

Main Chapters in the DIY Guide

1. GETTING IT – BEFORE YOU START	1
2. SETTING IT UP – PROJECT PLANNING	13
3. DOING IT – PHASE I OF THE PLAN	27
4. DOING IT – PHASE II	57
5. PROVING IT – PHASE III	97
6. PROVING IT – CERTIFICATION	115

Conventions in the DIY Guide

- Each Task/Activity is listed in a bullet point like this.
You can use the square as a checkbox and mark off tasks as you do them:

- × A cross is a Watchpoint. This warns you of a potential pitfall.

Examples

Examples usually appear in small text like this. They illustrate ways in which things may be done which will meet the requirements of the Standard. All are taken from real world examples, but naturally with identifying details altered to preserve confidentiality.

Detailed Contents

1. GETTING IT – BEFORE YOU START	1
1.1 About the IQ Approach	1
1.2 About Management Systems and Models.....	2
1.2.1 Management systems and systems thinking	2
1.2.2 Management models.....	3
1.2.3 What is a quality management system?.....	4
1.3 Basics of Quality	8
1.3.1 Eight Principles of Quality.....	8
1.3.2 An Essential Quality Tool	9
1.4 Managing Change	11
2. SETTING IT UP: PROJECT PLANNING.....	13
2.1 Treat it as a Project	13
2.2 Key Questions	13
2.2.1 Why do ISO 9001?.....	13
2.2.2 What will it look like?.....	16
2.3 Understanding the Standard	16
2.3.1 ISO 9001 Management System Model.....	17
2.3.2 Structure of ISO 9001 Standard.....	18
2.4 Getting Started	21
2.4.1 Project Launch.....	21
2.5.1 Where are we now? the Gap Analysis	22
2.5.2 Typical Baseline Findings.....	23
2.5.3 Creating a Baseline Plan.....	25
2.5.4 Indicative Project Schedule	26
2.5.5 How long 'should' it take?.....	26
3. DOING IT: PHASE I OF THE PLAN	27
3.1 Defining the What: Policy and Objectives	27
3.1.1 What it is and why policy matters.....	28
3.1.2 Planning: Setting Objectives.....	31
3.1.3 How to Set Objectives.....	32
3.1.4 Objectives: how are we going?.....	37
3.2 Understanding Documentation.....	40
3.2.1 Documentation you must have	40
3.2.2 Why documentation is important.....	40
3.2.3 Documentation patterns	41
3.2.4 How much do you need?.....	43
3.3 Getting Documents under Control.....	44
3.3.1 What needs control?.....	44
3.3.2 What does 'control' look like?	45
3.3.3 How to do identification.....	46
3.3.4 How to do document control easily and effectively.....	47
3.3.5 How to do version control.....	48
3.3.6 Controlling data	49
3.3.7 How to do approval or sign-off.....	49
3.4 Before You Start Writing	52
3.5 The 'Quality Manual'	52
3.5.1 Writing the Policy Handbook.....	53
3.5.2 Review Checklist for Policy	56
4. DOING IT: PHASE II	57
4.1 Managing Resources.....	57
4.1.1 Human – Your People.....	57
4.1.2 Other Resources: Infrastructure & Environment	61
4.2 Defining the 'How To' – Processes & Procedures.....	62
4.2.1 What <i>is</i> a Process?.....	62
4.2.2 Why processes are important.....	63
4.2.3 Grouping Processes	64

4.3	Your Business Processes	65
4.3.1	Identifying and Mapping Processes	66
4.3.2	About Design	69
4.3.3	Process measurement and monitoring	73
4.3.4	Process Relationships.....	75
4.3.5	What Is a Procedure?.....	76
4.3.6	Is it a Process or a Procedure?.....	76
4.4	Documenting 'How To'	78
4.4.1	Why Document Processes or Procedures?	78
4.4.2	Separate the Reference and Guidance Information	78
4.4.3	Words or Pictures?.....	78
4.4.4	Guidelines for Writing 'How to'.....	79
4.4.5	Review Checklist.....	84
4.5	Supporting Processes	85
4.6	Other Requirements	85
4.6.1	Control of equipment.....	85
4.6.2	Infrastructure and maintenance	86
4.6.3	Invoicing and billing.....	86
4.7	Progress Review	86
4.8	Purchasing, Outsourcing & Suppliers	87
4.9	Selecting a Certifier	89
4.10	The 'Management Review' stuff	91
4.10.1	Management Review – How Not to Do It.....	91
4.10.2	Management Review: the Real Stuff.....	92
5.	PROVING IT: PHASE III	97
5.1	About the Mandatory Procedures.....	97
5.2	The Problem Stuff.....	97
5.2.1	What is it?.....	97
5.2.2	About Nonconformity, Corrective Action and Preventive Action.....	98
5.2.3	Understanding the terms	99
5.2.4	What will the auditor look for?.....	101
5.2.5	How to manage problems systematically – 2 approaches	101
5.2.6	Reviewing actions	104
5.3	Problem-solving and Improvement.....	104
5.4	Managing Your Records.....	107
5.4.1	What's a Record?	107
5.5	Internal Audit	110
5.5.1	About Internal Audit.....	110
5.5.2	What Quality Audits Are Supposed to Do.....	111
5.5.3	Audit Guidelines.....	112
5.5.4	Suggested code of conduct for auditors	113
6.	PROVING IT: CERTIFICATION.....	115
6.1	Stage 1 Audit	115
6.2	Final Preparation	116
6.2.1	The 'Big Three' that Auditors Scrutinise Closely	117
6.2.2	Help! THE Audit is next week & we just changed something.....	117
6.3	Stage 2 Audit	118
6.3.1	What to Expect	118
6.3.2	During the Audit	119
6.3.3	Do We Get It?.....	120
6.3.4	Certifiers are service providers	121
6.3.5	Problem audit (very rare).....	122
6.4	Are We There Yet?	123
	APPENDIX A: RESOURCES LIST	124

1. Getting It – Before You Start

This chapter provides some important background theory, and explains basic concepts and terms.

If you understand a bit of the theory and a few concepts, you'll work more efficiently and run your project more easily. Many past clients have said they had difficulty with bits of ISO 9001 until they really 'got' this stuff, and wished they'd understood it earlier.

Bear with me, even if some of it seems a bit theoretical, because plunging ahead without it is a bit like trying to drive without reading the road rules.

1.1 About the IQ Approach

The Intelligent Quality (IQ) approach is based on three key principles. The intent is to make sure a quality management system is:

- Simple
- Practical
- Flexible.

Simple: A system should be as simple as it can be, as simple as it's possible for it to be.

Practical: It should be pragmatic, as easy as you can make it for people: a system that suits your organisation, its particular context and customers. You don't want something that's fine in theory but doesn't work in practice.

Flexible: The system can cope with changes and exceptions and 'special cases'. Because these do happen, and a system should be able to accommodate them, rather than being dogmatic or unyielding. It can also be adapted and scaled up to expand if and when needed.

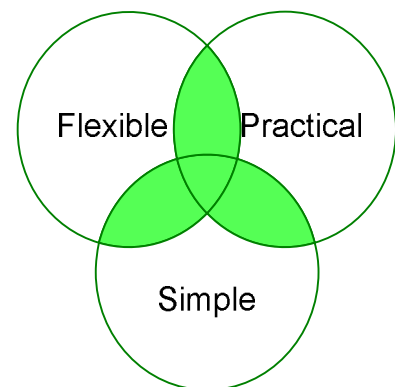
Simple, practical *and* flexible.

Some systems achieve one of these and some may achieve two out of the three. But the most effective quality management systems have all these three characteristics working together harmoniously.

At times, you may have to weigh up the pros and cons of one principle against another, to decide what is more important in that particular situation.

For example, one so-called solution to a problem is for someone to create a new form. *"From now on, every sale must be entered onto Form 123 and given to the salespeople to enter"*.

At first glance, it looks to be simple solution. Yes; everyone must always do it like so. But what happens if, for example, you get a new customer in a tearing hurry, throwing a cheque or cash at you and wanting the goods right then and there?



Different kinds of systems

1.2.3 What is a quality management system?

The term *quality management system* (often shortened just to *quality system*) is often used to mean different things. Because people may interpret it differently, you need a clear understanding in your company of what is meant, so everyone operates from a shared understanding.

Tip: I've mostly used the term 'business' or 'company' throughout this Guide for brevity. If you're a trust, foundation, non-profit, charity, government department, instead, please just swap that term where needed.

So, what *is* a quality management system? And does a company with a quality management system have something that your company doesn't?

Probably not.

In fact, you will almost certainly *already have* a quality management system, even if you think you don't.

Have you been operating for at least a couple of years? Are you successful? If you're a business, are you making a profit? Are customers returning? Is business expanding? If a non-profit, are you meeting the terms of your charter, the reason you exist?

If you answer yes, then you do already have a quality management system. Which isn't really surprising. You see, any successful organisation needs some kind of system, so that customers get what was agreed. You don't want to start making things up on an hourly or daily basis! And if customers don't get what they want or the product/service isn't what you said it was, delivered when or how you said it would be, or doesn't do what you said it would, then bad things happen, from losing customers to going out of business.

Yes, you may want to improve how some things are done, become more profitable, effective or efficient, expand your market, increase your customer base or a host of other things, but you do already have some kind of system for quality management – a quality management system that gets your services and/or products to customers.

But at this point, it isn't an 'ISO 9001 system'.

Typical pre-ISO 9001 small business

Over my many years of consulting to companies wanting ISO 9001, and doing many, many assessments of current status (a gap analysis, of which more soon), I've noted this one almost universal characteristic.

Pre-ISO 9001 organisations most often don't have a robust and well-developed **system** so much as they have some **people** who are invaluable.

These people are essential: they know the important things. Usually it's because they've been there for quite a while, and accumulated a store of knowledge. Usually kept between their ears.

Very little is codified or captured, ie, written down. Things are usually passed on by word of mouth. If things are written down, it is usually just some essential stuff –

perhaps because they found not having it written down caused mistakes, lost time/money and unhappy customers. Or Jenny went on holiday but the boss realised before she went that there were some essential things others needed to know. Or they brought in a lot more people, and then found that those new people just didn't seem to know what to do, because they hadn't been round long enough to find out.

Can you see that this isn't much of a 'system'? And definitely not one that would meet ISO 9001.

This picture is most frequent in small businesses, but surprisingly often the case in medium and even larger ones as well.

Businesses can grow and become quite successful, but struggle from a lack of good systems, because they are still trying to operate using the ad hoc 'growing like Topsy', people-dependent methods and processes that worked up to now, more or less.

Do you have a system or critical people?

- Your customers get what was agreed some, or even a lot of the time, but at times they don't and/or there's a great deal of frantic effort required behind the scenes to make it happen.
- Customers get the right products or services provided that Fred or Francesca is there – if they're away things fall apart.
- Tony leaves. His replacement keeps asking questions that no one knows the answers to, and there's nothing written down which says how things should be done. And no one knows where Tony kept certain things that someone else depends upon to do *their* work.
- You know, different people are doing things in many different ways. "Why don't those new people know it's done this way? Didn't anyone tell them?"
- Things quite often 'fall between the cracks'. Things work OK sometimes, but not others. The same or similar problems or failures keep cropping up.
- Business is expanding, you're growing very fast but some things are starting to fall apart, or you think they may do.
- You're the owner but you're working most if not all the time. You'd love to, but you just can't afford to take time away for a holiday.

Sound familiar to you? If so, you probably don't have a system as much as you have some good people. But don't worry, we're going to fix that.

Why are you in business?

Most profit-making businesses answer *to make money*, and that's a just fine answer. To do that, you will:

- Supply a service or product
- Give the market what it wants (deliver to your customers' requirements)
- Supply products/services when they are wanted (deliver on time).

The system you used to do that is a *quality management system*.

3. Doing It: Phase I of the Plan

This phase provides the foundation: setting up various elements and structures that will be needed. In PDSA terms, some parts of this Phase fall into 'Plan' and some parts into 'Do'.

3.1 Defining the What: Policy and Objectives

'What' means *what* you plan to do: your quality policy and your objectives. You should get some kind of high-level quality policy in place now, so that there is a shared and agreed understanding about what the Q-word means in your company, and to provide guidance for future decisions. It's the first step in defining your system.

Some people are thrown by the word 'policy'. Don't be. It's just a term for the stand your company takes toward various issues: the position it adopts on a particular topic. It says what the 'rules' are in your business, that you want your people to know and to follow.

Tasks – Quality Policy

- Write or revise the Quality Statement: clearly state your company's basic position on quality. Call it your quality policy, vision, mission statement, quality goal, or whatever other name you prefer.
- Review it with at least one other person, preferably a few, to see if it makes sense to them. (Whether you circulate it widely for discussion, or decide this only at management level depends on your organisation, internal dynamics and politics.)
- Sign it off (if you aren't the top person, have the MD do this)

Tip: Try asking 3 or 4 people in your organisation how they'd describe your company's position on quality. Suppose you (or they) had less than 30 seconds to say it to an impatient customer who doesn't like fancy words - *what would you say?* Often it's much simpler and plainer ('right in front of you') than you may think.

Some poor examples of Quality Statements

Wordy Company and its management have adopted, and fully support, a formal and continuing program of review, evaluation and modification of our operations, at all levels, so that the Company's ability to provide the highest quality products and related services, as required by our customers, may be verified and improved.

The Wordy Company Quality System Manual provides the framework through which this process of review and constant improvement is implemented.

Verbose and meaningless.

I *think* this is saying Wordy reviews, evaluates and modifies everything ... but I'm not really sure. Do you know what they actually do? Or aim to do? As for the manual... hmm.

The bit about 'and fully support' makes me wonder why they need to say this – do they adopt things *without* supporting them for example?

To me, this is just meaningless wordy garbage, tells no one anything, and is just a waste of time.

<i>Quality is everything we do</i>	Well, at least it's short. But every single thing? So if <i>anyone</i> does <i>anything</i> at all, that thing = quality? The mind boggles...
<i>Quality Assurance is a proactive process that is incorporated into every phase of the Nifty Developments software development lifecycle</i>	Uh huh. Other than the 'proactive' bit, this is just a slightly longer version of 'everything we do'. Equally ho hum and meaningless.
<i>Every employee at Bloggs Pty Ltd is responsible for quality, and is to apply a total commitment to quality at all times.</i>	OK, well I know I'm responsible and I have to 'apply' a commitment - but what <i>is</i> that? And how would anyone know when they are doing it right?
<i>Our commitment to quality is driven by our management team and extends to all our staff.</i>	Empty fluff. Again, what does quality actually <i>mean</i> to them? What exactly <i>is</i> management 'driving'? And what <i>is</i> it they are committed to?
<i>We aim to lead the next generation of outsourced solution development</i>	A bit iffy. It is short, and there is some kind of aim in there. It <i>might</i> be OK if it had some sound objectives supporting it, but it's still rather vague.
<i>... To achieve world's best practice in our operations</i>	Non-specific and hard to 'measure'. There was a proliferation of fluff-stuff like this at one time. If you insist on anything like this, you must be quite clear how you establish 'world's best practice', how you measure it, and where your company is in relation to that benchmark now, and how you know if you are achieving it or not. You must demonstrate this, not just claim it.
<i>Our key goal is to execute useability tests for our customers</i>	Yes, you can measure whether you tested or not – but is this a real goal? As a customer, I'd expect something that says your goal is to provide me with <i>useful information</i> as a result of testing, or to improve my system, make it easier to use, etc. not just an objective of doing tests. A bit like saying you're here because you're here. So what?

The real issue is: what do these statements actually *mean*?

3.1.1 What it is and why policy matters

The problem with fluff-stuff – that's a technical quality term in my company ☺ – is that it isn't useful. It **provides no value**.

How would Tim know if the work he is doing, whether that's answering email or taking phone calls, copying files, compiling code or talking to customers, is being part of the '*proactive process that is incorporated into every phase of the ABC Developments software development lifecycle*'?

Does Marilyn know whether she is '*applying a total commitment to quality*' if she takes 12 hours to complete a task instead of 8?

Or lets a phone ring 8 times, instead of 4, before she answers it?

Quality is the result of a carefully constructed cultural environment. It has to be the fabric of the organization, not part of the fabric.
Phillip Crosby

And does it matter?

Yes.

Because if **you** don't say what quality is at your company, then how can you expect anyone else to know, let alone care or act on it?



If Rodrigo is working on a business issue, will he remember a quality statement like any of the ones above?

Will your managers? Your sales people?

Can they recall your quality statement (more or less) without stumbling, stammering or blanching?

Does it give them principles they can refer to?

Something to use when making an important decision?

Is it clear enough and intelligible enough so that they have a good idea when they are following it, and when they are not? So they don't have to guess, hope, assume or just cross their fingers and pray?

Can you explain your quality policy to a moderately intelligent 12 year old with a short attention span? (Even better, can that 12 yo understand what you said, without having to have it explained?)

If not, what value does it add?

Quality starts in the boardroom.
W.E Deming

And **what use is it?**

Some better examples of quality statements

"Quality Performance is a commitment to excellence by each Dow employee. It is achieved by teamwork and a process of continuous improvement." (Dow Chemicals)

"Quality for us means that we get it right, first time and every time. It means we deliver on our promises and do what we said we'd do: on time, to specifications and budget." (Acme)

"Our goal is to provide prompt and cost-effective technology solutions to the business needs of our customers. We believe customer business needs must always lead the technology, rather than allowing technology to dictate the business." (Yellow IT)

"InterGen aims to understand the needs of the hospital sector, and to meet or exceed the needs of our customers promptly, efficiently and consistently, at a reasonable cost."

"At Jones & Fleming, our business is based on these principles.

Service – We provide outstanding customer service. We care about our customers, and constantly strive to improve all aspects of our service.

Integrity – we are an ethical company who conducts business openly.

Safety – we provide a safe and secure workplace that complies with all applicable health and safety laws, standards, and codes of practice.

Knowledge – we understand our business and our customers' needs. We constantly research new technologies and emerging trends within our industry.

Environment – we want to protect the environment and prevent pollution. We follow all environmental requirements, and work to continually reduce the negative environmental impacts of our operations.

Growth – we aim to be a major player in our field.

We expect everyone in our company to apply our company principles at all times."

I think the Jones & Fleming one's a bit long, but they wanted it that way. (And it's their company, not mine.)

You definitely don't have to have a long one. In fact, short and clear is usually **much** easier for people to remember, and so to act upon.

There's no such thing as the 'perfect quality policy' – it's whatever works for you.

Task – Quality Policy

- Include somewhere in your quality policy a formal commitment to comply with requirements and continually improve (5.3b).

Look at the Acme manual for an example of how. I favour short, clear statements of policy as people remember them better, so I wrote one of those, then included the commitment to improvement with some other important ones *after* the short policy on quality.

Watchpoint

- ✗ Please don't add to the many examples of meaningless wordy 'quality policies', 'mission statements' or 'visions' that are usually littered with buzz words and phrases ('world's best this and that'). You've probably seen them – but did *you* pay them any attention, let alone believe them?

Now that you have formally defined your company position on quality, it's time for those 'quality objectives'.

But first a word about values.

Company values

Having a set of company values isn't a requirement of ISO 9001, but I do urge you to consider it. There's a lot of evidence to say that the 'best' organisations do (see *Resources Appendix* at end). Their values are real: they're used to shape the company and to base decisions upon – even when that is difficult.

Good business leaders create a vision, articulate the vision, passionately own the vision, and relentlessly drive it to completion.
Jack Welch

Improving your quality management system is about doing things better. One way to improve is to get more definition and clarity into your management system. Being explicit about values that are important in the company is a way to keep its focus clear and to attract good people. (I firmly believe people want meaning and satisfaction from their work, beyond just a pay cheque.)

And having clear values can be both effective and very rewarding. And yes, I practice what I preach here. My core values are on my website and reproduced below.

I chose them for my consulting business and abide by them.

- ♦ **Honesty:** I tell the truth, which includes putting client interests first - if you don't need it or my company isn't right for you, I'll tell you
 - ♦ **Excellence:** doing the best work I am capable of
 - ♦ **Commitment:** you can depend on me to meet deadlines and do what was agreed
 - ♦ **Value:** if it isn't valuable, I don't do it, much less charge for it.
- ✘ Don't have values unless they are real. Unless you choose values that are important to you, suit the business and **are acted upon in practice**, that is, used to guide the organisation and make decisions. Values that are espoused but not really followed teach your people that, in your organisation, things are said but not meant. Which leads to cynicism and alienation, among other undesirable consequences.

3.1.2 Planning: Setting Objectives

The next thing that's important is to make clear what you're trying to achieve. You set objectives now, because you need to know where you're going, and periodically assess whether you're on track.

The Standard requires you to have 'quality objectives' that are 'measurable'.

What is a 'quality objective'?

It is a specific statement of a desired outcome. It can be used to assess whether something was achieved or not; a specific result that you use to try and reach one or more goals; the thing your company decides upon to get where it wants to go.

If you don't know where you are going, any road will get you there
Lewis Carroll.

Thinking of them as *business* objectives, rather than quality objectives, often makes more sense to people.

Setting objectives seems to be a difficult task for many companies: what objectives 'should' they set, and how? If you are unaccustomed to doing it, you may have to work at this area a few times, until it starts to make sense.

How much work is required here depends upon your level of organisational maturity: whether you already are accustomed to setting objectives and/or already do some formal business planning that results in some kind of written output and is used to guide your company's activities – or not.

Review the PDSA cycle. Setting objectives fits in the Plan phase. Because without anything written for Plan, how do you know what to Do? And then how can you really Study the results if you didn't know what you were aiming for?

If you are already doing business planning and setting goals and objectives, congratulations. What about if you think you're already doing it, 'but it's not really formal'? This usually means 'we don't write anything down', in which case there's work to do. Successful organisations do plan what they intend, setting some clear goals and targets. They have a way of assessing / measuring whether they met them

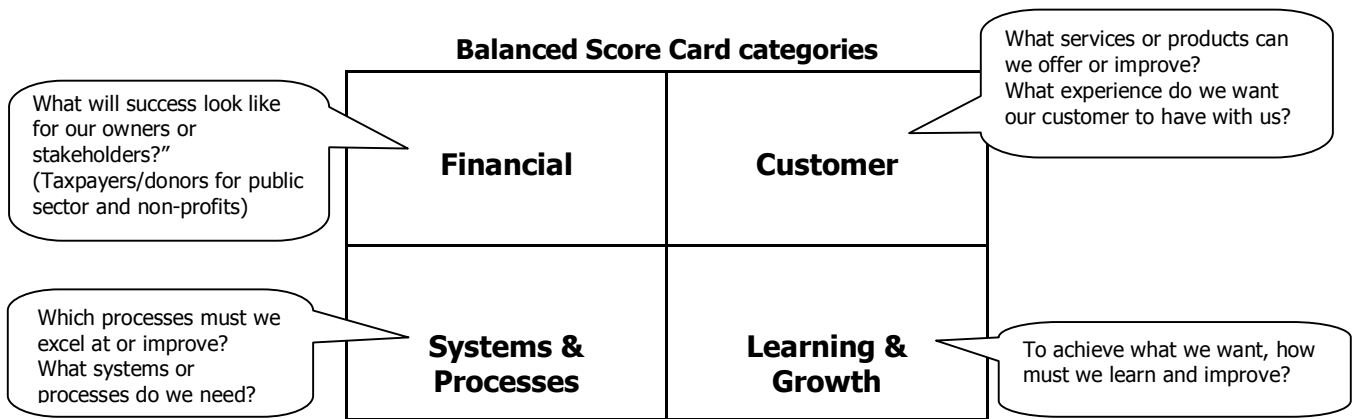
or not. And they use their plans to assess progress periodically, and assess if they're on track or not.

Note: If setting objectives is really difficult, you could leave it until later in Phase II, but it's better to do it now, and get in the habit of planning.

3.1.3 How to Set Objectives

Use the following approaches to help stimulate your thinking.

- i] **Balanced Score Card.** Pick at least one objective from each of the four perspectives below to 'balance' your score card.
This is an approach I often use and recommend, borrowing from the 'balanced score card' (BSC) approach, from Kaplan and Norton. In their book, *Strategy Maps* (2005), they presented four perspectives to use when forming business strategy.



Examples

- Financial:
 - Achieve 12% increase on last year's figures
 - Reach target sales budget for current FY
 - Reduce operating costs by 8% for next FY
- Customer:
 - Acquire at least 3 new 'high value customers' in new sectors in FY
 - Achieve an average of 98% or better customer satisfaction – calendar year
 - Be seen as one of the 'top 3' suppliers in our field within 3 years
- Processes:
 - Replace existing phone/fax order system with web-based sales by Dec
 - Release Product XYZ into marketplace by June
 - Develop a process for our new service offering in the next 2 months
- Learning:
 - Implement an internal mentoring program for staff by Oct
 - Become an employer of first choice within 3 years
 - Prove site safety training to all personnel within 2 months
 - Improve our internal project management capability within 6 months