Purpose:	Establish agreement on the firm's approach to documentation
Output:	Memo to staff; guidelines for documentation
To Be Completed By:	Management Representative + lead staff
Total Time Needed:	15 minutes

33. *HELPING STAFF UNDERSTAND DOCUMENTATION*

The need to document your quality system is the biggest barrier that most firms face in the registration process. In small firms, the resistance is often stronger because staff are accustomed to an informal work environment and so the documentation requirements may seem excessively rigid. You can help staff be more cooperative by providing them with information (see Table 5).

Table 5
Sample Staff Memo About Documentation

TO: All staff
FROM: Management Representative
RE: ISO 9000 documentation requirements

One of the fundamental requirements for our ISO 9001/2/3 registration is to be able to show the auditor that we are complying with the quality-related policies and procedures we are establishing. The way we do that is by having documentation that the auditor can review.

But documentation is not just for the auditor. It's for us, too. Here are some benefits we can gain if we structure our documentation approach appropriately:

- Clarify who is responsible for what
- Clarify service standards expectations
- Clarify the most efficient way to handle routine tasks
- Provide instructions for "back-up" staff
- Provide feedback on problems and how to prevent them
- Help us "do it right the first time" & avoid having to redo our work

34. *BASIC GUIDELINES FOR DOCUMENTATION*

Remember that documentation related to your quality system is "controlled" — i.e., you need a method to track any changes made and make sure everyone is using the correct version. Your documentation development will be easiest if you keep in mind the following guidelines:

- Create only as much detail as is needed for control/monitoring of your quality system.
- Where possible, build on existing documentation.
- Use simple, clear language, with short sentences and a consistent format.
- For each process in your service delivery system, there should be:
  - a policy, setting quality expectations
  - service standards for evaluating performance
  - procedures for implementing the policy
  - work instructions and/or forms
  - a tangible result/record that can be audited
- Make sure that "objective evidence" is not the only reason for a particular document; otherwise, you will begin developing parallel systems (your quality system, and the way you "really" operate).
- Involve the staff who actually perform the work in flow charting the process, designing (or reviewing) relevant forms, and identifying who/what/when/why.
- Use visuals (diagrams, flow charts) wherever possible.
- In cross-referencing, use reference section numbers not pages (again to facilitate the process of making changes).

- Try to address a given procedure in only one place, and then create cross-references (this will simplify making changes).

- Use a minimum of tracking documents (master lists) controlled forms; controlled lists.

- Develop the minimum number of forms.

- If a form is to serve more than one purpose, make sure that it works for all parties using it (see Table 6 for examples, referring to elements in the ISO 9000 standards).

Table 6
Examples Related to Combining Forms

Example of Combining Forms:

If the same staff person has several sequential responsibilities and the related forms are to be filed in the same place, then you may be able to combine the documentation of those activities into a single form. For example, you might be able to combine onto one form your "capabilities review" (for element 4.3) and your "project planning" (for element 4.9) as they are both preparatory activities undertaken by professional staff with documentation probably filed in the client's file.

Example of Needing Two Separate Forms:

If there are two related activities (or an activity within an activity) whose documentation is performed by different staff members or would be filed in separate places, then you probably need two forms. For example, you may need a form to plan for the production of a large report (for element 4.9, which would be kept and monitored by your support staff) and then a separate form for the editing of that report (for element 4.10, which might be done by another professional staff member).

35. *STRUCTURE OF YOUR DOCUMENTATION SYSTEM*

There is a hierarchy of types of documentation that you should keep in mind, with the first two levels typically needing to be submitted for audit:

Table 7
Hierarchy of Documentation

Level	Type of Document	Purpose of Document
1	Quality Manual	State quality-related policies
2	Procedures	Instructions for implementing the policies
3	Forms, lists, work instructions	Tools for implementing the procedures
4	Quality records (training, internal audits, problem logs, inspections)	Verify that the quality system is working properly

36. *COMMON CONTENT IN ALL DOCUMENTS*

Regardless of the "level" of document, there are common issues that need to be addressed in each one:

- Who has implementation responsibility
  This is the person who is held accountable if the policy, procedure, or task is not performed correctly. On forms, this designation could be handled by a subheading addressing responsibility.
- Who should perform the task
  This may or may not be the same person that has implementation responsibility. For forms, this could be handled by a subheading or instruction on who should fill it out.
- The purpose of the policy or procedure
- Reference information (computer file, date/version number)
- An indication of whether and how it is "controlled"

For quality records, you will also need a place for the initials of the staff member who performed the function or review (for accountability).

Purpose:	Create the firm's Quality Manual
Output:	Quality Manual
To Be Completed By:	Management
Total Time Needed:	2 days

37. ***PURPOSE OF THE QUALITY MANUAL***

Your Quality Manual should state your Quality Policy and all related policies that make up your quality system. It is for your firm as a whole, whether you have one office or several offices. It is the basis on which your quality system is audited by your Registrar so its contents are important. After your Quality Policy, this is the most public documentation of your quality system. You may find that some clients or some bid documents require that you provide them with a copy of your Quality Manual. Typically, your Quality Manual will be between 20-40 pages. See ISO/DIS 10013 for more information.

38. ***WARNINGS ABOUT YOUR QUALITY MANUAL***

WARNING #1: Because this could become a "public" document, your Quality Manual is not the place for proprietary information or highly sensitive material; rather, it should represent a statement of what your clients can expect from you ... the quality obligations you are undertaking.

WARNING #2: There are a number of computer programs on the market now that will "automate" your process and create a generic Quality Manual for you by simply restating the elements of the standard. A generic Manual does little for your firm ... it is too general to provide any real guidance to staff or assurance to a third party.

39. ***STRUCTURE OF THE QUALITY MANUAL***

Review of your Quality Manual by your Registrar's audit team is the first step in your registration audit — called the "document review" or the "desk audit." So your Quality Manual needs to be "auditor friendly" while still being useful to you internally. An auditor will approach your Quality Manual from the perspective of seeing if the structure of your quality system, as described in the Quality Manual, meets the requirements of the standard.

You can help that review process immensely (and make sure you don't overlook anything) if you organize the Quality Manual by the elements in the standard. Since you need to state explicitly if an element does not apply to your operations (as with "Design Control" if you have selected ISO 9002), you will have 20 sections to your Quality Manual.

Both the audit team and your staff will want to know which procedures are used to implement each policy; therefore, you will want to cross-reference your Quality Manual with your procedures binders.

40. *LAYOUT OF THE QUALITY MANUAL*

Keep in mind as you develop your Quality Manual that you have potentially three audiences: your staff, your Registrar, and your clients. In addition to the specific requirements of the standard regarding a Quality Manual (see ISO 9001:1994, Section 4.2.1), you have an opportunity to pull together all material relevant to your quality objectives.

a) **Front Material**

You will want to establish the context for your quality system, especially for the audit team. Some material you may wish to include:

- your firm's history (briefly) and present market position
- types of clients you serve and types of services you provide
- "corporate" structure, including who has approved the Quality Manual
- "corporate" mission statement, goals, and objectives
- the scope covered by your quality system
- schematic of the relationship between the Quality Manual and other documentation (e.g., procedures binders)
- definition of any special terms (refer to page 4)
- a table of contents

b) **Document Control**

You will need to include a distribution list, and some way to identify each copy — such as numbering the various copies. When you make extra copies (e.g., for client review), you will need to mark that copy clearly as "uncontrolled" or "sample only".

You will also need to include a statement about how updates to the Quality Manual will occur, covering the type of staff consultation that you would undertake.

c) **Management Commitment**
Throughout the documentation development process, you will want to simplify as much as possible. One way to simplify is to "do" rather than talk about doing ... and one opportunity for you to demonstrate management commitment is to develop and sign a customized Quality Manual for your staff.

41. *IDENTIFYING POLICY GAPS*

Some of the policies for your Quality Manual will already exist, while others will need to be developed. The following steps will help you identify any gaps:

Step 1: Locate the core processes flow chart you did in Work Sheet #2 which represents the "scope" as agreed to with your registrar.

Step 2: Collect (or have your lead staff collect) copies of all of your firm's policies and sort them using the categories in Work Sheet #14:

- Who does what (authorities and responsibilities)
- Service delivery process (performance for the client)
- Inputs needed (purchasing, client materials, training)
- Documentation approach
- Addressing problems
- Assessing quality system status

You will probably have the most policies documented for "service delivery process."

Step 3: Using the reference numbers for the standard's elements in Work Sheet #14, organize the policies in the above six categories by element. For the "service delivery process" pile, the correspondences you should have between your generic core processes and the standard's elements are outlined in Table 8.

Step 4: List the policy statements that need to be developed for all missing parts of the standard. Then double check your list by reading through each element in the standard.

Table 8
"Service Delivery Process" Elements & Your Core Processes

Your Core Process	Standard Element Number
Bids/quotes for client work	4.3
Contracting with clients	4.3
Designing the service	4.4
Implementing the work plan	4.8; 4.9; 4.19
Client review/approval	4.9; 4.10
Work completion	4.9; 4.12
Storage of closed files	4.15

42. ***POLICY TEXT***

A good policy should state an overall organizational objective. It should set the parameters for addressing each of the elements. It should not include specific procedures that might get modified over time, nor should it include specific work instructions. This is a document that presents management's expectations and helps staff identify what is most important. It should be specific enough that a staff member can make useful reference to a policy when trying to decide what to do in a unique client situation. Before you start drafting policies, create a standard format template to use for your text.

43. ***NAMING YOUR "QUALITY MANUAL"***

In the 1994 standards revisions, ISO recognized and addressed some of the areas of confusion experienced by firms. One of these is that there may be policies and procedures in place in your firm related to "quality" that are not part of your quality system scope for audit purposes. Several examples include:

- Standard instructions for administrative procedures
- Policy on confidentiality of personnel records
- Financial management guidelines

Therefore, ISO offers you the option of calling your "quality manual" a "quality assurance manual" to distinguish it from internal "quality management" documents.

Purpose:	Complete your quality system procedures
Output:	Procedures binder
To Be Completed By:	Lead staff + senior manager
Total Time Needed:	9 days

44. *THE PURPOSE OF PROCEDURES*

Policies are important because they give direction to staff and help them approach new situations appropriately. But in order to know how to implement a policy, staff members need a practical guide — which is precisely what your quality systems' procedures are. Those procedures should help a staff member visualize what steps to take in order to perform a particular process, in the context of the quality policy that has been established. Each procedure should identify "what to do" and "who is responsible".

Because a quality system cannot operate without procedures, registrars are now starting to require that your operating procedures be submitted for the "desk audit" along with your Quality Manual. Keep in mind that whenever you change "controlled" documentation that has been submitted for the "desk audit" and retained by the Registrar, you will have to forward a copy of the change to the Registrar. You may arrange to forward a "draft" for approval before formally issuing a change so that you don't inadvertently jeopardize your registration.

45. *OTHER LEVELS OF DOCUMENTATION*

Supporting your procedures are two other levels of documentation:

- Work instructions and forms (how to do it)
- Quality records

These documents stay in your office and are only audited during an on-site audit. Any detailed instructions or "how tos" should be kept at the working instruction level instead of included in the procedures. You avoid a lot of unnecessary changes and updating to procedures if you keep very detailed instructions out of your procedures (see Table 9 for an example).

NOTE: You may need to clarify with other staff that what people often call "procedures" are "work instructions" in the ISO 9000 context.

Table 9
Example of Using Different Levels of Documentation

Policy [4.10.4]

There shall be a formal, documented review of all final client deliverables before they are released to the client.

Procedure

Final client work shall be reviewed independently (if feasible), and that review shall be documented using the "Deliverables Review" form. If errors are found, they should be corrected and their cause evaluated. If there appears to be a consistent type of error, that fact shall be noted in the Problem Log for discussion at the next staff meeting.

Work Instructions

[Detailed explanation of how to use the "Deliverables Review" form and what to do with it once it is complete.]

Quality Records

[Completed and initialled "Deliverables Review" forms.]
[Relevant sections of problem log.]

46. *IDENTIFYING THE PROCEDURES NEEDED*

While the Quality Manual is being drafted, you can begin the process of identifying what written procedures you will need to develop, using the following steps:

Step 1: Locate the core processes flow chart you did in Work Sheet #2, and that represents the "scope" as agreed to with your registrar.

Step 2: Collect copies of all of your firm's procedures, work instructions, and forms and sort them using the categories in Work Sheet #14:

- Who does what (authorities and responsibilities)
- Service delivery process (performance for the client)
- Inputs needed (purchasing, client materials, training)

- Documentation approach
- Addressing problems
- Assessing quality system status

You will probably have the most documents for "service delivery process."

Step 3: Using the reference numbers for the standard's elements in Work Sheet #14, organize the documents in the above six categories by element.

Step 4: Check the materials you have against the responses you received in the Staff Status Questionnaire (see Work Sheet #6) and Work Sheet #14. If there are areas where staff said "fine" or "in place" but you have no documentation, check with other staff to locate what is missing.

Step 5: Make a list of the various procedures that need to be developed, using Work Sheet #14 and the ISO 9001/2/3 standard as references.

47. *WRITING THE PROCEDURES*

In order for your quality system to operate properly, every staff member needs to "own" it ... which means understanding and agreeing with the procedures to be used. As much as possible, you will want to involve staff in at least reviewing, if not writing, the procedures for their own work.

Step 6: If you do not already have some kind of operating procedures manual or binder, agree with the rest of the staff on a format for one.

If you already have some kind of operating procedures manual or binder, review its structure to identify how best to segregate "controlled" procedures into a "Quality System" section.

Step 7: Create a standard format for procedures and get it approved by the senior manager. Make sure it includes "what to do" and "who is responsible" without detailed "how tos".

Step 8: Identify which staff members are responsible for the activity or process involved, and either ask them to write a procedure or interview them and then write up a procedure for their review. You may find it helpful to create a flow chart of the procedure rather than using narrative.

Step 9: Determine where the completed procedures binder should be placed so that staff have easy access — i.e., one for each desk.

Step 10: Schedule a staff meeting to orient staff to the various procedures and their supporting forms, work instructions, and quality records.

Purpose:	Create documentation for quality system implementation
Output:	Quality records
To Be Completed By:	Lead staff person
Total Time Needed:	1 hour

48. *PURPOSE OF A QUALITY RECORD*

Quality records are documents or data files that demonstrate that the activities which form your quality system have been carried out. They are the evidence that an auditor will review.

Not all forms are quality records, as they may serve purposes other than to document implementation. For example:

Capabilities Review Form	This is a quality record that shows you have carried out the requirements of your policy and procedures related to element 4.3 in ISO 9001/2/3.
Contract Summary Form	This is not a quality record if its purpose is to present the details of a client contract to help your staff meet the terms of the contract.

49. *TYPES OF QUALITY RECORDS*

From a practical perspective, there are three types of quality records based on how you will file them (see Work Sheet #15 for a checklist).

- client-related quality records
- support-related quality records
- oversight quality records

You only need to create separate forms to function as quality records when regular documentation and client correspondence will not fulfil that function.

Work Sheet #15
Checklist of Quality Records Needed

QR?	Alternate?	Element	
____	____	4.1.3	Management Review
____	____	4.2.3	Quality planning
		4.3	Contract review for:
____	____		- comparing firm's capabilities to client's needs
____	____		- client agreement on Statement of Work
____	____		- client's authorization to proceed
____	____		Contract amendments
____	____	4.4	Directions for customizing work
____	____		Reviews of design work in progress
____	____		Design verification/validation
____	____		Coordination among all persons working on design
____	____	4.5	Master list of controlled documents
____	____		Designation of master computer files for controlled documents
____	____	4.6	Approved list of vendors/subcontractors
____	____		Non-approved list of vendors/subcontractors
____	____		Purchase orders for "controlled" items
____	____		Written contract with professional affiliates
____	____		Performance of vendors/subcontractors
____	____	4.8	List of unique client/contract identifiers
____	____	4.9	Work planning
____	____		Supervision and peer review
____	____		"Controlled" equipment maintenance
____	____	4.10	Final inspection, with authorization for release
____	____	4.13	Description of nonconformity and disposition

[continued on next page]

(Work Sheet #15 continued)

QR?	Alternate?	Element
		4.14 Problem logs, with corrective action, for:
____	____	- client relations
____	____	- client work
____	____	- "controlled" equipment
____	____	- vendors
____	____	- subcontractors/affiliates
____	____	- staff training
____	____	Forwarding of preventive actions for Management Review
____	____	4.16 Master list of quality records
____	____	4.17 Results of internal quality audits, and follow-up
____	____	Forwarding of audit results for Management Review
____	____	Results of external quality audits, and follow-up
____	____	4.18 Staff training
____	____	4.20 Forwarding of performance measures for Management Review

Key: QR = separate quality record
Alternate = use of existing documentation as quality record

50. *FILING QUALITY RECORDS*

Client-related quality records

If your client files are confidential, you may need to keep a copy (marked "COPY") of these forms in a file folder with your other quality records for review by quality system auditors so that client files themselves do not need to be reviewed during the audit.

Support-related quality records

These records would typically not be part of a client file. They should be grouped together for easy audit access rather than being part of other files; for example, staff training records should be with quality records rather than in confidential personnel files.

Oversight quality records

These audit records should be filed with support-related quality records.

51. *RESPONSIBILITY FOR QUALITY RECORDS*

The Management Representative has the ultimate responsibility for quality records as the person responsible for the quality system.

52. *REVIEW OF QUALITY RECORDS*

There are several internal reasons for review of quality records:

- To make sure that nonconformities have been corrected.
- To verify performance of vendors/subcontractors/equipment.
- To identify possible preventive actions.
- To plan for subsequent staff training.
- To plan for continuous improvement.
- To conduct Management Reviews.

Review of quality records is also one of the main activities in the on-site external audits by your Registrar.

Purpose:	Verify that all processes in the scope have been documented
Output:	Final procedures binder
To Be Completed By:	Lead staff person, reviewed with senior manager
Total Time Needed:	8 hours

53. *THE PURPOSE OF A PROCESS AUDIT*

Before beginning internal audits of your quality system, you will want to satisfy yourself that all "processes" included in your scope have been documented. The basic orientation of your Registrar will be:

Say what you do.
Do what you say.
Document that you have done it.

Your job now is to satisfy yourself that the first is true ... that you have truly said what you do.

54. *CONDUCTING A PROCESS AUDIT*

Starting with the general flow chart of your scope, you will want to interview each staff grouping within your firm using the checklist given in Work Sheet #16.

"Controlled" equipment refers to the equipment that is essential to the functioning of your quality system. You should check with your Registrar on interpretation. At a minimum, your computers and printers will probably be included.

Under "Purchasing" again you should check with your Registrar about coverage. Not all of your vendors/subcontractors are part of your quality system. For example, courier service would be included if that is the mode you use for delivery of final product to your clients, but not if you use couriers only occasionally. Printing services might be included if you use an external printer to produce all client reports, but would not be if the printer is only responsible for stationery, etc.

Work Sheet #16
Checklist for Your Process Audit

Covered?	Scope "Process"
	Client Service Processes:
_____	Bids/quotations for client work
_____	Contracting with clients
_____	Developing your work plan
_____	Designing the service [if ISO 9001]
_____	Implementing the work plan
_____	Reviews of client work
_____	Client review/approval
_____	Work completion
_____	Storage of client files
	"Controlled" equipment
_____	Computers/printers
_____	Other (photocopier; fax; etc)
	Quality System
_____	Purchasing
_____	Staff training
_____	Supervision
_____	Peer review
_____	Management Review
_____	Quality records

If you find any areas within your scope that have not been covered in your documentation, now is the time to correct it.

Purpose:	Ensure proper document control
Output:	Memo to staff; steps for exercising document control
To Be Completed By:	Management Representative
Total Time Needed:	1 hour

55. *RESPONSIBILITY FOR DOCUMENT CONTROL*

A lead staff member (who may or may not have been yourself), supported by senior management, has made every effort to put in place an appropriate quality system for your firm. Since you are responsible for that quality system, it is now time for you to check that the quality system will function properly. One of the key elements is document control.

56. *UNDERSTANDING DOCUMENT CONTROL*

After documentation itself, document control is usually the most difficult part of the quality system for staff to implement. In a small firm, document control is typically effective though quite informal; however, there are those embarrassing moments when an older version of a document is printed and forwarded to a client by mistake or an incorrect version of a form is used. Document control is intended to prevent such occurrences, as well as to eliminate staff time spent in trying to verify that the most current file/document/procedure is being used.

57. *IMPLEMENTING DOCUMENT CONTROL*

Poor document control is the most common reason for failing the registration audit. It will help if you brief all staff on the important principles of document control, and Table 10 provides you with a sample memo to do so. Your implementation process should include the following steps:

Step #1: Make sure that you have an up-to-date distribution list of all controlled copies of the Quality Manual and the procedures binder that you can use as a checklist for updating purposes (and you can use the opportunity to doublecheck each one).

Table 10
Sample Staff Memo on Document Control

TO: All staff
FROM: Management Representative
RE: Document control

Thanks to the efforts of everyone, but particularly _____, we now have an auditable quality system in place that addresses all the elements in ISO 9001/2/3. Because inadequate document control is the most common cause of registration failure, I want to share with you some of the principles for good document control:

#1. Our Quality Manual has only a stated number of copies, whose ownership is on the distribution list at the front of the Quality Manual. This is so that I can make sure pages in each manual are updated as appropriate so that you can always be sure you are looking at the current quality system policies. These official current versions have a number on the front and are initialled on each page. If you have an unnumbered copy (e.g., one that was made to show to a client), be aware that it will not be kept current and should be destroyed. If you want your own numbered copy, let me know and I'll add you to the list.

#2. Our procedures binder also has only a stated number of copies, with a distribution list so that I can update it. Again, you should be working with a numbered copy, initialled copy; if you want your own, let me know.

#3. You are responsible for following the policies and procedures as stated in the "controlled" copies. This means that, whenever we agree on a change in a procedure or policy, it is my responsibility to issue updated pages, replace the outdated pages in each controlled copy, and shred or otherwise destroy the outdated pages as soon as possible.

[continued on next page]

(Table 10 continued)

#4. To help facilitate the updating process, please keep these "controlled" documents easily accessible at the office, instead of taking them home.

#5. If you want to suggest a change in either "controlled" document or "controlled" forms, please see the front of the procedures binder for how to do so. If the change is agreed to, we will have a staff orientation to the new procedure and then begin using it.

#6. Please notice that in each manual all pages have been dated, with the latest dates for each section listed in the table of contents. If you are wondering if your controlled document has really been updated, you can check the date for the latest procedure change. If yours was not updated, please let me know immediately.

#7. If a procedural change is not immediately obvious on a page, I will provide you with a highlighted copy at the time of the staff orientation.

#8. With regard to forms, please note that the current version of each "controlled" form is in our Forms Binder, with a signed master copy and a "clean" copy for photocopying. If you notice any discrepancy between the "signed" copy and the one for photocopying, please bring it to my attention immediately.

Thank you for you assistance.

Step #2: In updating "controlled" documents, you will need to update both the Contents page (where the date of the latest version should be listed) and the changed section of the manual with its new date. You may find that updating is easier if printing is one-sided rather than double-sided.

Step #3: If you elect to initial all pages, you will save a lot of time if you initial a master and then make photocopies from that master.

Step #4: Schedule a staff orientation to the change prior to the implementation date, at which time you can either orally note the change(s) and/or distribute copies of the new pages with changes highlighted.

Step #5: Make the date on the new page(s) correspond to the date on the computer file (for easy checking), and inform staff of the implementation date if it is different.

Step #6: While you are not required to physically remove/replace pages, you may find this the best procedure to make sure it is done.

Step #7: Make sure that the computer files for your Quality Manual and procedures binder are "Read Only" so that other staff do not inadvertently make "uncontrolled" changes. This is particularly important if such files are stored in a networked environment.

58. ***DOCUMENT CONTROL OF FORMS***

The "controlled" forms that your firm uses typically exist loose so that they can be photocopied for staff use. You will probably want to create a Forms Binder, in which you can put (back-to-back) a master copy that is signed (or otherwise identified as the official current version) and a "clean" copy for photocopying.

When changes are made to forms, you will need to collect and shred or otherwise destroy older versions of the forms. Your job may be easier if quality system forms are photocopied onto coloured stock so that they are easily identifiable.

59. ***RECORDS OF DOCUMENT CHANGES***

You will need to maintain a file of changes to quality documents as part of your quality records. The easiest way is probably to keep a copy of the "replaced" pages, labelling them as replaced.