

7.1

• GETTING REGISTERED: Document Review

Purpose: Pass the registrar's document review successfully

Output: Documents to registrar; memo of results to staff

To Be Completed By: Management Representative

Total Time Needed: 30 minutes to review documents

30 minutes of follow-up activities

60. **IS YOUR DOCUMENTATION READY?**

At this point in your preparation process, you are about to have your first formal contact with your registrar since you reached the initial registration agreement. You will be submitting your documentation for a "desk audit." Work Sheet #17 has a check list for your review just to make absolutely sure you've covered everything, or your registrar may have a standard checklist you can use.

Work Sheet #17 Reviewing Your Documentation

Review your Quality Manual and supporting procedures from the perspective of the registrar's audit team:

YES NO

- | | | |
|-------|-------|--|
| _____ | _____ | Does your quality system documentation demonstrate that your firm has the structure in place to monitor itself? |
| _____ | _____ | Is there a master list of controlled forms/documents? |
| _____ | _____ | Does each controlled document contain: |
| _____ | _____ | a distribution list? |
| _____ | _____ | instructions on how to initiate changes? |
| _____ | _____ | a clear statement of who is responsible for updating? |
| _____ | _____ | dates on all pages? |
| _____ | _____ | a history of changes? |
| _____ | _____ | a notation as to the corresponding computer file? |
| _____ | _____ | Is each controlled document signed by the appropriate person? |
| _____ | _____ | Is each controlled copy numbered or otherwise identifiable? |
| _____ | _____ | Are the documents being sent to the registrar the correct controlled copies (i.e., the ones intended for the registrar)? |

● **GETTING REGISTERED: Document Review**

61. COMPLETING THE "DESK AUDIT"

Once your documentation has been submitted, you will of course be eager to learn the outcome of the "desk audit." As the Management Representative, it is your role to be the person in contact with the registrar as you are the one responsible for your quality system implementation. Once the "desk audit" has been completed, there are several outcomes that may occur:

- a) You may pass, without any need for changes.
- b) You may need to make minor changes, but none that would delay your on-site audit.
- c) You may need to make major changes and resubmit your documentation before an on-site audit can be considered.

Work Sheet #18 contains a memo you could send to staff, depending on the outcome from the registrar, in addition to "debriefing" the registrar's comments in a staff meeting.

Work Sheet #18
Sample Staff Memo About the Desk Audit Results

TO: All staff
FROM: [The Management Representative]
RE: Outcome of our ISO-9001/2/3 document review

- (a) I am pleased to be able to report that we have passed our document review successfully. Thank you all for your help in doing such an excellent job of documentation. Now we will need to focus on our internal audits to prepare for the on-site audit scheduled for _____.
- (b) I am pleased to be able to report that we have been asked to make only minor changes in our quality system. We will be reviewing the changes needed at our next staff meeting on _____. I will need cooperation from all of you in the revision and internal audit process so that we can keep our scheduled on-site audit date of _____.
- (c) Unfortunately, our registrar has informed me that we need to re-examine _____ in our quality system and then resubmit our documentation for another review. Please be sure to attend the staff meeting on _____ so that we can plan how best to address the registrar's concerns.

Purpose:	Complete successful internal audits
Output:	Internal audit reports
To Be Completed By:	Management Representative and internal audit team
Total Time Needed:	[variable]

62. **TRAINING YOUR INTERNAL AUDITORS**

You have already identified the persons likely to do the internal audits. Now they will need training. Your registrar probably offers a training course for internal auditors; if not, other trainers certainly do. The thing to keep in mind is that, at externally-given courses, most examples and audit design approached will be geared to manufacturing. As you will have more than one staff member needing the training, it may well be more cost-effective for you to hire a trainer to come on-site and give an internal auditor training course customized for your industry.

63. **CONDUCTING INTERNAL AUDITS**

Internal audits are intended to verify whether or not the requirements of the quality system you have designed are being followed precisely. The focus of the audit is on objective evidence of compliance. The purpose is to determine whether or not a procedure was followed, without worrying about why.

Because a staff member cannot audit their own area of work, you will need at least two internal auditors ... probably more. Internal auditors need to be able to form an independent judgement and resist inappropriate pressure to change it, interact tactfully with other staff, and pay attention to detail (regarding what is required and what has been done).

64. **PREPARING A REGULAR INTERNAL AUDIT SCHEDULE**

The Management Representative should be satisfied that a reasonable audit schedule has been developed for a twelve-month period, during which the entire quality system will have been audited. You will need to have specified in your Quality Manual how frequently internal quality audits are to be carried out — probably once a quarter.

● GETTING REGISTERED: Auditing Yourself

In developing your internal audit schedule, you can plan to audit by functional area (front office, professional staff) or by an element of the standard. Also, you need to launch additional audits if circumstances warrant (e.g., internal reorganization, excessive customer complaints, increase in nonconformances).

65. ***DETERMINING THE AUDIT SCOPE***

For each audit, the scope of the audit needs to be clarified with the Management Representative and then communicated to the staff being audited. Because each internal auditor also has regular job responsibilities, you will probably find it easier to have shorter, more frequent audits than to have to set aside a full day of an auditor's time. Of course, the shorter the audit period, the narrower the scope.

66. ***PREPARING CHECKLISTS FOR YOUR INTERNAL AUDITS***

Once the scope is established, you need to create checklists of the aspects to be audited, beginning with any areas where nonconformances were found earlier. Some of the decisions you will need to make include:

- ▶ Who to interview
- ▶ What quality records to examine
- ▶ How to sample from those quality records
- ▶ What activities to observe

These checklists can then serve as part of the records of the audit. If properly designed, they can also be used to give feedback to the persons being audited (see an example in Work Sheet #19) — both on what they are doing well and what needs improvement. Think about ways that you can use this form to reward and motivate staff to comply. For example, you might stamp happy "smileys" under "Fine" and sad faces when there is a problem. Or you could adopt a rating scale similar to that used in Consumers Report.

**Work Sheet #19
Sample Internal Audit Checklist Format**

Item Being Audited	Status		Observations and CARs
	Fine	Problem	

67. CONDUCTING AN INITIAL INTERNAL REVIEW

Before starting your regular audit schedule, you will probably want to do an initial audit to help staff get used to the quality system. You may also find it helpful to ask staff a series of questions similar to those that will be asked by the external auditor (see Appendix H).

68. NORMAL AUDIT PROCEDURES

You should confirm an audit time with the staff being audited and communicate the scope of the audit. After the audit is concluded, the auditor should complete a report and submit it to the Management Representative. The findings of the audit should be communicated to the persons audited, along with any Corrective Action Requests (CARs).

69. AUDIT REPORTS

In addition to the checklists described above, the auditor needs to prepare a brief report (quality record) that contains:

- ▶ Date of audit
- ▶ Who carried out the audit
- ▶ The scope of the audit
- ▶ The findings of the audit and any observations

● GETTING REGISTERED: Auditing Yourself

If any deficiencies are found, they need to be classified as follows:

- ▶ Major: the absence or breakdown of a procedure
- ▶ Minor: a single lapse in a procedure
- ▶ Observation: a minor deficiency that could lead to a major problem if not addressed

70. ***FOLLOWING UP ON NONCONFORMANCES***

It is the responsibility of the Management Representative to make sure that nonconformances are addressed (see Item #71). If the nonconformance was major, then a re-audit should be scheduled to make sure everything is O.K.

Remember that these follow-up activities, and their time frames, need to be documented in your quality records. The registrar's auditors will look for at least three months of internal audit records to see how well your quality system is functioning and how responsive your staff is to making the necessary corrections.

71. ***TAKING CORRECTIVE AND PREVENTIVE ACTION***

Once a nonconformance is identified (and there will be plenty of them at first!), you will need to take the following steps, with all relevant staff involved:

Step #1: Determine the facts — what actually happened, what actions did which persons take (or not take). It is critical for the functioning of your quality system that this determination be done objectively and without assigning blame. You want your staff to be direct and honest about their behaviours, rather than trying to excuse or coverup problems, as you can only resolve identifiable problems.

Step #2: Unless the reason for the nonconformance is very obvious, you will need to do a "root cause" analysis — i.e., identify the real reasons for the problem.

• GETTING REGISTERED: Auditing Yourself

- Step #3:** Next you will need to determine what actions to take to correct the present situation and make sure that similar problems do not recur in the future. Sometimes the answer will be that staff need more practice in a new procedure ... or need orientation to that new procedure. Other times you may find that the procedure itself needs to be redesigned.
- Step #4:** Once you know what needs to be done, do it! And keep attention on the problem until it is fully resolved. One of the most common difficulties is a lack of complete follow-through in addressing and resolving nonconformances.
- Step #5:** The actions that you have taken will need to be recorded in a quality record. You can either have a column for this on the audit report itself or a separate Corrective Action Form (see Table 11 for an example).
- Step #6:** Unless the matter is very minor, you also need to share the problem and its resolution with the rest of your staff. While not all staff may be likely to repeat that same error, more often than not they can learn from the experience in terms of possible preventive actions to take in their own areas of responsibility.

**Table 11
Sample Corrective Action Form**

Item for Corrective Action:	Responsible:
Description of Problem:	
Root Causes:	
Actions Recommended:	Taken? YES NO
	Effective? YES NO, so _____

● **GETTING REGISTERED: Auditing Yourself**

Step #7: Your corrective action cycle is not completed until you have evaluated the effectiveness of the corrective actions that you took. That evaluation may consist of a discussion on how the change is working out prior to the next internal audit, or it may be delayed until the next formal audit.

72. *MANAGEMENT REVIEW OF RESULTS*

Management needs to receive copies of the internal audits and schedule a review of those results according to the timetable committed to in the Quality Manual. It is the responsibility of the Management Representative to make sure that those management reviews take place and are documented properly.

73. *AUDITING YOUR INTERNAL AUDITORS*

Because all aspects of your quality system need to be audited, someone who is not one of the regular internal auditors is needed to audit the audit function. Most likely, the Management Representative will fill this role. Again, a record of this audit should be kept with the other "oversight" quality records.

74. *ARE YOU READY FOR AN EXTERNAL AUDIT?*

Remember that your quality system needs to be functioning for a period of not less than ninety (90) days without any major nonconformances before your registrar can perform an on-site assessment of your quality system.

Purpose:	Be ready for the Registrar's audit team
Output:	Audited premises and knowledgeable staff
To Be Completed By:	Management Representative and all staff
Total Time Needed:	1 day for preparation (Management Rep) 2 hours staff meeting time

75. *BECOMING FAMILIAR WITH THE AUDIT TEAM*

Prior to your on-site registration audit, you should talk with your Registrar about who will be auditing you. Ask to see the credentials of the audit team to assure yourself that someone on the team is familiar with your industry and with firms your size.

In addition to the size and composition of the audit team, you can also learn the scope of the registration audit and the general approach. If they are coming from out of town, be as helpful as possible with travel arrangements and local transportation.

76. *TIDYING UP LOOSE ENDS*

In preparation for the on-site visit, you will need to take time making sure that what you said in your documentation is the way the office is actually operating. The items in Work Sheet #20 give you examples of some of the most common oversights.

77. *PRACTISING ANSWERING QUESTIONS*

Since the auditors will be asking questions of all staff members, it can help people prepare if you practice answering obvious questions, such as those in Appendix I (modify as appropriate). You may find it useful to schedule a two-hour staff meeting at least one week in advance of the on-site audit to go through the questions together. Some areas that you should be sure to clarify with staff include:

- ▶ The difference between quality records and quality documents
- ▶ The role of the Management Representative

● **GETTING REGISTERED: Preparing for Audit**

Work Sheet #20
Checklist for Registration Audit Preparation

_____	Training records current and separate from personnel records?
_____	All client materials correctly labelled and filed?
_____	Forms Binder up to date?
_____	Approved/Non-Approved vendor lists up to date?
_____	Other master lists up to date?
_____	Outdated computer files removed?
_____	"Controlled" computer files set for "read only" or passworded?
_____	All quality records up to date?
_____	Corrective actions current for problem logs?
_____	Management Review of internal audits reported and filed?
_____	Staff meeting of registration audit scheduled?
_____	Management review of registration audit scheduled?

- ▶ The meaning of each standard element
- ▶ The scope of activities being registered
- ▶ The differences between ISO 9001, ISO 9002, and ISO 9003
- ▶ How management supports your quality system
- ▶ What to do if unsure about a quality-related procedure
- ▶ When the staff review of audit findings will be held

At that staff meeting you should also review with staff the on-site audit objectives and scope.

78. ON-SITE PREPARATIONS

The Management Representative will need to be free all day to escort the auditors so you will need to arrange appropriate back-up. If more than one auditor is coming, you will need to designate other staff members to also act as escorts (one per auditor).

The auditor team will need a good workspace, with copies of relevant documentation handy. They may also respond well to having a sandwich lunch ordered in so that they can visit informally with members of your staff over lunch.

Purpose:	Successful registration audit
Output:	Audit report
To Be Completed By:	All staff
Total Time Needed:	All of on-site audit (Management Rep) 2 hours staff time (rotating)

79. **MEETINGS WITH THE AUDIT TEAM**

The Lead Auditor will hold an opening meeting with you to introduce the audit team and clarify the following:

- ▶ The audit scope and objectives
- ▶ The approach to be taken
- ▶ The communication link
(Lead Auditor to Management Representative)
- ▶ The date/time for the closing meeting

At the end of the audit process, the Lead Auditor will hold a closing meeting with you to present the audit findings, clarify any nonconformances found, and determine a time table for any corrective actions needed. The Lead Auditor may ask that you sign a CAR (corrective action request).

80. **TIPS FOR THE "SHOW ME"**

One of the most important "show me" items is management commitment. It is critical that senior management and professionals actually be on-site during part or all of the audit, and make themselves available for questioning. Other tips:

- ▶ Answer questions, but don't volunteer extra information.
- ▶ If you don't know an answer, don't guess. Just say you would ask the Management Representative.
- ▶ Don't bring out documents that have not been specifically addressed or cross-referenced in your Quality Manual.

● **GETTING REGISTERED: On-Site Audit**

81. ADDRESSING THE AUDITOR'S FINDINGS

Depending on the seriousness of the noncompliance, the auditor will probably offer one of three options:

"If you can correct this before we leave..."

"If you can correct this in 30 days..."

"We will need to re-audit after your corrective action."

82. BECOMING REGISTERED

You should be prepared for the fact that, even if you have a successful registration audit, you are not automatically registered. The Lead Auditor will have to file a report recommending that your firm be registered to ISO 9001/2/3.

83. CELEBRATING

You've worked hard and deserve to celebrate! You may want to just have an internal celebration, or you may want to have an Open House and generate some publicity about your registration.

Purpose:	Maximize your competitive advantage from registration
Output:	Revised promotional material; letters to clients and vendors
To Be Completed By:	Management Representative
Total Time Needed:	4 hours

84. **ADVERTISING YOUR REGISTRATION**

ISO has published guidelines on what you can and can't do (Publicizing Your ISO 9000 Registration), with examples of appropriate advertising. Basically, you need to rehearse with your staff that what is registered is your quality system, not your client services. Your firm has been registered by your Registrar, not by ISO. Common errors to avoid:

Don't say ISO-registered
 registered by ISO

Do say registered to [ISO 9001/2/3]
 registered by [your Registrar]
 ISO-9000 registered

You need to be specific about which office and the scope of your quality system, when that level of detail is appropriate.

You will need to be proactive about making sure that your firm gets listed in the various directories of registered companies (such as the one published by CEEM/Quality Systems Update), not just listed in your Registrar's directory. If you paid for co-registrations, obtain proof that your firm is also listed in those directories abroad.

85. **REVISING YOUR PROMOTIONAL MATERIALS**

Your Registrar will supply you with a "mark" that you can use on your letterhead and promotional materials, but not on client reports or other products. Remember, it is your ability to assure quality that has been registered, not the quality of a particular service deliverable.

● AFTER REGISTRATION: Visibility

You will also want to revise text that you use in promotional literature and proposals to clients to indicate that your firm is now registered. Consider including a copy of your Quality Policy (perhaps a short version).

86. **COMMUNICATING WITH CLIENTS**

If you receive repeat and/or referral business from clients, then you will want to send out a letter announcing your registration. Again, consider including a copy of your Quality Policy.

87. **COMMUNICATING WITH VENDORS**

Because of your responsibility for the quality of inputs, you should consider writing to each of your present vendors and letting them know of your registration. By asking them if they are registered, you can put them on notice that you will be evaluating their quality performance more closely. As a small firm, you probably don't have the luxury of restricting yourself to only other ISO-9000 registered firms; but you may be able to get your vendors to be more careful about their quality to you.

88. **TAKING ADVANTAGE OF REGISTRATION**

One of the recognized benefits of ISO-9000 registration should be that your firm is less likely to have client complaints or non-payment due to unsatisfactory quality control. Consider approaching your banker and your professional liability insurance firm about better terms due to your firm being a better risk.

Purpose: Maintain your registration

To Be Completed By: Management Representative

Total Time Needed: [varied]

89. **GUARDING AGAINST SAGGING MORALE**

Preparing for registration will have required a lot of energy and extra work, so it is not surprising that there should be a let down afterwards. It will be up to you to help maintain the momentum. Staff members will need periodic reminders about quality system procedures and records. You can help by techniques such as:

- ▶ Recommending special recognition for staff that worked above and beyond what they had to do (e.g., a certificate, a paid day off)
- ▶ Placing quality system review on the agenda of staff meetings.
- ▶ Identifying ways to stimulate interest in continuous improvement (see Item #94).

Remember...you can always lose your registration!

90. **COMMUNICATION WITH YOUR REGISTRAR**

Remember that your Registrar has controlled copies of at least your Quality Manual, if not your procedures binder. Every time you update documentation, you must send updates to the Registrar. Again, you may wish to consult with your registrar on "draft" changes prior to implementation to make sure that you are not acting contrary to the ISO 9000 standard.

91. **SURVEILLANCE AUDITS**

Probably within six months of the registration audit, your Registrar will begin a series of surveillance audits to make sure that the quality system is still running well. These audits will each begin with any nonconformances noted the last time, to make sure that area is running smoothly. You can usually expect a portion of the quality system to be audited every six months.

- **AFTER REGISTRATION: Surveillance**

92. RE-REGISTRATION

The next major audit will be in three years, when the Registrar will review the entire quality system once again for the purposes of re-registration. Keep in mind that you can lose your registration if your quality system is not still operating properly.

8.3

• AFTER REGISTRATION: Continuous Improvement

Purpose: Continue to gain from the registration process

Output: Revisions to existing policies and procedures

To Be Completed By: Management Representative and all staff

Total Time Needed: [ongoing]

93. **CONTINUOUS IMPROVEMENT**

With the 1994 revisions to the standards, ISO has signalled clearly its interest in firms focusing on continuous improvement, not just a static standard. The types of improvements you have undertaken is one of the aspects in which your Registrar will take an interest.

94. **USING YOUR PROBLEM LOGS CONSTRUCTIVELY**

Your Problem Logs are a wealth of information on opportunities for prevention and improvement. Consider providing an incentive to staff for persons who identify the most useful quality system revision.

GOOD LUCK!

● FEEDBACK FORM ●

Please let us know about your experience with this Workbook and ways in which it could be improved by faxing the following form to: Industry Canada at 613-952-9054.

Your firm: _____ I n d u s t r y :

Number of employees: _____

Staff who used the workbook : _____

1. Please rate the extent to which the workbook was a useful resource in:

	Not Useful			Very Useful	
- understanding ISO 9000 registration	1	2	3	4	5
- understanding the key decisions to be made	1	2	3	4	5
- adapting the standards to your industry	1	2	3	4	5
- helping you select a registrar	1	2	3	4	5
- helping you plan your approach	1	2	3	4	5
- helping you create your quality system	1	2	3	4	5
- helping you document your quality system	1	2	3	4	5
- helping you get ready for the audits	1	2	3	4	5
- helping you get registered successfully	1	2	3	4	5
- helping you promote your registration	1	2	3	4	5
- helping you make links in your province	1	2	3	4	5
- helping reduce the amount of time for registration	1	2	3	4	5

2. What aspect(s) of the workbook did you find most useful?

3. What aspect(s) of the workbook did you find least useful?

4. Did you get registered successfully? **YES** **NO** **Decided not to**

5. Would you recommend this workbook to another professional service firm considering ISO 9000 registration:

- _____ yes, enthusiastically
- _____ yes
- _____ maybe
- _____ probably not
- _____ definitely not