a Part

To find a part in the parts database select “View Parts” from the left column.

The main window will open a table listing all part records.

Select the desired part category from the Part Type drop down box.

Select the part from the table to view or modify the part details.

Delete a Part

Only delete a part if it was created in error, such as a wrong Part Number was assigned, or if it will no longer be used.

To delete a part open up it's part record window and click delete. A window will pop up asking you to confirm the deletion.

You can not delete a part if it is included in an assembly's bill of materials. Remove the part from all BOM's then delete it.

Number Format

Each brought in part (which differs from a product part number) will be assigned a part number with the following attributes

- category prefix – As described below in Component Categories
- 3 digit version / revision number
- 3 digit ID which is unique to each category

Example

An example of a fastener is

FA001037

With category prefix FA revision number 001 and unique ID 037.

Component Categories

Prefix	*Description*
FA	Fasteners and related hardware including bolts, nuts, washers, roll pins, set screws, etc.
BE	Bearings
LC	Load Cell Transducers including load cells, pressure, strain, etc.
SE	General sensors including length, angle, etc.
MA	Materials
CA	Capacitors
CN	Connectors
EN	Enclosures
OP	Optical Components, LEDS, Displays, etc.
PO	Power Components
RE	Resistors
SE	Sealing Components, O-Rings, etc.
IC	Semiconductors
SW	Switches
HW	Miscellaneous Hardware
PB	Printed Circuit Board
CB	Cable
ME	Mechanical
MT	Manufacturing
AU	Audio Components
DO	Documentation and Manuals

Table 61: Part Number Category Prefixes

Materials

Materials (especially when defined in Autodesk Inventor) are virtual components, meaning that they are assigned a reference, but there is no specific component associated with the material.

Each material used in Autodesk Inventor must be assigned a unique material ID (From the parts database), and that ID must be entered in the style library and the parameters of the material correctly adjusted.

Assemblies and Bill Of Materials

When a new product is created from a set of brought in parts, it must be recorded in the parts database as a new assembly.

This will generate a Bill Of Materials (BOM) for that assembly, which is used in purchasing components.

Add an Assembly

To add a new assembly to the database select “Add Assembly” from the left column.

The main window will open with a new assembly record.

Enter the Assembly Number as described above in Number Format except with the prefix 'AS'. All assemblies must have the prefix 'AS'.

Fill in the remaining assembly details and click 'Update'.

Find an Assembly

To find an assembly in the parts database select “View Assemblies” from the left column.

The main window will open a table listing all assembly records.

Select the assembly from the table to view or modify the assembly details or the assemblies Bill Of Materials.

Bill Of Materials

Each assembly has a bill of materials which lists the parts and sub-assemblies it is made of.

The bill of materials can be accessed by open the assembly record and clicking 'Bill Of Materials'.

The Bill Of Materials page contains a list of all the items that belong to that assembly.

Listed for each item is

- Item Number – Either Part Number or Sub-Assembly Number
- Quantity – The amount of the item in the assembly
- Description – A listing of the description field for each item
- Type – Whether the item is a part or a sub-assembly

Add Item

When an assembly is first created it's BOM is empty, to add items to the assembly click either 'Add Part' or 'Add Sub-Assembly'.

The item record screen will not list items that are already listed in the assembly's BOM.

Add Part

Clicking on the 'Add Part' button will open the part records screen, allowing you to add a new part to the BOM.

Select the desired part type from the drop down box and navigate through the records using the page numbers at the bottom of the page.

Once the part has been found click it to add it to the BOM.

Add Sub-Assembly

Clicking on the 'Add Sub-Assembly' button will open the sub-assembly records screen.

This will list other assemblies which can be added to the assembly as a sub-assembly.

Sub-assemblies that would result in a Circular Reference Error if they were added to the assembly are not listed.

Navigate through the sub-assembly records using the page numbers at the bottom of the page, once the sub-assembly has been found click it to add it to the BOM.

Modify Quantity

Once an item has been added to the BOM it's quantity is set to 1. If there is more one of this item in the assembly change it's quantity field to the proper amount and press Enter.

Remove Item

To remove an item from the BOM set it's quantity to 0 and press Enter. Once the page has finished loading the item will disappear.

Save As CSV

To generate a top level BOM for all parts in the assembly and all sub-assemblies click 'Save As CSV' and a file download window will pop-up.

This will generate a Comma Separated Values (CSV) file which can be opened with most spreadsheet programs.

If the download window does not have an Open button then the windows file associations have not been set-up for CSV. The following instructions assume that the file associations for CSV have been set as described in Setting Windows File Associations.

Click Open to open the file with OpenOffice Calc. A Text Import window will open up, click OK to continue.

The CSV BOM consists of 5 columns and a variable number of rows.

The first row contains the assembly number for this BOM.

The remaining rows list the parts in the BOM.

Each row contains the following columns

- Number – This is the Part Number of the component
- Description – This is the part description, according to the part record
- Quantity – This is the total quantity of the part including sub-assemblies
- Cost (Each) – This is the cost of the part, according to the part record
- Cost (Total) – This is the cost of the part given the quantity specified

The last row lists the total number and cost of the parts that make up this assembly.

Setting Windows File Associations

To set the file association for CSV file to open in OpenOffice, follow the procedure below.

1. Open up windows explorer by holding Win + E or another method.
2. Select Tools -> Folder Options...
3. Select the File Types tab
4. Click New
5. Enter CSV into the File Extension field and click OK
6. Select CSV from the extensions column and click Change...
7. Click Select the program from a list and click OK
8. Find and select OpenOffice.org 2.0 in the programs list and click OK
9. Click Close and close windows explorer.
10. The file association has now been set.

Circular Reference Error

When a BOM is generated for an assembly, the procedure below is followed.

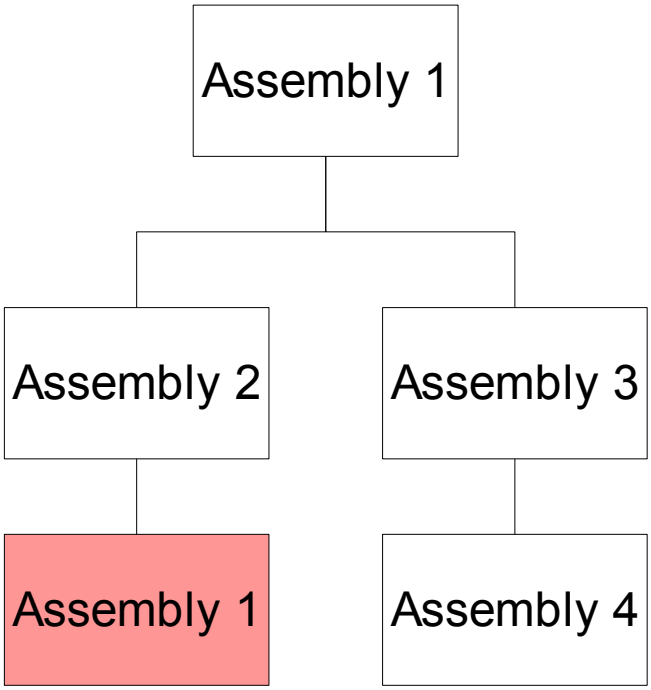
1. First the parts of the assembly are added to the BOM list
2. If the assembly has sub-assemblies, the parts of each sub-assembly are added to the BOM list.
3. If those sub-assemblies have sub-assemblies of their own, the parts of those sub-assemblies are added to the BOM list.
4. Step 3 is repeated until there are no more sub-assemblies

A circular reference error occurs when an upper level assembly is added to a lower level assembly. When a BOM of parts is generated it continues to count the number of parts going round in a circle from the upper level assembly to the lower level assembly then back up to the top level assembly.

The parts database stops this from happening by hiding all upper level assemblies from an assembly.

The example below illustrates the circular reference problem.

The following drawing shows the structure of 4 assemblies.



Drawing 1: Circular Reference Example

From the drawing it can be seen that Assembly 2 can add as sub-assemblies Assembly 3 and Assembly 4 but not assembly 1 which would cause a circular reference as shown by the red Assembly 1 box.

It should also be noted that Assembly 4 can add Assembly 2 as a sub-assembly

since it is not a direct upper assembly.

However if Assembly 2 was added to Assembly 4, Assembly 2 could no long add Assemblies 3 and 4 as sub-assemblies.

Production And Service

Requirements

Control of Production and Service Provision[37]

The organisation shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

Item	*Requirement*
1.	The availability of information that describes the characteristics of the product.
2.	The availability of work instructions, as necessary.
3.	The use of suitable equipment,
4.	The availability of monitoring and measuring devices.
5.	The implementation of monitoring and measurements
6.	The implementation of release, delivery and post delivery instructions.

Table 62: Requirements - Control of Production and Service

37 Referenced Directly From AS9001:2000

Validation of Processes for Production and Service provision[38]

The organisation shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measuring. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

Item	*Requirement*
1.	Defined criteria for review and approval processes
2.	Approval of equipment and qualification of personnel
3.	Use of specific methods and procedures
4.	Requirements for records. See Control of Records on Page 51
5.	Revalidation

Table 63: Requirements - Validation or Processes

Identification and Traceability[39]

Item	*Requirement*
1.	Where appropriate, the organisation shall identify the product by suitable means throughout the product realisation process.
2.	The organisation shall identify the product status with respect to the monitoring and measuring requirements.
3.	Where traceability is a requirements, the organisation shall control and record the unique identification of the product as per Control of Records on Page 51

Table 64: Requirements - Identification & Traceability

38 Referenced Directly From AS9001:2000
39 Referenced Directly From AS9001:2000

Customer Property[40]

The organisation shall exercise care with customer property while it is under the organisations control or being used by the organisation. The organisation shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use it shall be reported to the customer and records maintained as per Control of Records on Page 51.

Customer property can include intellectual property.

Preservation of Product[41]

The organisation shall preserve the conformity of the product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

40 Referenced Directly From AS9001:2000
41 Referenced Directly From AS9001:2000

Control of Monitoring and Measuring Devices[42]

Item	*Requirement*
1.	The organisation shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.
2.	The organisation shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.
3.	Where necessary to ensure valid results, measuring equipment shall. 1. Be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded. 2. Be adjusted or re-adjusted as necessary. 3. Be identified to enable the calibration status to be determined 4. Be safeguarded from adjustments that would invalidate the measurement result. 5. Be protected from damage and deterioration during handling, maintenance and storage.
4.	In addition, the organisation shall assess and record the validity of the previous measuring results when the equipment is found not to conform to the requirements. The organisation shall take appropriate action on the equipment and any product affected. Records of the calibration and verification shall be maintained.
5.	When used in monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

Table 65: Requirements - Control of Measuring devices

42 Referenced Directly From AS9001:2000

Quality Assurance Inspection, Component Failure

Realization of Component Failure

Any component that does not meet the Quality Assurance dimensions, or specific requirements as nominated by its corresponding Green Stamp Approved technical drawing fails QA.

An A&DM Quality Assurance Failure certificate is be filled with the component drawings attached to the rear of the certificate. The certificate, drawings and component are to be placed in a zip lock bag and moved to the nominated component quarantine area where a course of action is formulated by the QA officer

Course of Action

When a component is in QA quarantine it is the duty of the QA officer to determine the course of action. There are three possibilities to consider

1. Remedial work is carried out by A&DM. This is limited to minor work such as de-burring, thread depth correction, minor hole diameter correction etc.

2. Deficiencies are discussed with the subcontractor, and methods of correction are discussed and a plan of action formulated. After rework is finished the parts are QA'd with special attention to the specific areas of correction.

3. If a parts QA criteria can not be accommodated with rework by A&DM or the subcontractor, or if the cost of rework out weighs the cost of the component. The component is condemned and disposed of. The reason for the failure of the component to meet the quality standard is analysed and the production processes that require variation are determined, and technical drawings are modified to reflect the changes.

QA Component Failure Certificate

Analogue & Digital Measurements P/L
ABN: 57 005 531 484

http://admeasure.com.au
sales@admeasure.com.au

27 Cumberland Drive
Seaford, 3198
Victoria Australia

Ph: 03 8770 6500
Fax: 03 8770 6590

QA COMPONENT FAILURE CERTIFICATE

This Quality Assurance component failure certificate is to be used for components that do not meet the QA dimensions or specific requirements as nominated by its corresponding green stamp approved technical drawing.

DATE OF INSPECTION	**COMPONENT SERIAL NUMBER**
QA INSPECTOR	
	COMPONENT DRAWING NUMBER
INSPECTOR SIGNATURE	

REASON FOR COMPONENT FAILURE

SUGGESTED ACTION

Rework by A&DM.	
Rework by Subcontractor.	
Dispose of Component.	

Note 1. The component drawings are to be attached to the rear of this certificate.

Note 2. Component, Certificate & Drawings to be sealed in zip lock back.

Note 3. To be placed in the A&DM component quarantine area.

Customer Property

As a matter of policy A&DM does not accept any customer property without:

1. A purchase order stating what work or function the customer's property is to have conducted on it.
2. Where A&DM is required to hold customers property which is radioactive (storage) in nature, special agreements are formed on a per contract basis.

Customer property may be in the form of intellectual property. In this case electronic security measures are in place to safeguard and control this information.

Preservation Of Product

This section discusses the necessary steps for:

- Identification and storage of materials
- Identification and storage of components.

Materials

Materials which are purchased for use in the manufacture of products must be correctly identified and stored while on our premises. It is up to the supplier of a material to ensure that their control methods are adequate.

In general, all materials which are delivered to our premises must be labelled with the purchase record (PR) number on which they were ordered.

Details of the PR numbering may be found in Purchasing Process on page 127

Service Testing

Currently Being Reviewed.

Measuring Devices

Requirements

Control of Monitoring and Measuring Devices[43]

Item	*Requirement*
1.	The organisation shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.
2.	The organisation shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.
3.	Where necessary to ensure valid results, measuring equipment shall. 1. Be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded. 2. Be adjusted or re-adjusted as necessary. 3. Be identified to enable the calibration status to be determined 4. Be safeguarded from adjustments that would invalidate the measurement result. 5. Be protected from damage and deterioration during handling, maintenance and storage.
4.	In addition, the organisation shall assess and record the validity of the previous measuring results when the equipment is found not to conform to the requirements. The organisation shall take appropriate action on the equipment and any product affected. Records of the calibration and verification shall be maintained.
5.	When used in monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

Table 66: Requirements - Control of Measuring devices

43 Referenced Directly From AS9001:2000

Measurement, Analysis and Improvement

Requirements

General[44]

The organisation shall plan and implement the monitoring, measurement, analysis and improvement processes needed

Item	*Requirement*
1.	To demonstrate conformity of the product
2.	The ensure conformity of the quality management system
3.	The continually improve the effectiveness of the quality management system
4.	Include determination of applicable methods, including statistical techniques and the extent of their use.

Table 67: Requirements - General

44 Referenced Directly From AS9001:2000

Monitoring and Measurement

As one of the measurements of the performance of the quality management system, the organisation shall monitor information relating to customer perception as to weather the organising has met customer requirements. The methods for obtaining and using this information shall be determined.

Internal Audit

The organisation shall conduct internal audits at planned intervals to determine whether the quality management system conforms to the planned arrangements and to the quality management system requirements established by this organisation; and is effectively implemented and maintained.

Monitoring and Measurements

Customer Satisfaction

Please see Customer Focus on page 66.

Internal Audits

Internal audits are conducted at regular intervals by all levels of the company to ensure that the products and services being offered meet the stated design requirements and that any changes to standards covering these products or services are addressed.

The companies procedures are audited, along with any industry specific regulations or contractual requirements.

Basic Procedures

The basic procedures for an internal audit of a product, service or quality management system is:

1. Organise a meeting between management parties (either face to face or electronically).
2. Discuss and resolve any current concerns about products, services or quality level objectives that are not being met.
3. Discuss what changes need to be made to the QMS
4. Document and record results.

Monitoring and Measurement of Processes

Many of the processed used at A&DM require the use of outside labour or machinery or services.. These include:

- Mechanical machining
- Mechanical Assembly
- PCB assembly
- Automated PCB loading
- Web hosting and data services
- Plastic Moulding
- Supply of various materials

The quality procedures for each outside process ensures that problems that may occur can be dealt with.

Monitoring and Measurement of Product

Critical to the success of the company, is the performance of its products to meet its customer's expectations.

Improvement

This section covers the improvements to a product or service that may be gained as a result of an effective QMS.

Continual Improvement

Corrective Action

There are many situations when corrective actions need to be performed after a product is manufactured. These fall into the categories of:

1. Hardware Failures
2. Software Failures
3. Documentation Deficiencies
4. Operational Deficiencies

Hardware Failures

In general, hardware failures are among the most common failures in products that A&DM designs and manufactures.

Hardware failures fit into the following groups

1. Minor feature failure, such as a blown light globe
2. Major defect, such as a faulty PCB
3. Wiring failure, such as a damaged cable and connector.

Whenever A&DM learns about a hardware failure the following items take place.

1. The design team is alerted to the problem
2. The design team will try and re-create the problem on its simulation platforms.
3. The the defect can be repaired by the customer an instruction will be issued on a per customer basis.
4. The details on the defect and possible solutions will be added to the “trouble shooting” section of the manual.
5. Future thought will be placed to avoiding the defect in future manufacturing runs.

Software Failures

Software failures usually result in total or partial loss of functionality of the product or service on offer. Software failures are generally a result of:

1. Customer setting invalid configurations
2. A software bug
3. Software not performing to its stated objectives.

When A&DM learns about a software failure its design team will.

1. Re-create the failure on its simulation platform.
2. Attempt to fix the software
3. Update the customer with new firmware
4. Update the necessary technical documentation.
5. Ensure that all products leaving A&DM will contain the future revision of software.

Documentation Deficiencies

Documentation Deficiencies are generally found by the customer. When a documentation deficiencies is found, A&DM will move quickly to update the customer (generally via electronic means) with enough information to prevent them from incurring any further delays.

A&DM will then move quickly to update its documentation, including web references if necessary.

Customers on a documentation list will also receive updates.

Preventative Action

By default, A&DM takes large amounts of preventative action to ensure that the quality of its products always remains high.

The following methods are used:

1. Past performance data, (design revisions)
2. Mechanical simulation of components, Finite Element Analysis, to detect early failures of products
3. Software and hardware co-simulation to test hardware systems over various conditions (temperature and power fluctuations) before the product is built.
4. Testing of new designs in the factory, followed by pre-production systems being delivered to customers for trial.

Management Of Non-Conformities

currently being reviewed

Indexes

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Bibliography

IAEA requirement	A&DM response	ARPANSA comment
QUALITY ASSURANCE PROGRAMMES		
Organization and structure of the quality assurance programme		
The quality assurance programme should be prescribed in a document describing • the structure and overall composition of the quality programme	See ADM Quality Manual Quality Management System on page 15 See Also: Model 1860 Transport Cask Manual "Quality Assurance Programme" section "Structure Composition"	
• The document should include or make reference to the necessary procedures and/or instructions, and describe the way in which they combine to form the overall quality programme	See ADM Quality Manual Quality Management System on page 15 See Also: Model 1860 Transport Cask Manual "Quality Assurance Programme" section "QAP – Design" and onwards	
• the program should cover all activities of the company related to the safe transport of radioactive materials and compliance with the IAEA Regulations.	See Also: Model 1860 Transport Cask Manual "Quality Assurance Programme" also see "Radiation Protection Programme"	
Included in the quality assurance programme must be the company's quality policy statement which clearly reflects the commitment of senior management to the attainment and continuous improvement of quality, and to compliance with applicable regulations.	See ADM Quality Manual Quality Management System on page 15 See Also: Model 1860 Transport Cask Manual "Quality Assurance Programme"	
Documenting the quality assurance programme		
All constituent parts of the quality assurance programme developed and maintained by the company should be systematically produced in the form of appropriate written documents.	See ADM Quality Manual Accessing the Quality Manual on page 18 See Also: Model 1860 Transport Cask Manual "Quality Assurance Programme"	
Review and evaluation of the quality assurance programme		

Provision should be made by the company management for periodic review and evaluation of the quality assurance programme. These reviews should ensure that the quality assurance programme continues to be effective and appropriate to the company's activities, and that the quality policy objectives continue to be met. The results of such reviews should be documented and appropriate action taken by company management.	See ADM Quality Manual Management Reviews on page 64	

IAEA requirement	A&DM response	ARPANSA comment
ORGANISATION		
Responsibility and authority		
A clearly defined and documented organizational structure, complete with functional responsibilities, levels of authority and lines of internal and external communication, should be established. The organizational structure and functional assignments should recognize that application of a quality assurance programme is the responsibility of management, of those performing the work and of those verifying the effectiveness of the management processes involved. It is binding on everyone and is not the sole domain of any single group. The organizational structure and the functional assignments should be such that: • Attainment of quality objectives is accomplished by those who have been assigned responsibility for performing the work; this may include examination, checks and inspections of the work by the individuals performing the work; and • When verification of conformity to established requirements is necessary, it is carried out by those who do not have direct responsibility for performing the work.	See ADM Quality Manual Resource Management on page 70 See Also: Model 1860 Transport Cask Manual "Quality Assurance Programme" section "Responsibilities of the Engineers"	Structure and functional responsibilities defined in the application,
The persons and organizations ensuring that an appropriate quality assurance programme is established and effectively applied should have sufficient authority and organizational freedom to identify quality problems, to review all pertinent information and to initiate, recommend or provide solutions. Such persons or organizations should also have the authority to initiate actions to control further processing, delivery, installation or use of an item, package, process, or part of the quality assurance programme which is non-conforming, deficient or unsatisfactory until proper compliance has been achieved. They should be sufficiently independent of cost and schedule considerations.	See ADM Quality Manual on page See Also: Model 1860 Transport Cask Manual "Quality Assurance Programme" section "Responsibilities of the Engineers"	
Contract review		
Documented procedures should be established to ensure that contracts, orders or tenders placed between those different participating organizations in transport are reviewed for their adequacy and accuracy; any subsequent changes should be similarly reviewed and passed to the relevant parts of those organizations concerned.	See ADM Quality Manual Management Review on page 68 See Also: Management Commitment on page 63 See Also: Management Review on page 68	Contractors issue addressed in the application

Organisational interfaces		
The quality assurance programme and associated procedures should provide for the documented recognition and control of interfaces, both internal and external, wherever they occur.	See Resource Management on page 70	
Where several organizations are involved in a transport operation, the responsibility of each organization should be clearly established, and interfaces and co-ordination among organizations should be achieved by appropriate measures, with provision made for regular review and amendment when necessary.	See Model 1860 Transport Cask Manual. “Quality Assurance Programme” section “organisational interfaces”	

IAEA requirement	A&DM response	ARPANSA comment
DOCUMENT CONTROL		
Document preparation, review and approval		
The preparation, review, approval and issue of documents essential to the performance and verification of the work, such as instructions, procedures and drawings (these may be held in hard copy or other media such as computer disk or microfilm), concerned with all activities affecting quality of design, manufacture, use, etc., of the packaging and transport operations, should be subject to control. Instructions, procedures and drawings should include appropriate qualitative and quantitative acceptance criteria for determining that important activities have been satisfactorily accomplished. Documents should be independently (of the original author) reviewed to ensure they meet the company's technical and quality requirements, and should be approved prior to release. Individuals and organizations responsible for document review and approval should be clearly identified and should have the necessary authority.	See ADM Quality Manual Documentation Requirements on page 19 See Also: Document Approvals on page 27	Verification of work described in the application
Document release and distribution		
Measures should be provided for ensuring that those participating in an activity are aware of, and use, appropriate and up to date documents for performing the activity.	See ADM Quality Manual Document Control on page 23 See Also: Distribution Control on page 26 See Also: Document Awareness on page 23	
A document release and distribution system should be established to make the documents readily available by means of up to date distribution lists or other methods appropriate to the complexity of the company and its activities.	See ADM Quality Manual Distribution Control on page 26	
Document change control		
Changes to documents should be identified and recorded, and should be subject to review and approval, in accordance with documented procedures, by the original document review and approval functionaries or other designated persons or organizations having access to the relevant information. Distribution of revised documents, and information concerning their status, should be prompt and timely. Care should be taken to ensure that out of date, redundant documents are destroyed or clearly marked as such to prevent further use. When necessary an original document file should be established to maintain the history and to assure traceability; these documents should be marked as obsolete to prevent any further use.	See ADM Quality Manual Approval Check List on page 28 See Also: Changes and Revision Control on page 30	Change control described in the submitted QA documentation

IAEA requirement	A&DM response	ARPANSA comment
DESIGN CONTROL		
Design control measures should be established and documented to ensure that all design requirements are identified, specified and met by the final design.	See ADM Quality Manual Product Planning on page 96 See Also: Project Life Cycle on page 97 See Also: 1860 Transport Cask Manual: *"QAP – Design"*	
Where the design process involves more than one organization or function, appropriate interfaces and responsibilities should be established and documented in order to maintain the required design control. Design planning	See 1860 Transport Cask Manual: "Quality Assurance Programme " section "Organisational Interfaces"	
The organization responsible for the design process should establish and review appropriate plans for those design activities to be carried out, assigning responsibilities, personnel and resources as necessary	See ADM Quality Manual Development Planning on page 116 See Also: 1860 Transport Cask Manual: "QAP - Design"	
Design input requirements such as regulatory requirements, quality requirements, design bases, codes, standards, specifications, drawings, results of contract reviews, etc., should be identified, documented and reviewed to ensure that they are sufficient for the final design. They should include, where applicable, quantitative and qualitative acceptance criteria	See ADM Quality Manual Development Inputs on page 117 See Also: 1860 Transport Cask Manual: "QAP – Design" section "Regulatory Authority Compliance"	
Measures should also be established for the selection and for the review for suitability of materials, parts, equipment and processes that are essential to the function of the packaging, subassembly, systems or components relative to their operating environments.	See Verification of Purchased Product on page 131 See Also: 1860 Transport Cask Manual: "QAP – Design" section 'Design Flow Control"	
Design output, as the final product of the design process, should be documented to demonstrate its conformance to the agreed design input requirements and to the defined acceptance criteria. It should be reviewed and approved by the defined level of management in the company or organization responsible for the design. Design output documents may include drawings, specifications, handling and maintenance instructions, etc., and can be in the form of hard copy, electronic data or other acceptable media. Other parties such as the end user, customer, manufacturer or the regulatory body may comment on design output and influence its final approval.	See ADM Quality Manual on page See Also: 1860 Transport Cask Manual: "QAP – Design" See Also: 1860 Transport Cask Manual: "Detailed Design"	

Design control measures should be established and documented for verifying the adequacy of design, by the performance of design review(s). Design reviews and verification can be supported by the use of alternative calculation methods, or by the performance of a suitable test programme in accordance with the requirements of the IAEA Regulations as appropriate.	See ADM Quality Manual on page See Also: 860 Transport Cask Manual: "QAP - Design"	
Design verification and review should involve all functions or personnel concerned with the final design quality and/or the design phase under consideration.	See ADM Quality Manual on page See Also: 1860 Transport Cask Manual: "QAP - Design"	
Design validation activities should be carried out as necessary to confirm that the finished item, packaging or service conforms to the end user's requirement. This can be done by means of commissioning tests, package handling trials or similar methods.	See ADM Quality Manual on page See Also: 1860 Transport Cask Manual: "QAP - Design"	
The results of all these design activities should be appropriately recorded in order to demonstrate control throughout the design process and confirm that the finished design meets all requirements.	See Customer Focus on page 66 See Also: 1860 Transport Cask Manual: "QAP – Design" See Also: 1860 Transport Cask Manual: "Detailed design"	
Procedures should be established for effecting design changes, including in-service changes or modification, in a manner consistent with the design control measures for the original design. Design changes should be approved by the original design organization/function or a technically qualified substitute. The full impact of changes should be carefully considered and the need, justifications and required actions recorded. Written information concerning the changes should be sent to all affected persons and organizations in a controlled and timely manner.	See 1860 Transport Cask Manual: "QAP - Design"	

IAEA requirement	A&DM response	ARPANSA comment
PROCUREMENT CONTROL		
Procurement control measures should be documented and ensure that purchased items and services meet defined requirements and performance criteria.	See ADM Quality Manual, Purchasing on page 124	
Items or services may be procured to different levels of quality, depending on their importance and impact on safety. A graded approach to quality, as described in Safety Series No. 113, may be used in the procurement of such items and services.	See 1860 Transport Cask Manual: "QAP – Manufacture - Purchasing"	
Purchasing documents should contain data clearly describing the product or service required; such documents should be reviewed and approved before release. These data may include reference to applicable regulatory requirements, standards or codes, drawings, specifications, quality and other requirements as necessary.	See ADM Quality Manual, Purchasing Process On page 127 See Also: 1860 Transport Cask Manual: "QAP – Manufacture - Purchasing"	
Purchasing verification measures should provide for agreement between the supplier and the purchaser on methods used to verify that all purchasing requirements will be met. Where verification of the purchased product will be performed at the subcontractor's premises, the verification arrangements should be clearly specified in the purchasing documents. The supplier, competent authority (when necessary), or their representatives, should have access to plant facilities, items, materials and records for inspection and audit and have appropriate records forwarded when required for review or approval. These records should be retained for an appropriate time.	See Verification of Purchased Product on page 131 See Also: 1860 Transport Cask Manual: "QAP – Manufacture"	
Verification that the purchased product conforms to the requirements is the prime responsibility of the supplier. In the case of a purchased packaging, the purchaser should obtain adequate documented evidence that the packaging has been designed, manufactured and tested to meet specified requirements and that acceptable national or international standards on quality assurance have been applied throughout. Where the customer, end user or competent authority verify the product at the subcontractor's or the supplier's premises, this verification should not replace responsibility of the supplier for effective control	See See ADM Quality Manual, Verification of Purchased Product on page 131	
Documented procedures should be established to ensure that any material or equipment provided by the purchaser, for use in the final product or service, is suitably protected and controlled by the supplier.	See See ADM Quality Manual, Verification of Purchased Product on page 131	

IAEA requirement	A&DM response	ARPANSA comment
MATERIAL CONTROL		
Measures should be established and documented for the identification and control of packagings, package contents, associated transport equipment, materials and components; these measures should cover all relevant phases of transport including the entire production process, handling, loading, labelling and despatch, carriage, receipt, servicing and maintenance, storage, etc.	See ADM Quality Manual Preservation Of Product on page 151 Also See 1860 Transport Cask Manual: "QAP – Manufacture" section "Procedure for ordering materials and vendor parts"	
Similar measures should provide for sufficient traceability throughout the transport cycle, and also prevent damage, deterioration, loss, or the use of time expired material. Records of identification and traceability should be appropriately maintained, detailing batch or individual item identity when required.	See ADM Quality Manual Preservation Of Product on page 151	

IAEA requirement	A&DM response	ARPANSA comment
PROCESS CONTROL		
All processes involved in design, manufacture, use or servicing activities should be subject to documented control procedures. These process controls should be developed where the absence of such procedures would have an adverse effect on quality or where the required quality cannot be verified by post-process examination. The training and qualification of personnel, when relevant to the process, should be specified or referenced in these control procedures. Where processes are verified by statistical sampling or similar techniques, the application of these techniques should be in accordance with documented procedures.	See ADM Quality Manual Product Planning on page 96 Also See 1860 Transport Cask Manual: "QAP – Manufacture" section "Construction procedures"	
Control of the transport operation as a process should be accomplished by documented procedures or quality plans. These procedures should cover, when applicable, identification and control of contents, packing, handling, labelling, despatch, carriage, receipt, cleaning, storage, servicing and maintenance, etc., and any special process controls, including monitoring of leak tightness, radiation and contamination levels relating to package material. These measures should also identify relevant interfaces and their controls, prevent damage, deterioration or loss of contents, and enable compliance with the relevant regulations for packages or consignments to be confirmed.	See 1860 Transport Cask Manual: "Requirements And Controls For Transport" also see 1860 Transport Cask Manual: "Radiation Protection Programme" also see 1860 Transport Cask Manual: "Emergency Response Plan"	
Processes affecting the finished product/service quality, where the required quality cannot be verified by post-process examination alone, and where pre qualification of the process is necessary, e.g. welding or heat treatment, should be controlled in accordance with documented procedures. Such procedures should refer to relevant codes, standards, specifications or dedicated requirements. Where specified, measures should be taken to ensure that these processes are accomplished by qualified personnel, procedures and equipment	See 1860 Transport Cask Manual: "Quality Assurance Programme" also see 1860 Transport Cask Manual: "Production Manual A- F"	

IAEA requirement	A&DM response	ARPANSA comment
INSPECTION AND TEST CONTROL		
Documented procedures should provide for in-process, final, and in-service inspection carried out during all phases of testing, production, transport and maintenance against specified requirements. These procedures should include provision for measuring and test equipment used to be calibrated, adjusted and maintained at defined intervals.	See 1860 Transport Cask Manual: "Maintenance and Inspection Manual"	
Test and inspection status of packagings or their parts should be identified by the use of markings, stamps, tags, labels, routing cards, inspection records, security seals or other appropriate means to indicate the acceptability or non-conformity of items. The identification of the inspection and test status should be maintained as necessary throughout manufacturing, use, servicing and maintenance of the item, to ensure that only items that meet the specified requirements are used.	See 1860 Transport Cask Manual: "Maintenance and Inspection Manual"	
Receipt inspection, in-process inspection, and final inspection measures should be planned and carried out to meet the requirements specified in regulations, standards, design and manufacturing documents, transport, servicing, maintenance, and operating procedures, instructions, applicable quality plans, etc. Essential criteria to be included in such inspection measures can be found in Safety Series No. 113	See 1860 Transport Cask Manual: "Maintenance and Inspection Manual"	
All testing required to demonstrate that the package, and its components, will perform satisfactorily in continued service should be carried out in accordance with documented procedures. Such testing may include prototype qualification and regulatory proof testing, production, operational, servicing and maintenance tests, etc. These procedures, incorporating the requirements and acceptance criteria specified in design documents, should be carried out by trained personnel using properly calibrated instrumentation and equipment. All test results should be recorded and evaluated to confirm that the defined requirements have been met.	See 1860 Transport Cask Manual: "Maintenance and Inspection Manual" See Also: See 1860 Transport Cask Manual: "Test Procedures" also see ANSTO Engineering Report	

Documented measures should ensure that tools, gauges, instruments, test software and other inspection, measuring and test equipment, and other devices used in determining conformity to acceptance criteria, are of the proper range, type, accuracy and precision. They should be properly handled and stored, controlled, calibrated and adjusted at specified intervals to maintain accuracy. Records of calibration should be maintained and be adequate for traceability of measurement, to national or international standards, when necessary. When deviations beyond prescribed limits are detected, an evaluation should be made of the validity of previous measurements and tests, and acceptance of tested items reassessed	See ADM Quality Manual "Measuring Devices"	

IAEA requirement	A&DM response	ARPANSA comment
NON-CONFORMITY CONTROL		
Documented measures should control items such as packagings, package contents, services and processes which do not conform to requirements, in order to prevent their inadvertent use before or during transport. These measures should also ensure that non-conforming items be identified by marking, tagging and/or by physical segregation, where practical, in order to control further processing, delivery or assembly. Such items should be reviewed and rejected, modified, repaired, reworked or accepted without modification. The responsibility for review and authority for disposal or acceptance of non-conforming items should be defined.	See: Model 1860 Transport Cask. "Maintenance and Inspection" Also see Dispatch Inspection Check-list Also see Dispatch Documentation check-list	

IAEA requirement	A&DM response	ARPANSA comment
CORRECTIVE ACTIONS		
Documented procedures should provide for corrective and preventive action to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective or incorrect material and equipment, and any other non-conformities, are promptly identified, corrected and prevented from recurring. Such procedures should provide for: • investigation and determination of the root causes of non-conformities and of corrective actions required to prevent their recurrence; • processing of customer, regulator or other complaints, and appropriate responsive or corrective action; • controls to ensure that corrective action is promptly implemented and effective; • detection of potential quality failures and the identification of appropriate preventive action.	See ADM Quality Manual, Measurement, Analysis and Improvement on page 154 See: Model 1860 Transport Cask Manual: "Emergency Response Plan" Also "Maintenance And Inspection"	
Corrective and preventive action reports should be documented and provided to appropriate levels of management in order to support management review and quality improvement	See ADM Quality Manual, Measurement, Analysis and Improvement on page 154 See: Model 1860 Transport Cask Manual: "Emergency Response Plan" Also "Maintenance And Inspection"	

IAEA requirement	A&DM response	ARPANSA comment
RECORDS		
Documented procedures for the identification, collection, indexing, filing, storage, maintenance, retrieval and disposal of pertinent quality documentation and records should be established. Records should demonstrate that the product or service has met the specified requirements, and that the quality assurance programme is operating effectively. Such records should be retained for defined periods, be readily retrievable and maintained in good condition. They may take the form of hard copy, electronic data or any other acceptable media.	See: ADM Quality Manual " Documentation Requirements – Requirements – Control Of Records"	
Records relating to appropriate radioactive material packagings should be established and maintained to record the complete manufacturing, operational and service/maintenance history of such packagings.	See Model 1860 Transport Cask Manual *"Radiation Protection Programme"*	

IAEA requirement	A&DM response	ARPANSA comment
STAFF AND TRAINING		
All personnel responsible for performing activities affecting quality should be suitably trained and qualified to perform their specifically assigned tasks.	See: Model 1860 Transport Cask Manual "Training" See: Model 1860 Transport Cask Manual "Radiation Protection programme" section "Radiation Protection Safety Control"	
Documented procedures should provide for the identification of training needs and training programmes, including, when necessary, specialist qualification training; records of training should be maintained	See: Model 1860 Transport Cask Manual "Training" See: Model 1860 Transport Cask Manual "Radiation Protection programme" section "Radiation Protection Safety Control"	

IAEA requirement	A&DM response	ARPANSA comment
SERVICING		
Documented measures should be established to control all servicing and maintenance activities relative to packaging, transport related equipment and other items, in order to ensure continued compliance with specified requirements. Servicing and maintenance schedules should be based on design input and experience, and also take account of normal or harsh operating conditions. The measures should provide for the identification of specified requirements, confirm that they have been met, and produce the necessary records.	See 1860 Transport Cask Manual. "Maintenance & Inspection"	

IAEA requirement	A&DM response	ARPANSA comment
AUDITS		
Documented procedures should ensure that internal audits are carried out on a regular basis to verify compliance with all aspects of the quality assurance programme and to confirm its continuing effectiveness. Similarly, when conducting external audits, to verify the quality arrangements of suppliers, they should be planned and carried out in accordance with written procedures. Audits should be conducted by qualified persons selected for their independence from the activity under audit.	See ADM Quality Manual, Internal Audits on page 156	
The documented audit results should be brought to the attention of the management personnel responsible for the activity audited. The responsible management should take timely improvement or corrective action in response to the audit findings. Verification of the effective implemented corrective action should be established and recorded.	See ADM Quality Manual, Internal Audits on page 156	
Further guidance on the various phases of audits such as audit programme elements, audit scheduling, team selection, pre- and post-audit meeting, reporting and response, and follow-up action can be found in Safety Series No. 113	Model 1860 Transport Cask Manual "Quality Assurance Programme"	