



# Quality Management in Photovoltaics

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## Quality Control Manual for Manufacturers

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# Preface



Photovoltaic (PV) products are manufactured in many countries and sold all over the world. Most work well and are very reliable, with the result that industry market growth is higher now than at any time in the last 15 years. From available worldwide statistics, it appears that product failures are rather few, but they are still significant. In addition, the module performances produced by some manufacturers do not always meet customer expectations.

Even though the overwhelming majority of PV companies deploy products and systems of uniform quality (hereinafter referred to as "quality products and systems"), those that do not need to be brought up to the level of the rest of the PV industry in order to avoid jeopardizing customer confidence in the quality and reliability of PV products and systems. The purpose of this *Quality Management in Photovoltaics* training manual is to help the PV firms install their own quality management systems and meet established international quality standards. Achieving a benchmark international quality for PV components and systems will not happen overnight. Some very real barriers must be removed. Good quality always costs less in the end, however, and companies that strive for it can expect to be rewarded with greater profits.

Establishing a quality manufacturing process and maintaining a quality assurance system are sometimes viewed as expensive undertakings, especially for small or medium-size companies. On the contrary, it has been proved that the presence of a quality manufacturing management system actually results in cost savings, even in the first year the system is installed.

Other types of industries that are facing similar quality assurance challenges have created solutions that the PV industry can study and adopt. Today the ISO 9001:2000 standard is the internationally accepted system for quality management of the manufacturing process for distributors, system assemblers, and installers. This is a generic standard used by many industries. Several PV module manufacturers presently meet the ISO 9001:2000 standard and are certified, but many do not. Of the latter, some simply may not know about the standard, whereas others may think that implementing the ISO 9001:2000 is too technical or expensive, or both, to be practical for small and medium-size companies.

The Global Approval Program for Photovoltaics (PV GAP) was created by the worldwide PV industry to establish a uniform approach to quality assurance. This training manual is part of that effort. PV GAP has developed this manual to spell out in simple terms what is required by the ISO 9001:2000 standard and to help PV companies install a quality management system easily and inexpensively, without need for outside consultant assistance.

The manual builds on an earlier manual and training courses developed by PV GAP under a contract from the World Bank. That work focused on the existing standard at the time (ISO 9000). Since then, the ISO 9000 standard has been replaced by the ISO 9001:2000 standard. This training manual consequently explains the new ISO 9001:2000 and provides companies with the tools needed to comply fully, yet with an economy of effort, with all the International Organization for Standardization (ISO) requirements.

Quality assurance calls for a quality manufacturing process (for example, ISO 9001:2000). It also requires that products be manufactured and tested according to a standard, and that the manufacturing process include continuous verification, auditing, and improvement. This training manual describes the various elements of the quality management system. The manual also introduces the PV Quality Mark and Seal and explains how these labels help customers distinguish high-quality PV components and systems from those of poor or unknown quality. The PV Quality Mark and Seal also enhance the internationally competitive position of PV manufacturers that are qualified and licensed to use these labels.

French, German, and Spanish translations of the authors' original version of the manual are available.



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# Abbreviations and Acronyms



<b>ASTM</b>	American Society for Testing Material
<b>B-PQAS</b>	Blank Product Quality Assessment Specification
<b>CENELEC</b>	European Committee for Electrotechnical Standardization
<b>DMR</b>	Designated management representative
<b>EA</b>	European Co-operation for Accreditation
<b>ECN</b>	The Netherlands Energy Research Foundation
<b>EPIA</b>	European Photovoltaic Industry Association
<b>ETDC</b>	Electronics Test & Development Centre, Bangalore
<b>FMEA</b>	Failure mode effect analysis
<b>FSEC</b>	Florida Solar Energy Center
<b>IEC</b>	International Electrotechnical Commission
<b>IECQ</b>	International Electrotechnical Commission Quality Assessment System for Electronic Components
<b>IEEE</b>	Institute of Electrical and Electronics Engineers
<b>ISO</b>	International Organization for Standardization
<b>ITU</b>	International Telecommunication Union
<b>JEMA</b>	Japan Electrical Manufacturers Association
<b>JET</b>	Japan Electrical Safety and Environment Technology Laboratories
<b>JPL</b>	Jet Propulsion Laboratory of the California Institute of Technology
<b>JQAO</b>	Japan Quality Assurance Organization
<b>JRC Ispra</b>	Joint Research Centre—Ispra (Italy)
<b>kWp</b>	Kilowatts peak
<b>MW</b>	Megawatt
<b>MWp</b>	Megawatts peak
<b>NP</b>	New proposal
<b>NREL</b>	National Renewable Energy Laboratory
<b>QOPs</b>	Quality Operating Procedures
<b>PQAS</b>	Product Quality Assessment Specification
<b>PV</b>	Photovoltaic
<b>PV GAP</b>	Global Approval Program for Photovoltaics
<b>PVRS</b>	PV GAP Recommended Specifications
<b>QIS</b>	Quality improvement system
<b>SEIA</b>	Solar Energy Industry Association
<b>SI</b>	Supervising inspectorate

<b>SPC</b>	Statistical process control
<b>TQC</b>	Total Quality Control
<b>UL</b>	Underwriters Laboratories
<b>WG</b>	Working group
<b>Wp</b>	Watt(s) peak



# Chapter 1.

## Quality in Manufacturing— General Concepts



Every company entrusts its managers with defining its goals. Typically, goals are established for sales levels, profits, products, service to the customers, finances, personnel, strategic planning, and the like. Establishing goals for the quality of a company's products or services is absolutely essential to assuring its future. Products and services are your company's connection to its customers and the only reason for its existence. Without customers—**satisfied customers**—the company will not survive.

This manual describes a five-day training program for *Quality Management in Photovoltaics* that is focused on helping PV manufacturers adopt methods that lead to consistent quality in products or services. The methodology is based on a concept of “total quality,” which requires commitment at all levels of a company to deliver products of uniform quality (hereinafter referred to as “quality products”) to its customers all the time. The training program further explains how your PV company can achieve and maintain recognition of the quality of its products and certification by world-recognized authorities. It also explains how your company could profit from the training program.

Viewgraphs are provided for a five-day seminar and also for a compressed two-day training program.

### 1.1 The Photovoltaic Industry

If they are to achieve their full market potential, photovoltaic (PV) systems must be cost-effective and must also meet and, ideally, surpass customer expectations. Most older applications for telecommunications and space use have proven the cost-effectiveness of PV technology, because of its high reliability and performance. New, large-scale terrestrial PV applications must similarly demonstrate their reliability and long life to prove their cost-effectiveness. Indeed, the PV industry will rise or fall based on the quality of PV products. Ultimately, consumers must see economic value from their investment in PV systems, above and beyond the satisfaction of knowing that they are opting for a form of renewable energy that has no detrimental impact on the environment.

Manufacturers that do not produce quality products cannot survive long in the marketplace. Thus, every manufacturer must be concerned with the quality of company products. Quality

management processes vary from manufacturer to manufacturer, but the goal is always the same: to ensure that products and processes meet specified expectations.

PV products are manufactured in many countries and sold all over the world. They are also supplied in response to tenders, such as those issued for projects sponsored by the World Bank. Putting in place international standards and quality procedures that are accepted everywhere will assure a uniform quality of PV products. Equally important, it will also benefit the individual manufacturer by broadening markets and making quality products competitive everywhere.

Manufacturing a quality product requires designing the specified quality into the product from the outset. Assuring a quality product requires more than post-production inspection, which simply separates acceptable products from unacceptable ones or “rejects.” Rejects at the end of the production line are really added expenses for the manufacturer. Instead, a consistent quality manufacturing process, based on statistical measures, maintains quality and allows for improved customer satisfaction, as well as added profits for the manufacturer.

As a participant in this training program, you will be given tools your company can use to manage and improve the quality of its products and thereby enhance the value provided to the customer. When value surpasses cost, the market will support the development and promotion of hundreds of new PV applications. In such a scenario, the initial expense of putting quality systems in place will be recouped many times over, which will confirm the wisdom of investing in quality.

## 1.2 Elements of a Quality Manufacturing System

The elements of an internationally acceptable quality system are as follows:

- \* A quality manufacturing process based on the ISO 9001:2000 standard.
- \* Manufacturing of products according to a standard.
- \* Testing of products and periodic retesting of the same models in an approved testing laboratory.
- \* Auditing by an outside organization.
- \* The delivery of products that provide customer satisfaction.

The photovoltaic industries have identified these elements as the basic components for a program to guide end users toward selection of companies that produce quality products. To establish a quality system for photovoltaics with easy recognition of quality products and worldwide acceptance, the Global Approval Program for

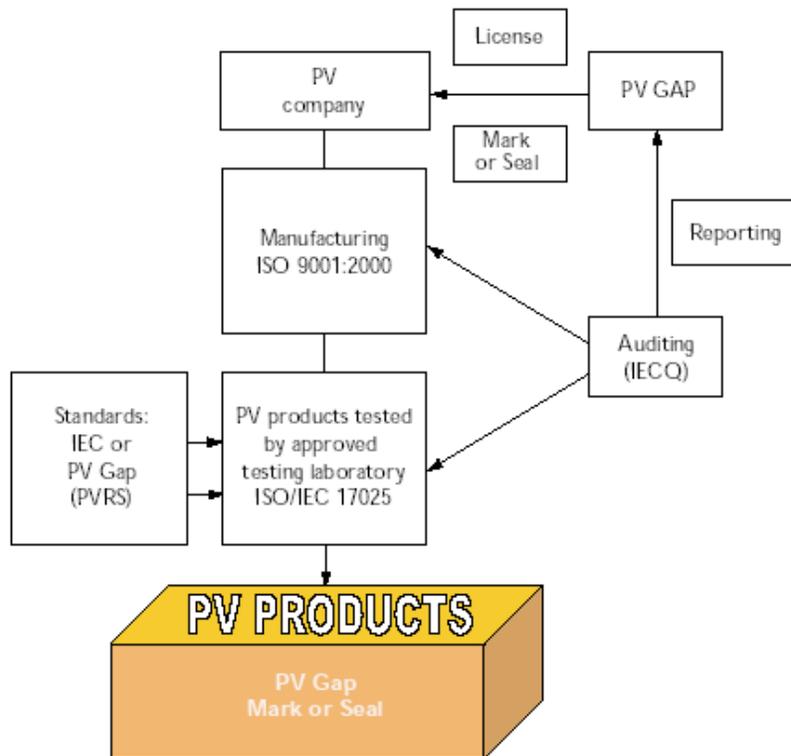


Photovoltaics (PV GAP) was set up to incorporate these elements and issue a Mark or a Seal of distinction. Information on PV GAP is given in the following chapters.

### 1.3 Global Approval Program for Photovoltaics

See box 1.1 for a description of the mission of the Global Approval Program for Photovoltaics (PV GAP). The elements of PV GAP are shown in figure 1.1.

**Figure 1.1 Elements of the Global Approval Program for Photovoltaics (PV GAP)**



#### Box 1.1 The PV GAP Mission Statement

PV GAP, a not-for-profit international organization, is dedicated to the sustained growth of global photovoltaics (PV) markets to meet energy needs worldwide in an environmentally sound manner.

Our mission is to promote and encourage the use of internationally accepted standards, quality management processes, and organizational training in the design, fabrication, installation, sales, and services of PV systems. To this end, we partner with PV and related industries, international organizations, testing laboratories, government agencies, financing institutions, nongovernmental organizations, and private foundations in developing and developed countries.

### 1.3.1 Why Is There a Need for a Global Approval Program for Photovoltaics?

Photovoltaics have proved to be one of the most reliable sources of electricity. Practically all satellites in orbit are powered reliably by PV systems and, for the past 30 years, PV has been successfully used for many terrestrial applications. Some PV modules are now sold with a 25-year warranty.

The reliability of PV systems is a sine qua non for ensuring confidence in the PV industry. Lack of consistency of quality in PV products could jeopardize the credibility of both the industry and its underlying technology. It could also dampen customer acceptance and limit the interest of potential financiers.

This has happened in recent years, as evidenced by inconsistencies in the quality of terrestrial PV components, systems, installations, and after-sales maintenance, especially in off-grid rural electrification projects deployed by local manufacturers and integrators in developing countries:

- ✦ The virtual absence of standards for anything but PV modules is a major cause of quality inconsistency in solar home systems.
- ✦ Manufacturers lack uniform guidelines on how to produce reliable systems or components and on how to install or service them.
- ✦ The lack of accredited testing laboratories has also complicated product testing for many small and medium-size manufacturers.
- ✦ Even when testing has occurred, problems still arise. After submitting samples of their PV products to a testing laboratory and receiving a test report indicating compliance, some manufacturers have labeled **all** of the same type of product as tested by the testing lab, with no assurance that the tested product was truly representative of the manufacturer's production, since **no audit of the manufacturer's production process had been carried out**.

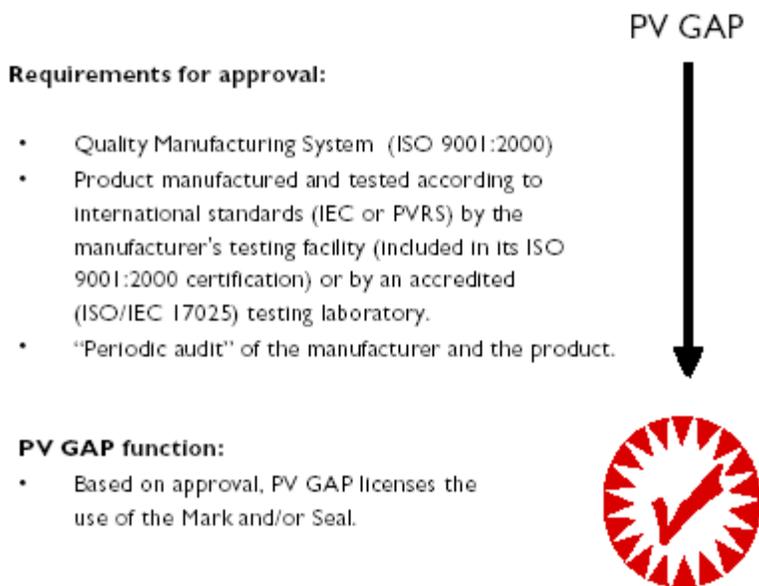
Given these serious quality issues, the international PV industry, supported by financial institutions and government agency funding programs, jointly agreed on the need for an international PV quality assurance program. The result, with the guidance of the PV industry and the PV community, was the formation of PV GAP in 1997.

### 1.3.2 Elements of the PV GAP Approval System

The PV GAP approval system includes the elements of an internationally acceptable quality system, as noted in section 1.2. It also provides the approved manufacturer with a distinctive PV Quality Mark for PV components and a Seal for systems. The Quality Mark and Seal serve to help customers recognize a quality product and distinguish it from a product of unknown quality. The elements of the PV GAP approval system are summarized in figure 1.2.



**Figure 1.2 PV GAP Approval System**



The following is a brief description of the requirements for approval of a quality management system for manufacturers.

### **1.3.3 ISO Standards for Quality in Manufacturing**

The ISO 9001:2000 standard is an international quality management system for any organization. It is applicable to PV manufacturers, as well as installers, service providers, distributors, and the like. The system is a proved methodology to enhance the performance of an organization that delivers products or services to its customers. It allows the organization to enhance customer satisfaction and to continually improve the quality system.

Several years ago, the application of this standard was somewhat complex, and only large companies with extensive quality departments initiated its use. Today many companies are initiating its use because of the benefits they receive. The design and implementation of the quality management system vary according to the needs and objective of the organization, and also its size and structure. PV GAP developed a detailed but simple training manual that provided simplified forms and methods to benefit small PV organizations. The *PV GAP Manufacturing Quality Process Manual for Photovoltaic Components and Systems* (see the bibliography) was written and reviewed by many organizations, including manufacturers in both industrial and developing countries. They found the manual, with its examples and instructions, to be very effective in helping small and medium-size companies to develop a Quality Manual and implement a quality management process. The World Bank sponsored PV GAP's preparation of this training

*Quality manufacturing of products according to standards results in high-quality products that are useful and durable, and capable of meeting requirements.*

manual in 1999. The manual was tested in several training courses held for PV manufacturers.

A number of consulting organizations have recently developed programs to help small and medium-size manufacturers implement the ISO 9000:2000 quality system. Because several such consulting organizations now exist, and the process is simplified and better understood, the cost of implementing the ISO 9000:2000 system has become very affordable.

The revision of ISO 9000 and the 9001 standards in 2000 necessitated an update of the *Manufacturers Training Manual* developed for the World Bank so as to incorporate all the changes introduced by the new ISO 9001:2000 version, as well as changes in the PV GAP approval process since release of the manual in 1999. This current manual incorporates all the above changes.

### **1.3.4 Standards for the Performance of Products**

Why is a standard needed for product performance when a quality manufacturing process already assures that every product is manufactured within an acceptable range?

The answer is simple. A quality manufacturing process assures that every manufactured product falls within acceptable limits—but alone it does not assure that the resulting product is functional. For example, one might manufacture life jackets from concrete. The quality manufacturing process assures that they are identical in quality, but in order to be functional, the life jackets must be made to certain standards. One standard could be that the life jacket has to keep a 100-kilogram person afloat. The life jacket then has to be tested according to this standard.

Standards will be discussed extensively in chapter 5 of the course and in associated sections of this manual. As indicated above, the development and utilization of internationally accepted PV standards is a pressing need in the PV industry today. The International Electrotechnical Commission (IEC) standards are accepted worldwide and already include some standards relevant to photovoltaics. More are needed. As a bridging mechanism, PV GAP has established the mechanism of “PV GAP Recommended Specifications” for use until final IEC standards can be established.

### **1.3.5 Testing Laboratories**

Normally, a manufacturer sends a product to an approved testing laboratory. If it passes the test, the manufacturer will receive a test report approving the product.

What is an approved testing laboratory? The worldwide accepted criteria for the approval of a testing laboratory are in compliance with ISO/IEC 17025, whose rules have been adopted by both the ISO



and IEC. This standard establishes the quality process and procedures for a testing laboratory.

At present there are only a few testing laboratories in the entire world for photovoltaics, even though testing laboratories are ideally needed in every country where PV products are being manufactured. A key PV GAP task is to help establish and approve as many testing laboratories as possible. The names of approved PV testing laboratories are listed on PV GAP's Web site ([www.pvgap.org](http://www.pvgap.org)).

### **1.3.6 Auditing by an Outside Organization**

The requirement that a manufacturer's quality system be reviewed and its products verified and tested by an independent organization and testing laboratory does not stem from mistrust of the manufacturer. The main purpose of this requirement is to assure reciprocity. Reciprocity ensures that products are accepted everywhere in the world and that no retesting will be needed in other countries. Naturally, the outside audit also protects honest manufacturers and customers from unscrupulous operators.

An outside organization must approve the manufacturer's compliance with the ISO 9001:2000 standard. Furthermore, to maintain an ISO 9001:2000 approval, periodic auditing of the manufacturer's quality system by an outside organization is required. The audit process should also verify that the manufacturer has a PV product tested in an approved testing laboratory, and that it is going to be retested after a certain time or when the manufacturer makes certain changes in the product.

The purchase or acquisition of a solar PV system by a customer is a significant event. The customers are putting themselves, or an organization or company, at the forefront of wise and environmentally friendly use of energy. The reliability of the system, however, is equally significant for the customers. They must be assured that the whole solar PV system, including all components, have been made and tested according to international standards for reliability and durability.

How can the individual customer be reasonably sure that the performance of concerned manufacturers, distributors, dealers, and installers meets these standards? Should they merely be taken at their word? For everyone's peace of mind, an independent check or audit is essential to verify that standards have really been followed. That independent activity is called certification of conformity. Without periodic outside audits, the door would be left open for unscrupulous competitors to disappoint customers and damage the reputation of the entire PV industry.



### **1.3.7 Internationally Utilized “PV Quality Mark and Seal”**

When samples are tested by an approved testing laboratory, can the manufacturer print the words “Tested by XY Testing Laboratory” on every product of the same type?

The answer is “no.” Because only some samples were tested, labeling every product of the same type with the words “Tested by XY Testing Laboratory” would be false and misleading unless the samples were representative of the manufacturing quality, and the manufacturer had proven a consistent quality process that had been established and verified. Customers need to be able to easily distinguish quality products from products of unknown quality. For PV products, PV GAP has adopted a labeling system similar to that used successfully in other industries—for example, UL for electrical safety, the “Wool Mark” for woolen products, and the Green Seal for environmental friendliness. The PV Quality Mark is used for PV components, whereas the PV Quality Seal covers complete PV systems. (More information about the Mark and Seal is provided in section 6.3.)

### **1.3.8 PV GAP Program Administered by an Internationally Accepted Approval Body**

PV GAP has elected to use an existing and internationally accepted approval process, the IEC's Quality Assessment System for Electronic Components (IECQ), which is administered by the IEC. PVGAP has arranged for IECQ to administer the PV GAP approval program. PV GAP's responsibility is to implement the program and coordinate worldwide efforts to ensure PV system reliability and durability and, if the manufacturer's product is approved by IECQ, to issue a license to the company to authorize display of the PV GAP PV Quality Mark and/or Seal on the product.

The IECQ system

- ✦ requires no maintenance fee from the PV industry.
- ✦ has an approval system for testing laboratories and establishes international reciprocity of all test results.
- ✦ establishes an international auditing procedure, with which manufacturers are periodically checked.

### **1.3.9 How Expensive Is It to Set Up and to Operate a Quality System?**

Obvious, important benefits accrue to the manufacturer in being able to display the PV GAP PV Quality Mark or Seal on a product (see table 1.1).



**Table 1.1 The Rewards of Quality Assurance**

Leveling the playing field	Customers can differentiate between quality products and products of poor or unknown quality.  The same quality standard is used globally.
Reliability and durability of PV products	The reputation of PV products is important.  Financing of PV products will become easier.
Customer satisfaction	Market expansion will be a natural result.
Participation in tenders	Tenders require quality products. Globally uniform quality standards make it possible for tenders to specify the same testing.
Opening export markets	Reciprocity of testing will open export markets.
Customer recognition of quality products by the "PV Quality Mark and Seal"	The "PV Quality Mark and Seal" will help all companies, large or small, differentiate their products from products of inferior quality.
Cost reduction by manufacturing improvements	The in-line rejects and finished product nonconformity have been reduced by 9% in most companies where the system is established.
Cost reduction for system companies buying PV GAP marked products	Purchasing components from a company that is approved to use the Mark and Seal means not having to retest these products, because they are identified as good quality and meeting all specified requirements. Significant savings and confidence in the products purchased gives a significant advantage.



1. It distinguishes the manufacturer's quality product from products of unknown quality not having the PV Quality Mark or Seal.
2. A marketing advantage is gained by increased customer confidence in the products,
3. Products displaying the PV Quality Mark or Seal are accepted in every country, whereas those not qualified with the Mark or Seal must gain independent credentials in every country.
4. It allows the purchase of system components tested under known conditions, specifications, and standards, which assures a uniform quality and reliable performance.

As an example, the World Bank has advised its clients (see <http://www.worldbank.org/html/fpd/energy/photovoltaics.htm>) to accept products displaying the PV GAP PV Mark and Seal (see box 1.2). Those not having the Mark or Seal must be recertified country by country according to the country's requirements.

### Box 1.2 World Bank Recognition of PV Quality Mark and Seal

Washington, D.C., and Geneva: The World Bank now recognizes the approval of products displaying the Global Approval Program for Photovoltaics (PV GAP) Quality Mark (for PV components) and Seal (for PV systems) for Bank-sponsored projects. The announcement encourages Bank staff to inform its clients undertaking PV projects about this decision (<http://www.worldbank.org/energy>).

The decision of the World Bank states the following:

PV components or systems eligible for use in Bank-assisted projects should either comply with: (a) relevant standards issued by IEC, ISO or similar standards/certification organizations of international standing, (b) appropriate national standards, or (c) bear the Global Approval Program for Photovoltaics (PV GAP) Mark or Seal.

This visual recognition simplifies for customers the selection of quality products. It also eliminates the need of country-by-country re-certification, as the credentials of the PV manufacturer and the product were established by PV GAP.

This eliminates, for products so marked, the review of the credentials of each product a PV manufacturer wants to sell for a project supported by the World Bank. This simplifies administrative procedures, is less costly to suppliers, gives the buyers a greater confidence in the quality of the products, and can encourage inter-country trade.

Manufacturers may therefore make one of the following choices:

- to have their credentials recertified country by country.
- (simpler and less expensive) to obtain a PV GAP license to display the Mark or Seal and receive global acceptance for their products.

The World Bank Group is supporting PV projects in Argentina, Benin, Cape Verde, China, Honduras, India, Indonesia, Kenya, Lao PDR, Mexico, Morocco, the Philippines, Sri Lanka, Togo, Uganda, Vietnam, and elsewhere.

PV GAP (<http://www.pvgap.org>), established in 1997 by three PV associations (EPIA, JEMA, SEIA), is a not-for-profit international organization, registered in Geneva, Switzerland. It promotes the utilization of quality-controlled PV products to distinguish them from PV products of unknown quality.

PV GAP is achieving this through a close working relationship with the International Electrotechnical Commission (IEC, <http://www.iec.ch>). PV GAP has a formal liaison with IEC's Quality Assessment System for Electronic Components (IECQ, <http://www.iecq.org>), which is currently providing supplier approval, product approval, and laboratory accreditation services for PV GAP.

What costs does a PV manufacturer incur in obtaining the PV GAP approval to display the PV Quality Mark or Seal, or both, on products? Can a small or medium-size company afford these costs?

Apart from testing expenses, the cost of setting up a quality process that meets requirements for a manufacturer varies with the size of the company. Appendix 1 provides an example for a company producing 1MW per year and having 50 employees. The example assumes that the manufacturer has no established system and that the modules will have to be tested in an accredited testing laboratory. The calculation indicates that the total cost is \$0.06 per watt in the first year and \$0.0025 per watt in the second year. Because the savings from the quality system are an order of magnitude higher, the implementation of the system is a significant savings for the organization rather than a cost in the long term.

## 1.4 The Evolution and Merits of Quality Systems

Since the early 1970s, manufacturers in the United States have used a variety of quality improvement systems to improve product and service quality as a means of reducing product costs and gaining market share. Their initiative was a response to growing competition from Japanese manufacturers who were producing products that were leading the world in quality, reliability, and cost. The basic philosophy of quality improvement system (QIS) theory emphasizes control of the manufacturing process with the aim of being statistically capable of producing products within established performance limits, thereby avoiding defective products.

QIS represented a significant departure from prior quality efforts in which manufacturers used end-of-line inspection techniques to prevent defective products from reaching customers. End-of-line inspection is costly because of the high value of products at that point, and not effective enough, since some defective products still reach customers. End-of-line inspection of products could not compete with manufacturing processes that were under statistical process control.

The Japanese manufacturers were the first to implement QIS or Total Quality Control (TQC) on a large scale as part of a strategy to gain competitive advantage in world markets. Even though many of the QIS procedures and the concepts of statistical process control were developed in the United States in the 1930s, Japanese manufacturers in the 1960s and 1970s were the first to embrace these techniques. Their success in capturing world market share demonstrated the value of QIS and the need for change.

To regain market share, U.S. and European manufacturers started to introduce their own QIS. For example, U.S. car manufacturers have made significant improvements in the quality of cars produced



in the United States and have regained market share during the past 20 years.

Following the success in manufacturing, service companies, such as banks, insurance companies, and hotels, have implemented QIS to gain a competitive advantage. In addition to commercial entities, governments and international organizations have also implemented QIS, although at a slower pace. QIS applies equally well to small manufacturers and large ones, because customers expect and deserve quality products and services, regardless of size. The lesson learned by the U.S. car manufacturers is that quality products and services are necessary to survive in international markets.

In most manufacturing companies, implementation of a QIS starts with the Quality Manual. The Quality Manual establishes the policies, procedures, and control for the manufacturing organization, as well as the documentation and audit system to ensure compliance. The main elements of a QIS are described in the Quality Manual and include organization charts, job descriptions, product and process specifications, process control statistics, production flow diagrams, use of shop floor teams for problem-solving, and training of the entire organization in QIS, just to name a few.

Any discussion of quality must start with a common definition, which must be easily understood by the entire organization and which must be measurable. A good exercise to demonstrate different perceptions of quality is to ask members of an organization their definition of quality products. Some usual responses are as follows:

- \* Quality products are reliable.
- \* Quality products produce value.
- \* Quality products have many features.
- \* Quality products perform well.
- \* Quality products have long warranties.
- \* Quality products have a good appearance.

All of these are correct responses and can be classified into product attributes that satisfy customer needs. These attributes are considered part of a transaction between a supplier (manufacturer, integrator, or installer) and a customer where the customer establishes the criteria for the transaction through negotiation with the supplier. A simple definition of quality is **“satisfying customers' needs.”** In essence, the transaction becomes a quality contract specifying the customer's needs and the supplier's deliverables.

A similar list could be developed for quality services provided by a manufacturer. These include managing information on orders, handling complaints, fulfilling orders, and handling other requests



coming from customers. A separate exercise should be done for quality services.

Because needs vary from customer to customer, it is important to establish each customer's needs through direct negotiation. The needs must be quantitative and well documented to prevent confusion about when the transaction is completed and the need satisfied, or, if a need is not satisfied, to clarify what corrective actions are required. Based on many surveys and interactions with customers, manufacturers have learned that all customer product-related needs fit into the following three major categories:

- ✱ Price and terms.
- ✱ Product or service definition and performance.
- ✱ Time schedules.

A customer will be satisfied if all three category needs are satisfied by the transaction. Only by satisfying all three simultaneously can the manufacturer be considered to have provided a quality product. Customer needs must be measurable, so that the performance of a manufacturer can be quantified and tracked. This promotes comparisons among competitors.

Using the definition of quality control as satisfying customer needs, many examples of both good and poor quality products and services can be found. These include a piece of furniture that is not the same color as the one seen in the showroom, a restaurant that serves consistently delicious meals, or a computer program that does not operate properly. A good exercise for a group is to identify examples of poor and good quality based on personal experiences and the specific customer needs that were involved.

True quality manufacturers that embrace QIS can consistently produce quality products and services over a long period. These world-class manufacturers provide product designs and production processes that are capable of meeting the quality criteria of customers. It is not sufficient to have a good design for the engineering sample if the production processes are unable to reproduce the performance of the design on a predictable basis. For example, manufacturers that have unreliable equipment with frequent breakdowns cannot meet customers' schedules. Manufacturers that have high reject rates leading to high production costs cannot consistently meet the customers' prices. And manufacturers that have uncontrolled production processes cannot meet customers' product performance specifications.

A manufacturer can achieve world-class status by motivating and training the entire organization in the principles of QIS, including compliance with the policies and procedures listed in its Quality Manual. ISO 9000:2000 can help establish the framework for the documentation system used in the Quality Manual to assure compliance with QIS.



The implementation of QIS for an organization must be comprehensive and involve all employees, from management to operators. Resources must be committed to training the organization about QIS and the need for a team-based organization. Although small companies are more likely to function in a team environment, it is nonetheless important to emphasize the critical need for team participation by the workforce in any successful QIS process.

Training in statistics, control charts, cause-and-effect diagrams, and brainstorming are important elements of an effective QIS process. Frequent internal and external auditing of procedures, as required by ISO 9000:2000, are essential for a successful QIS process. In addition, the workforce must understand that customers, subcontractors, and vendors also exist within the organization and that the same quality criteria used for external customers apply to interactions between departments and employees.

And last, clear accountability and responsibility for all activities in the organization must be established through job descriptions and organization charts. These, in turn, must be communicated and made available to each employee. QIS and ISO 9000 can be effective tools in producing products of consistent high quality, but they require management's commitment to develop an organization to achieve and accept nothing less than doing the job right the first time.

## 1.5 Quality Manufacturing Process: Introducing the IEC, IECQ, and ISO

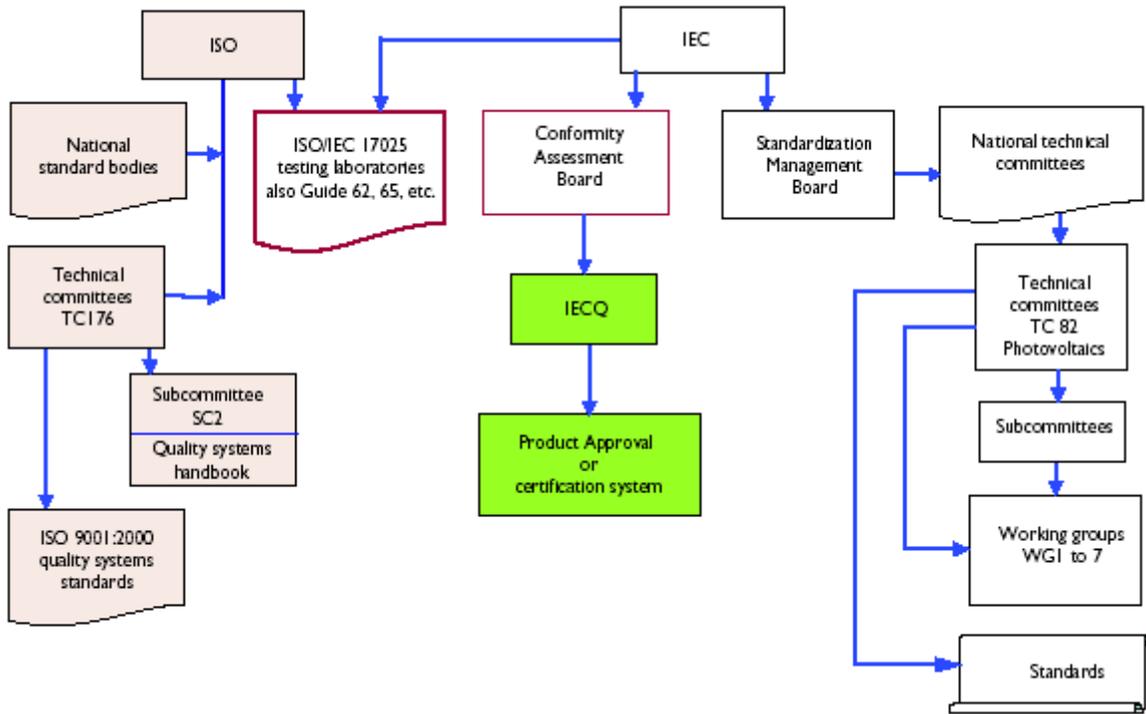
The IEC and the International Organization for Standardization (ISO), together with the International Telecommunication Union (ITU), are the three bodies responsible for standardization and related matters at the international level. They work closely together and occupy adjacent premises in Geneva, Switzerland. Figure 1.3 shows the relationship between the IEC and ISO.

The IEC, through more than 100 technical committees, prepares international standards for the electrotechnical field and is also parent to several autonomous certification schemes, one of which is the IECQ.

The ISO and ITU take care of all other fields—some jointly with the IEC. The ISO, however, also has a special committee for developing jointly with the IEC what are called ISO/IEC Guides, many of which are fundamental to the whole activity of conformity assessment.<sup>1</sup> With the existence of these internationally accepted guides, the rules for an approval scheme like the IECQ can be concise. In many cases, such as in the approval of testing laboratories, reference can simply be made to the relevant guide (in that case, Guide 17025).



**Figure 1.3 How ISO, IEC, and IECQ are Related**



The ISO is a worldwide federation of national standards bodies (ISO member bodies). The edition of the ISO 9001 standard that is discussed in this course and manual was issued in the year 2000.

Instituting the ISO 9001:2000 standard in manufacturing assures that every product will have similar quality. This means that each product falls within an acceptable range, which in turn means there are potentially no rejects at the end of the production line. If there are any rejects, corrective action is taken immediately and rejects are not allowed to leave the factory. It also means that a continuous evaluation process will take place for the review of the process and its potential improvement. The goal of the standard is also to achieve customer satisfaction at all times.

1. Conformity assessment is an activity concerned with determining that relevant requirements are fulfilled. Typical examples of conformity assessment activities are sampling, testing and inspection, evaluation, verification, registration, accreditation, and approval.

## 1.6 ISO Standards for Quality in Manufacturing



The quest for quality is neither new nor a passing fad. It is an essential need for any business in today's competitive international economy. Customers expect that the products they buy will perform as advertised and meet their expectations. To meet customer expectations, a company must first know what its customers want and then do its very best to deliver it. Otherwise, the customer may choose to buy from a competitor the next time.

Many companies sincerely want to deliver a quality product, but they do not plan their activities in a way that makes it possible to meet this goal. If you want quality, you have to implement it in a consistent way. The quality effort cannot be left to chance; it must be managed very carefully and persistently. Only through continuous effort and planning can the quality of products be improved.

Other companies may already have an existing quality system, but it may be not well documented or organized, which can lead to undetected deficiencies that curtail an easy correction of problems.

This training program provides the framework and tools for a system to produce quality products and services and to incorporate as part of the system proper review and audit of activities to enhance the quality system's performance. The objective is not to make a complex system that will generate lots of paperwork. Rather, the objective is to develop a system **as simple as possible** that will generate quality products and services and that will protect the company's interest and make it a financial success. The successful experience with quality systems and their benefits and costs will be studied.

In 1979 the ISO, with the support of several industries and quality organizations, established a series of international standard practices with the goal of setting up generic quality systems applicable everywhere. The ISO standards are used to manage quality once methods and procedures are developed. The past methodology of inspecting every final product to assure quality was changed into a process in which quality considerations are introduced during the design of the product or service. With this new method in mind, quality is managed at every stage in the production process, and the company does not depend solely on the inspection of its products after completion.

### 1.6.1 What Is ISO 9000?

Once designs and procedures are established that can render a quality product that meets the desired specifications, the quality system takes over to assure that the processes are strictly observed to maintain a consistent quality level. The objective is to be able to make a good product the same way thousands of times.

ISO 9000 is a series of generic quality management standards that have the goal of organizing the way in which a company carries out the quality functions. It has been designed to be flexible for a wide range of requirements and situations. Whether a business is large or small, the ISO 9000 system allows the organization to manage the business in a systematic and documented way that prevents inconsistencies caused by individual deviation from accepted methods and procedures.

The ISO 9000 family of standards promotes the responsibility of all the company's personnel in establishing processes for the quality of the end product or service. It includes all personnel, including the management and all those involved in the manufacturing activities and development and design. The process includes reviewing the resources available and planning the quality functions. It promotes the establishment of quality goals, responsibilities, and measurements, as well as general quality management improvements.

The ISO 9001:2000 standard has recently been released. It changed the 1994 version in the approach to management of the system. It has similar elements of the quality system (applicable to any business), but its approach has been changed into a process methodology to enhance its efficiency. In general, the standard tells a company **what** it must do to implement a quality system without dictating **how** it should do it. It does not specify what kind of processes must occur, but it does require that appropriate quality activities be defined and documented and that the company prove its consistent adherence. Guidelines explain which elements are necessary for maintaining certification. The implementation process is intended to be as simple as possible, to minimize paperwork and records, yet ensure that essential records are kept to verify that quality is being maintained. Processes must be documented and consistent to maintain quality.

The ISO 9000 methodology leads to the measurement of performance, and therefore promotes the use of statistical measurements and controls to document and measure performance of the quality system. The data are used for the continuous analysis and management review of the methods and procedures that potentially can improve quality and performance. The rest is up to the company. Using this quality philosophy, a company will achieve consistent quality, as well as the ability to continuously improve it.

### **1.6.2 Quality System Requirements**

The ISO 9000:2000 family of standards includes a set of concepts, principles, and vocabulary common to all quality management systems (see table 1.2). All the requirements for certification are specified in ISO 9001:2000. In the 1994 version of the ISO 9000 standards, three different series—the 9001, 9002, and the 9003—





**Table 1.2 ISO 9000:2000 Family of Standards**

ISO 9000-2000	Quality Management Systems Fundamentals and Vocabulary	This standard describes the concepts of the quality system and establishes a process approach to the pursuit of quality management.
ISO 9001-2000	Quality Management Systems Requirements	This standard addresses the requirements for an organization to demonstrate its capability to meet customer needs all the time.
ISO 9004-2000	Quality Management Systems Guidelines for Performance Improvements	This standard addresses the need for a continuous improvement process to enhance satisfaction.
ISO 19011-2002	Guidelines for Auditing Quality and Environmental Systems	This standard is currently under review. It addresses the need for audits of quality and environmental systems.

were applicable to companies that deal with design, manufacturing, and services (9001); companies that deal only with manufacturing and services (9002); or companies that deal only with final testing and inspection (9003) of their products or services.

This distinction has been eliminated from the new ISO 9001:2000 version. A unique set of requirements now exists for all companies, irrespective of products, service, or size. The requirements listed in ISO 9001:2000 apply to all companies. Those elements found irrelevant for the type of business can be excluded from the process, but they must be identified.

The ISO 9001:2000 contains all the normative references and is the basic requirement for obtaining certification. It demonstrates the capability of a company to satisfy the customer needs. The ISO 9000:2000 also contains two important separate standards. One is the ISO 9004:2000, which is strongly recommended in order to pursue the continued improvement process that will make a business a world class business. This standard is not essential to achieve the certification.

The second is ISO 19011, a standard that provides guidance in audits for quality and environmental management systems. All these standards are part of the ISO 9000:2000 family of standards and follow the same basic principles.

This training manual is designed to help your company meet the requirements of the ISO 9001:2000. The manual reviews the implications and philosophy of the ISO 9001:2000 and the way to implement its various requirements and to achieve certification.

### 1.6.3 General Description of ISO 9000:2000

The fundamental concept of the new quality management system is the approach to quality management as a process model, in which several processes are interlinked to achieve the business goals, as well as to satisfy customer needs and possibly exceed customer expectations.

The standard develops a series of elements that are required to achieve customer satisfaction, but which are dependent on the type of business, either manufacturing or service, and which your organization must define in its Quality Manual as necessary or not. The system is very flexible and adaptable to all sorts of businesses, large or small, and either manufacturing or service organizations. The only requirement is that the Quality Manual must justify any of the elements that are not necessary to achieve the service or product.

The new standard is based on eight quality management principles that are the guidelines to help the management of the organization achieve the quality goals:

1. **Customer focus:** The main goal of a business is to understand and fulfill the customer's expectations. The success of a business is based on customer satisfaction.
2. **Leadership:** The company management must establish the direction of the organization. They must foster an environment where the people see their interest and involvement in the quality and other goals of the organization by participation, review, and support.
3. **Involvement of people:** All members of the organization must be unified and involved in the pursuit of the goals within their operating parameters. All employees should identify their contribution and responsibility toward achieving customer satisfaction.
4. **Process approach:** The desired service or product requires several activities, which are always intended for a customer, internal or external. The management of resources and time for the required activities is optimized when this approach is taken. This approach is discussed below.
5. **System approach to management:** Each individual is responsible for adding some value to the previous step and fulfilling the expectations of the next. This approach allows management to more efficiently and effectively understand



and identify the needs and problems, and to achieve the goals and objectives of the organization.

6. **Continual improvement:** This is a major goal because the organization benefits by continuous efforts at improvement.
7. **Factual approach to decisionmaking:** Decisions and changes shall be based on factual data or information in order to be effective and reproducible.
8. **Mutually beneficial supplier relationship:** Good supplier relationships are an important goal for the organization. A close relationship and quality performance is beneficial and indispensable for the ability to create value and satisfy customer needs.

### ***1.6.3.1 Process Approach***

Under this approach, any activity that uses resources to transform inputs to outputs is identified as a process. Several of these processes are linked to each other until the output is the desired product or service. Identifying processes and managing the interactions among processes allow for their improvement, thus making output efficient and assuring a more effective use of resources.

The terminology in this standard has been changed to adapt it to the "process" approach. The organization is the entity that is intending to use this certification. The "supplier" is the subcontractor or the entity that supplies materials or services to the organization, which are then processed and transformed into the product or service delivered to the "customer."

These terms differ considerably from all previous issues of the standard and must be revised carefully if previous documentation exists.

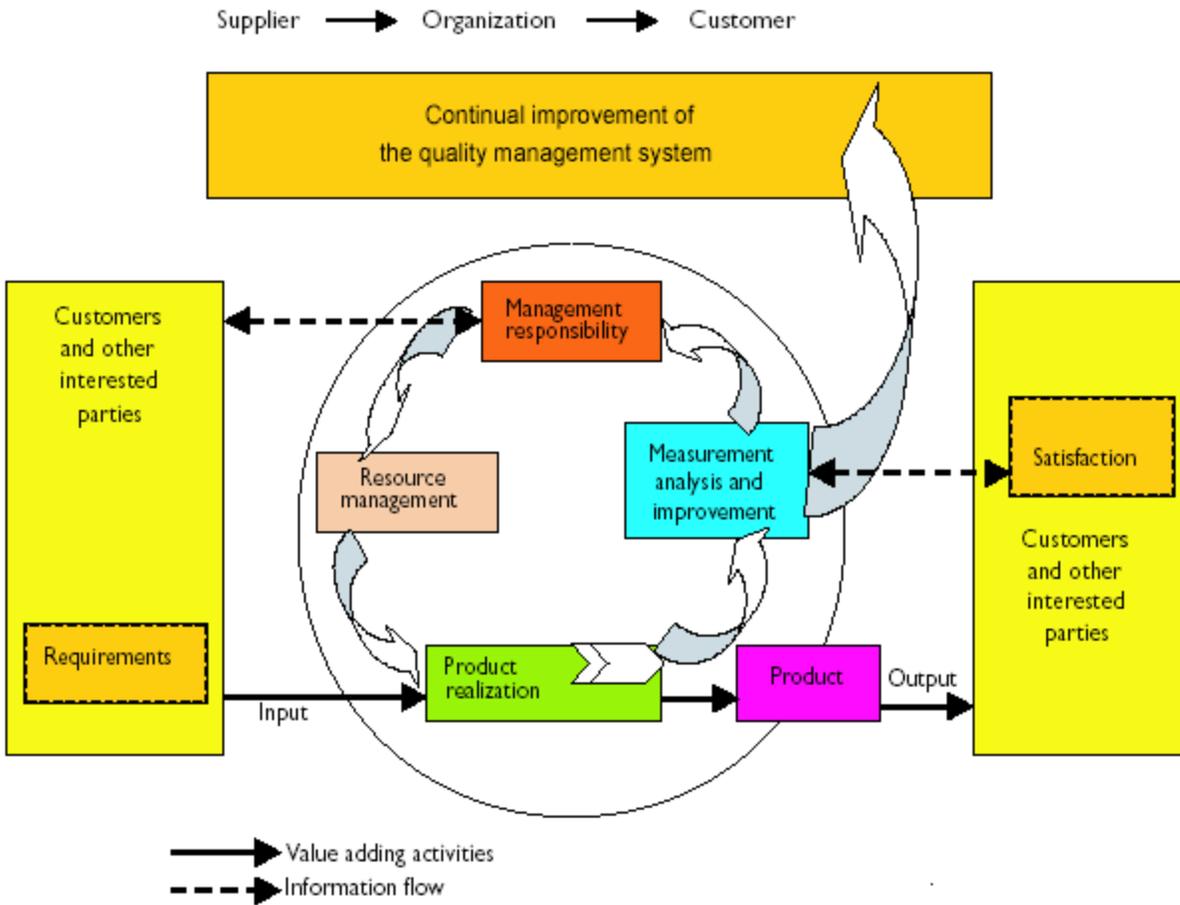
The process starts with a full understanding of the customer needs and requirements, which is labeled as the "input" in figure 1.4, and is linked by the product realization process or processes that result in a product or "output" that is delivered to the customer; therefore, the process starts at the customer and is **for** the customer. The information flow loop is the feedback that the customer provides on satisfaction, with the results of the organization effort in providing the "product."

The quality management approach emphasizes the control and evaluation of the effectiveness and efficiency of the various processes that changed the input into the output and uses the customer feedback to implement corrective actions, if necessary. Each process is evaluated based on its added value, and emphasis is made in the interfaces between the various processes and their impact on the resultant product.

The methodology typically used for this evaluation is called **PDCA**, which means **Plan, Do, Check, and Act**. It proposes that



**Figure 1.4 Model of a Process-Based Quality Management System**



Source ISO 9001:2000

every action should be planned and implemented, and the details and data of the implementation reviewed, followed by actions taken according to and consistent with the results of the first action. The purpose of this methodology is a continual evaluation of the performance of the processes and their interfaces so as to improve the output quality continuously. The use of ISO 9004:2000 in this effort is recommended.

The model indicates an internal flow of information coming from the customer to the box labeled *Measurement, analysis, and improvement*. This information must be presented to management, and proper decisions should be made based in the information obtained. If flaws are found in the quality system, corrective action is taken and if additional resources are needed in the form of equipment, space, or human resources, they should be provided or

planned. Changes in the process are typically identified in this feedback.

These activities provide management with the information and tools needed to improve the quality management system, which is represented with the outside arrow focusing in the *Continual improvement* box in figure 1.4.

### 1.6.4 Components of the Quality Management System

The ISO 9001:2000 has changed the previous 20 elements and 18 documented procedures of the quality management system to 5 processes and 6 basic documentation requirements. This does not mean that other documentation may not be useful; but only that it is not a requirement.

The five basic processes and their supporting functions are summarized as follows:

1. General requirements.(**PLAN and ACT**)
  - Definitions.
  - Documentation requirements.
  - Quality Manual.
  - Control of documents.
  - Control of records.
2. Management responsibility.(**PLAN and ACT**)
  - Management commitment.
  - Quality policy.
  - Quality planning.
  - Responsibility, authority, and communication.
  - Management review.
3. Human and other resources.(**DO**)
  - Resource management.
  - Human resources.
  - Infrastructure.
  - Work environment.
4. Planning and product realization.(**DO**)
  - Customer-related processes.
  - Design and development.
  - Purchasing.
  - Production and service provisions.
  - Control of measuring devices.
5. Monitoring and measurement.(**CHECK and ACT**)
  - General considerations.
  - Customer satisfaction.
  - Internal audit.



- Control of nonconforming products.
- Analysis of data.
- Improvement.

All these processes and their components are analyzed in the following chapters of the manual. Where documentation is a requirement, forms are supplied, in addition to typical documentation forms used in the past for the convenience of the process.

### 1.6.5 Definitions (from ISO 9000:2000)

Following are definitions from ISO 9000:2000:

<b>Organization</b>	A group of people and facilities with an arrangement of responsibilities, authorities, and relationships.
<b>Supplier</b>	An organization or person that provides a product. This product is transformed by the organization into its output or product. In general terms, the supplier could be internal or external to the organization. Sometimes this is called a contractor.
<b>Process</b>	A set of interrelated activities that transform inputs into outputs.
<b>Customer</b>	An organization or person that receives a product. Can also be defined as a client, end-user, or purchaser. These are external customers. In the process approach, there are internal customers who are the recipients of the output of the various processes that integrate the system.
<b>Customer Satisfaction</b>	Refers to the perceived degree of fulfillment of customer needs and requirements. This is the best measure for the efficiency and effectiveness of the quality system.
<b>Contract</b>	This term applies to all transactions between a customer and an organization that provides a product or service. It may be verbal or documented, for example: <ul style="list-style-type: none"> <li>✦ A purchase order.</li> <li>✦ A telephone order or a verbal order in a restaurant.</li> <li>✦ A written agreement to deliver a new product with specified requirements.</li> </ul>



ISO section 3.3 defines a contract as "agreed requirements between supplier and customer transmitted by any means."

**Product** Any form by which a business can provide a saleable outcome of its activities to meet a customer requirement.

ISO defines it as the result of interacting activities and processes of the supplier that transforms input into output.

**Nonconformity** The nonfulfillment of a specified requirement. It could be internal (during processing) or external at or after delivery.

Following are clarifications of several words used in the ISO standards:

**Should/May** Used with reference to things that are recommended to make the quality system effective. They are never used to indicate a requirement that must be fulfilled.

**Shall** Used with reference to things that must be followed or carried out, whenever they occur in the standards.

An extensive list of terms and definitions is included in the Glossary of Terms.

### 1.6.6 ISO Documentation Levels

Proper documentation is a fundamental step in the process of conforming with the standard. All auditors, internal or external, will evaluate the performance from its adherence to the documentation available. It is very important, therefore, that documents reflect what is being done and not what is desired. The documentation should be basic and simple. Most companies have existing processes and procedures that work adequately, as indicated by their experience; these processes and procedures should be described in the simplest and clearest, but most effective, way. There is no need to create lots of paperwork and new procedures. The system should be as simple and brief as possible, but consistent with the methods and processes used.

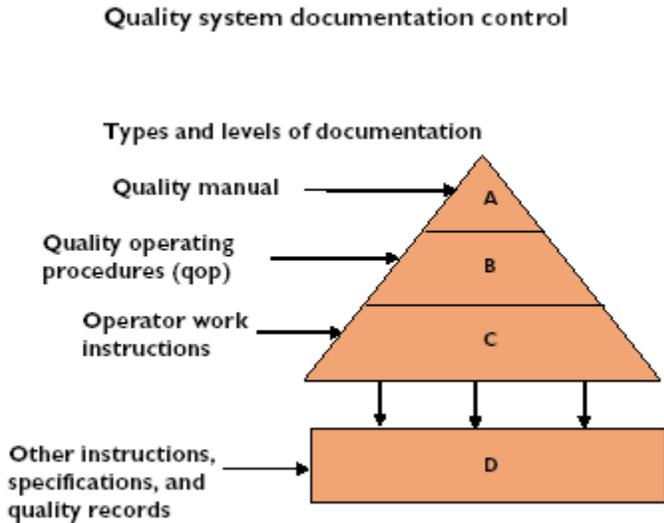
Documentation is of utmost importance in the quality system. At the top of the hierarchy of documentation is the Quality Manual. It must contain references to all processes and documents and indicate where they can be found. It must also explain the procedures for changing processes and documents. It does not need to contain all



the technical or processing details, but it must include references to them. The various kinds and levels of documentation are briefly described below (see figure 1.5).



**Figure 1.5. Typical Documentation Levels for ISO 9001:2000**



### ***Level A: Quality Manual***

This document reflects the company's quality policy. It includes the reference to the operating processes and their interaction. During external audits, this is the most critical document to follow. It should provide a comprehensive view of the overall system, and it is frequently used to show customers the quality procedures and philosophy of the company.

### ***Level B: Quality Operating Procedures***

Quality Operating Procedures (QOPs) explain exactly how a company's quality management plan and policies are implemented. They describe each operating procedure, and state its purpose, who is responsible for it, when and how it should be done, and the associated quality records. The operating procedures are audited frequently, especially in critical operations. Usually these audits are carried out by observation or interview. The operating procedures aim at assuring that the person doing a task will always do it according to a predetermined procedure, which prevents a nonconformity of the product.

### ***Level C: Operator Work Instructions***

Work instructions are usually written in narrative format, but are sometimes presented as charts or flow diagrams. These instructions are descriptions of activities that take place at each workstation or work center. They detail how and when the product arrives and what to do with it prior to sending it to the next processing step. Work instructions may or may not include the details of how to perform a given activity, which are typically part of level D.

### ***Level D: Other Instructions, Specifications, and Records***

This level includes the records and results of activities achieved or provides evidence of the activities that have been performed. It also includes additional documentation required for training and certification of operators, task instructions, maintenance instructions, job descriptions, technical specifications, standards, fire and safety codes, regulatory requirements, equipment operation training, and so forth.

## **1.6.7 ISO Quality Definitions**

A number of definitions differentiate the meaning of the quality terminology used by the ISO 9000:2000 standard:

<b>Quality</b>	Degree to which a set of characteristics of a product or service fulfills requirements. It includes the ability to satisfy stated or implied needs.
<b>Quality policy</b>	The overall intentions and direction of an organization with regard to quality as formally expressed by top management.
<b>Quality management</b>	That aspect of overall management that coordinates activities, directs the organization, and implements the company's quality function.
<b>Quality system</b>	The organizational structure, responsibilities, processes, procedures, and resources for implementing quality management.
<b>Quality control</b>	The operational techniques and the activities used to fulfill the requirements of quality.
<b>Quality plan</b>	A document from management that sets out quality objectives and identifies the specific quality practices, resources, and activities relevant to a particular product, process, service, contract, or project.



**Quality assurance** All those planned or systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

**IMPORTANT NOTE:** All the forms in the following sections of this training manual have been numbered according to the appropriate clause of the ISO requirement followed by a sequential number for the various forms that correspond to that clause.

## 1.7 The Quality Management System (Clause 4.0)

### 1.7.1 General Requirements (Clause 4.1)

#### 1.7.1.1 What Does Quality Mean for Your Business?

Quality means something different for every business. In general, quality is typically defined with reference to the manufacturing of products to meet customer expectation for performance, cost, effectiveness, and on-time service. However, your business must define quality for itself. It should begin to do so by identifying specific customer expectations for products or services. This can be done by customer surveys and interviews, focus groups, market studies, and other means of gathering both qualitative and quantitative information. These expectations can be stated or implied, such as through anticipated regulatory requirements or meeting established product standards.

Before we start the establishment of the system, the organization has to decide why they want to implement the system. This is a strategic decision that must be made based on a benefit for the performance of the organization from a commercial or a competitive point of view. This decision is of great importance to convince internal and external customers of the advantages of certification and to facilitate continuous support in the future.

The system shall also demonstrate that in order to preserve the level of customer satisfaction, a continuous review of the performance is established to maintain a proper quality improvement process of the system. Quality objectives should be established only once the company is clear about customer needs and expectations. Every aspect of the business should have measurable quality objectives. Management should ensure that every employee understands the quality objectives and precisely how his or her job contributes to their accomplishment. In short, quality should not be a vague or abstract concept, but a set of clear expectations and actions that contribute directly to customer satisfaction.



### 1.7.1.2 Reviewing the General Requirements

The standard ISO 9001:2000 requires here that an overall description of the system be outlined. This step requires several actions that **must** be made by the management of the organization.

The intent is to identify the processes that will be the basic components of the service or product to be delivered to the customer. Once the processes or steps are identified and their input and output defined, the organization must proceed with the following actions:

1. Identify processes.
2. Determine their sequence and their interaction, such as requirements for inputs and outputs.
3. Define documentation, criteria, and methods of control and measurement of each process.
4. Provide the resources and information required by each of the processes to achieve success.
5. Set up a system to audit, review, and monitor progress and results of these processes.
6. Implement any corrective action required for the proper operation and improvement of each process, especially the most important ones.
7. Make sure that any process performed outside the organization is properly documented and controlled. Set up a process for control of nonconforming materials or products purchased.

The easiest way to describe the overall system is to create a flow chart that uses task blocks and decision diamonds. It should be made based on the present steps taken in your business and the interface between them. The critical points are the interfaces between the steps and the requirements between them, such as booking of a sales order and providing a manufacturing group with the details of the product required—for example, standard or special—as well as the delivery date and special requirements for delivery or measurements. All these items are further defined in the subsequent steps of the standard. At this point, an overall chart is sufficient. More detailed charts can be developed to describe further needs, such as for a purchasing agent:

- \* Supplier identification.
- \* Supplier selection.
- \* Purchasing procedures.
- \* Supplier evaluation and certification.
- \* Verification of purchased product.
- \* Procedures for rejection of materials that do not meet specifications.



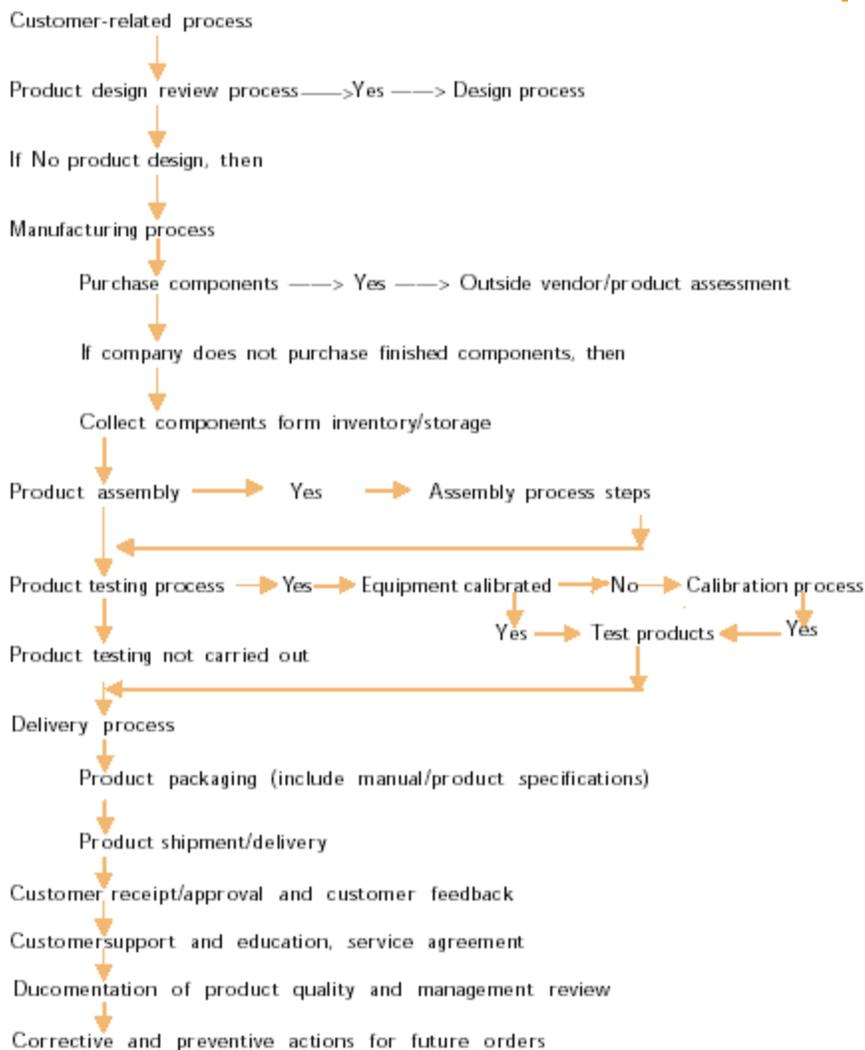
It is most important that a continuous review and update of these processes be made to maintain a good control of the following:

- \* **How** things are made.
- \* **Who** makes them.
- \* **When** they are made.

Updating the system allows the continuous improvement desired by this standard, but proper communication and documentation of these changes is indispensable for the smooth operation of the system.

A simple overview of a work flow diagram (form 4.1-1) could be used in a typical manufacturing operation to start the development of the Process Flow Diagram

### Form 4.1-1 Work Flow Diagram



## Homework Assignment—Day One

YOUR NAME: \_\_\_\_\_

YOUR COMPANY: \_\_\_\_\_

Today you began to learn about the general requirements of quality systems and the requirements for PV GAP. Ultimately you will need to tailor a system that meets your company's unique needs and creates a framework and structure within which it will operate to ensure that its results or products are known, consistent, and repeatable. The homework assignments during this training are designed to help you think about how to apply what you learn here when you go back to your company and be able to organize the effort to qualify for ISO 9001:2000 and for PV GAP Mark or Seal achievement.

The first step in designing a quality system is to step back and carefully consider exactly what happens in your business and what the implications are for the type of quality system it should implement. Your first homework assignment is to do just that in two steps, as follows:

1. Determining why the ISO standard applies to your business is essential. Why do you feel that receiving certification can improve your company? To determine why, answer the following questions:
  - \* Does your company do design work? This entails taking raw concepts and—through drawings, computer designs, or academic thought processes—developing a product, service, or project plan to meet the needs of your customers.
    - Yes
    - No
  - \* (If you do not design) Does your company manufacture products or perform services under existing standards and specifications?
    - Yes
    - No
  - \* Does your company deliver a very simple, fully verified product or service for which it provides only final tests and visual inspection?
    - Yes
    - No
  - \* Does your company deliver custom designs based on detailed customer specifications?
    - Yes
    - No



\* Does your company have to meet special statutory and regulatory requirements?

.Yes

No

\* Based on your responses above, state whether your company needs to fulfill all the requirements of ISO 9001:2000. If not, give a detailed explanation of where you feel there should be exceptions.

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2. On a separate sheet of paper, make a detailed flow chart showing the sequence of the processes involved in what your company manufactures, services, or sells. For each item on the flow chart, indicate the specific steps taken, the workflow, paperwork, and other activities involved in its accomplishment. Make sure that you not only capture what happens within the company, but also what happens with regard to outside suppliers and subcontractors. Put question marks beside the areas where you do not have the information.

This could be the first draft of the process flow. You may highlight the interfaces where troubles or difficulties are most likely to develop.



# Chapter 2. ISO 9001:2000 Standard—Clauses 4–6



## 2.1 Documentation Requirements (Clause 4.2)

### 2.1.1 General Requirements (Clause 4.2.1)

The ISO 9001:2000 standard requires that a documentation system be established. It has reduced the minimum required procedures from the 1994 version. The main reason behind the changes is to make it easier to apply to various sizes or types of organizations. The organization is therefore supposed to implement as many procedures as required to make its processes efficient and effective, but it must maintain a basic list of documented procedures. The need for extra documented procedures will be dependent on the complexity of the processes and the training and skills of its employees.

The required documented procedures and the clauses that describe them are as follows:

1. Document control	4.2.3
2. Control of records	4.2.4
3. Internal quality audits	8.2.2
4. Control of nonconforming products and materials	8.3
5. Corrective action	8.5.2
6. Preventive action	8.5.3

A documented procedure implies that the procedure has been established, documented, and implemented, and that it is being maintained and reviewed for potential improvements.

Several basic documents are also required independent of the size or type of organization:

- \* Quality policy
- \* Quality objectives
- \* Quality manual
- \* Documents needed by the organization to ensure effective planning, operation, and control of its processes
- \* Documented procedures (including those listed above) as required by the standard
- \* Records required

These documents should be as simple and effective as possible. Extensive paperwork should be avoided when it is not directly contributing to the effectiveness and efficiency of the quality system. This is one of the main goals of the revision of the standard.

Several activities are important, which may be included as part of your documented system. They could be work practices, work procedures, operating instructions, or maintenance records. These procedures are included as information and instructions for the personnel so that they can do their job consistently or, in some cases, like production schedules or audit schedules, serve as means of communication with the various departments in a larger organization.

In general, the documented procedures should indicate **who** does **what**, **where**, and **when** and, if possible, **why** and **how**. They should be based on what is really happening and not on what is desirable. If the process requires something different from what is happening, it should be worked out through a change, and the personnel involved in the process should be part of this change, so as to provide ownership of the process to those who have to execute it.

### 2.1.2 Quality Manual (Clause 4.2.2)

The first step in establishing a quality system is for company management to issue a quality policy statement that defines the quality goals and commits all the resources necessary to ensure that the product or service conforms to specific customer requirements. This will be discussed in section 2.2.3. It is important to post this statement throughout the various departments to signal the managers' commitment to ensuring that the policy is understood, implemented, and maintained at all levels.

The second step is to develop a written Quality Manual. The Quality Manual is a controlled document that should describe what is being done and the procedures used to make sure that things are done properly. The Quality Manual is the place where you establish, document, and maintain the processes that ensure that quality goals are met at all times. This manual usually incorporates all the applicable sections of the ISO 9001:2000 standard. The manual is focused on **preventing** quality problems rather than **detecting** them after they have already occurred. If ISO certification is the company's goal, its processes and procedures should be able to be audited by internal or external sources; they should also be clearly correlated to ISO sections. If some of the ISO sections are deemed irrelevant for your business, they may be excluded, but the Quality Manual must identify the reason why each section is not relevant. It must be noted why the section is not relevant and also demonstrated that the sections not included have no effect on the quality of the product or service being provided.



The quality system should be explained in detail in the Quality Manual. The main purpose of the manual is to assure that all relevant processes are under control at all times. The most important processes and procedures to specify are those that assure consistency in the way of doing things. The manual is the main source of guidance; it contains references to the other levels of documentation. The manual is the "road map" of the quality system and should reflect all the activities in the processes and the interfaces necessary to make and deliver the final products or services. The manual documents all its reviews and should be maintained and kept current at all times.

The quality system should be described in the various sections of the Quality Manual, which contains the way the business is conducted, the processes used, and the way they provide assurance that the organization will meet customer requirements and continuously improve customer satisfaction.

The system documentation should be continuously updated to reflect current working conditions. It should state what is **actually** being done, rather than what should be done. The system should be flexible and have clearly established procedures to change the processes, as required, to optimize the quality of the products. Manufacturing or design processes could be part of secondary documentation. In that case, the manual should indicate where they might be found.

The Quality Manual should be concise and straightforward with all processes explained in as simple terms as possible. The use and maintenance of the system is highly dependent on its simplicity.

The usual contents of the manual are as follows:

1. Quality policy and objectives.
2. Scope of the quality management system and justification for any exclusion.
3. Business processes or activities, such as sales, manufacturing, design, purchasing, shipping, and servicing.
4. Document flow and processes interactions, maintenance, and information about how to do things.
5. Outline of procedures for documenting quality requirements.
6. Organizational charts.
7. Definition of terms that are unique for your business.
8. Statements of responsibility and authority.

The manual should be a living document that is meaningful for the organization and not a showpiece to fulfill a requirement.

### **2.1.3 Control of Documents (Clause 4.2.3)**

The ISO standard requires a procedure to control and maintain the documentation and data related to products, services, suppliers,



materials, and the like, as well as some key external documents, such as industry standards and customer drawings. This documentation, shown in form 4.2.3-1, concerns all processes and acceptance criteria for the intermediate steps or the finished product, as well as general business processes that could affect the end service of the supplier.

To maintain the proper documentation system, the following steps may be necessary:

1. Set up a document control procedure to release documents or data in use at present.
2. Compile a master list of all documents and data. The master list should include specifications for materials and processes, as well as controlled data, such as stock numbers, and customers list. **(Form 4.2.3-2)**
3. Establish a master list of all personnel who received copies, as well as the issue date in the organization's facility or supplier. This list shall be updated as needed and used to control all copies released. The number of copies issued should be minimized as much as possible. When changes are made, old versions of a document must be removed and replaced.
4. Set up a signature authorization process by which all necessary approvals are obtained prior to the release of all new documents. The manager should always authorize and sign all changes before implementation. Data should be recorded and submitted to the authorized personnel to justify the changes proposed and predict the impact for further analysis after implementation.
5. Establish a distribution system that will confirm removal of all previous issues of the document and their replacement with the new revised copy.
6. Advise all personnel involved in the process about the new release. This will minimize errors in processing that can occur when changes in procedures take place.
7. If a copy of the old document is retained, make an appropriate marking to distinguish it from the current document in use.
8. Keep properly marked copies of old documentation and record all changes in the system for future legal or reference needs.
9. Do not confuse controlled data with data that are the result of some activity or its measurement. Take, for example, the output test of a solar module or solar cell. Those data, or the statistical average of test results, are fixed and are the result of a test. In comparison, controlled data are variable, such as customer listings, supplier listings, materials specifications, and industry standards. Controlled data should be stored separately, and someone should be assigned responsibility for



### Form 4.2.3-1 Document Flow and Control Form

The purpose of this form is to ensure that the documents and forms in use in the quality process system are the correct and most current forms, and that these forms have been reviewed and approved by the appropriate authorities. In addition, this form is to ensure that, in the appropriate cases, documents are modified, withdrawn, or classified properly. NOTE: All changes MUST be dated and numbered in the specifications or product documentation.

#### ■ Issuance of documents and data

- Document developed in accordance with requirements
- Document reviewed and approved by appropriate manager
- Document title and designation added to master list of documents
- Document distributed to appropriate staff and placed in appropriate files

#### ■ Modification of documents and data

- Document reviewed by appropriate manager and staff
- Document changes approved by appropriate manager
- New document developed
- Document designation modified (new date, new revision number, new title, etc.)
- Final document reviewed and approved by appropriate manager
- Master document list updated

#### ■ Withdrawal of documents and data

- Document reviewed by appropriate manager and staff
- Document changes approved by appropriate manager
- New document developed
- Final document withdrawal approved by appropriate manager
- Master document list updated (note date of withdrawal and superseding document)

#### ■ Classification of documents and data

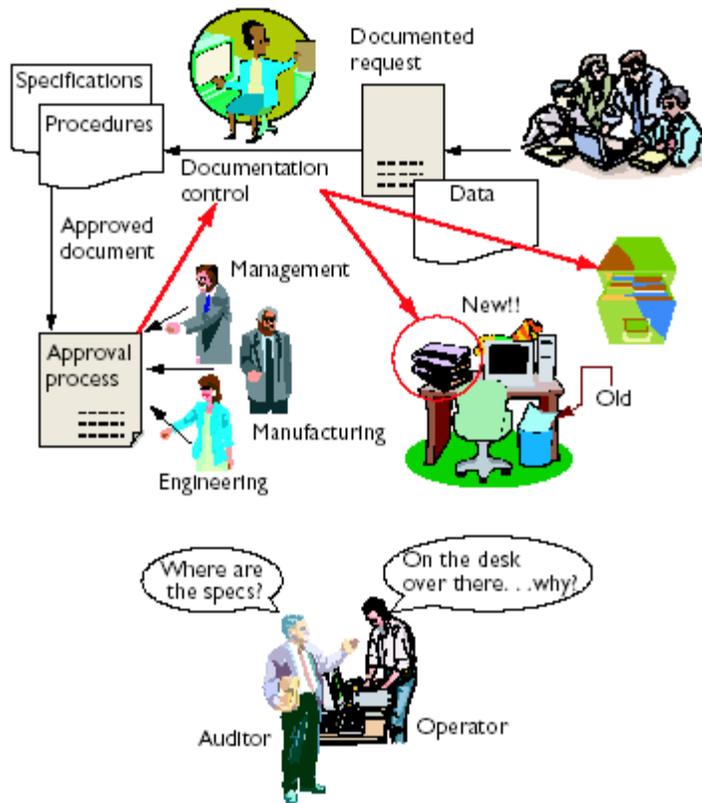
- Document reviewed by appropriate manager
- Document classification approved by appropriate manager
  - controlled
  - proprietary
  - public
  - other
- Master document list updated (note classification)



controlling changes and distributing them to all affected parties.

An example of a document control cycle is shown in figure 2.1. Documentation control is frequently hampered by lack of communications or the assumption of knowledge by all parties involved. The establishment of controls should not limit the free flow of information. It is intended to provide a formal way of communicating the changes, which might not be noticed by all parties involved, if they are not properly notified. Even in small companies where communications are relatively uncomplicated, the use of controls is important to keep records for future reference about when specific changes took place.

**Figure 2.1 Example of a Documentation Control Cycle**



Documents can be maintained by a paper system or by a computerized system. In either case, provisions have to be made that the only copy accessible at the system is the latest version of the document. In the case of the computer version of the system, it is imperative that the system has a backup in case of failure and that control by password is made for the updating capability. In this case, it must be stated that the paper versions of the documents are not "controlled" copies and therefore are not officially acceptable and only used as references. Personnel must have access to the network or computer issue to verify that the approved and latest copy is being utilized.

The documentation procedure is one of the most important and necessary procedures for the ISO 9000 system. In the past it has been the most frequent reason for noncompliance; therefore it should be handled with rigor and accuracy. The listed requirements are as follows:

1. All documents shall be approved for accuracy and adequacy.
2. All documents shall be reviewed, updated and reapproved as necessary.
3. Documents must have a revision status visibly noted.
4. Only the latest revised and approved version should be available.
5. The use of obsolete documents must be prevented internally and externally.
6. Documents of external origin must be controlled.
7. All documents must remain legible and identifiable.

External documents, such as standards, statutory regulations, codes, and specifications from the customer or international agencies, are examples of the external documents that should be controlled.

Proper authority for the approval sequence and final approval must be established in the documentation control procedure.

#### **2.1.4 Control of Records (Clause 4.2.4)**

All businesses keep records of their various operations to some extent. Typically, records are kept on such things as contracts, purchase orders received, special requirements for products, deliveries, and meeting notes (clause 7.2.2). Records are the result of some activity and as such are means of providing information to management on how the system is performing.

ISO clause 4.2.4 requires the establishment of procedures to ensure the safe storage of records, their future availability, and also their ease of retrieval.

Every product should have an identifier that allows traceability to the significant parameters during manufacture and also its



destination or contract. Records shall be kept for a specified period to demonstrate that the product conforms with the specified contract performance, warranty periods, and final manufacturing tests conducted prior to shipment (clause 7.5.3).

The quality control aspect of the business goes further. It maintains manufacturing records of the quality process, including tests performed to check product operating parameters, records of the results of these tests, stock records, shipping, and the disposition of noncompliant products. These records are important in case a calibration defect is found.

It is important to avoid maintaining records that are not significant to the quality or performance of the product. Records can be kept in any media—computerized, written, or otherwise—but a methodology and index should assure availability, good maintenance, and prevention of loss. Electronic media are particularly sensitive to the electronic programs and equipment needed, so changes or upgrades of the equipment or software must guarantee that the data are not lost or difficult to read.

Examples of the types of quality records that are usually kept are as follows:

- ✱ Customer's order or contracts and specified requirements (clause 7.2.2). Design files and calculations (clause 7.3).
- ✱ Meeting notes for contracts and management reviews.
- ✱ Record of validation of processes for production and service provision (clause 7.5.2).
- ✱ Internal audit reports.
- ✱ Records on nonconforming products and their disposition.
- ✱ Service reports, warranty complaints, product returns, and complaints in general.
- ✱ Process control records and traceability of product (clause 7.5.3).
- ✱ Supplier evaluation or customer-supplied product records.
- ✱ Inspection and test records.
- ✱ Final acceptance records and approval authorities.
- ✱ Education, training, and skills certifications.
- ✱ Equipment maintenance and calibration records.
- ✱ Delivery date records, shipping records, paperwork, and insurance, labeling and crating records.
- ✱ Management review records.
- ✱ Management representative reports.
- ✱ Records of corrective and preventive actions.



## 2.2 Management Responsibility (Clause 5)



### 2.2.1 Management Commitment (Clause 5.1)

In any company, large or small, quality in all its forms is attainable only with the total commitment of management. Management must first establish quality as a fundamental principle of doing business and ensure that the entire workforce understands that quality is essential for survival and growth of the business. Second, management must take responsibility for mobilizing all personnel and company resources around the goal of quality in all the processes, products and services; that is, meeting customer needs and expectations in all the areas of interface and services, including products that meet all the specifications and regulatory and statutory requirements. Managers should ensure that official company quality policy reflects the high priority given to quality. But that is by no means enough. The responsibility of management extends to making a habit of quality commitment by establishing goals and infusing quality throughout the company's processes through norms and culture.

For this to happen, management must be consistently involved and uncompromising in its commitment to quality. Rhetoric alone is not enough. A significant portion of managers' time should be devoted to initiating quality-related actions, identifying quality systems requirements, delegating authority and providing resources in support of quality systems, and constantly reviewing performance and monitoring customer satisfaction. In this way, managers demonstrate the importance of quality and instill a positive attitude toward quality throughout the workplace. They can further improve employees' attitude toward this crucial function by acknowledging and rewarding employees who uphold and enhance the manufacturing of products of highest quality.

The result of management's commitment to quality is a company aligned around a consistently effective quality management system. In other words, the result is a company that is well positioned to be competitive and profitable. The standard asks for a continued effort in internal communication within the organization with the aim of establishing a quality policy and quality goals, and then following up with reviews of performance to assure that enough resources are available to meet the established goals.

This effort is subdivided into several sections that can build the framework required to streamline and focus the management responsibility in meeting the objectives of the standard. They are summarized as follows:

1. Customer focus.
2. Quality policy.
3. Quality objectives.
4. Quality planning.
5. Responsibility, authority, and communication.
  - Management representative.
  - Internal communication.
6. Management review.

### **2.2.2 Customer Focus (Clause 5.2)**

This clause centers on the previously discussed quality concept: Good quality means customer satisfaction. In order to achieve this, management must set up a customer-related process that starts by understanding customer needs and expectations through the contract or purchase orders. These needs and expectations must be communicated to all the organization. The resources required and product qualifications or service needs must be evaluated before accepting the order or contract.

The final step is the evaluation of customer satisfaction after the order is completed. Feedback and management evaluation of the quality system's performance shall be performed at this time. Corrective actions shall be taken to promote improved performance whenever necessary. Customer satisfaction is sometimes difficult to measure; hence, frequent questionnaires and review of customer complaints are very useful tools to assert this information. This process was outlined in figure 1.4.

The products of the organization must reflect the needs of the customers. These are usually determined by means of industry reports or marketing surveys and analysis.

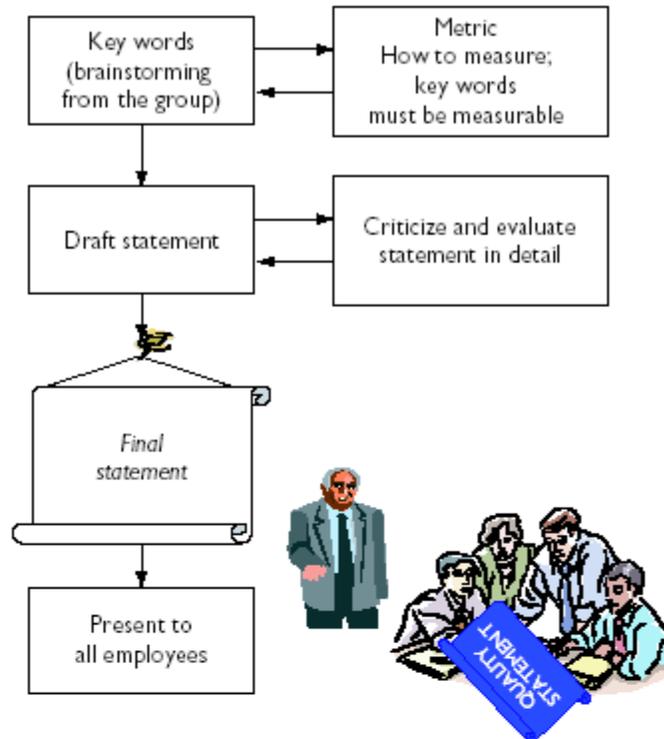
### **2.2.3 Quality Policy (Clause 5.3)**

Creating a quality policy statement or document is a basic and important step for the organization (see figure 2.2). The quality policy shall indicate what basic commitments are pursued and specific objectives for all the efforts in the delivery of services and products. The new ISO standard also requires a management commitment to pursue quality improvement goals.

Because the basic quality objective is always customer satisfaction, the senior management of the organization shall list all the key parameters required to meet customer needs, and establish a plan to fulfill them. It is important that the quality policy address the appropriate issues related to the organization's business, and that the policy and goals are realistic and can be carried out. Management should provide the required resources and training, and establish measurable goals. Each distinct objective to be pursued should be monitored by the top management and



Figure 2.2 Procedure to Elaborate a Quality Statement



### STATEMENT OF COMMITMENT TO QUALITY

The company, including its owners, managers, and staff, believe that quality is the primary means by which the company will succeed, and so have agreed to make it a critical priority. To this end, the company expects quality within the organization and from those organizations and individuals with which it does business.

Through meeting quality goals, the company expects to provide its customers with products that are of excellent quality and that are reliable and cost-effective. These products will be delivered on time, and will be backed by a level of service that is second to none in the industry.

\_\_\_\_\_  
Managing Director

\_\_\_\_\_  
Date

periodically reviewed to assert progress and adjust the goals, as appropriate, to promote continuous improvement.

These goals should be set in conjunction with all personnel to enlist the buy-in of all employees and managers. Goals should be achievable within a set period. They should be communicated and discussed internally to indicate a firm commitment on the part of the senior managers to the policy. The quality policy is not a static statement. It is a strategic document that requires constant review, validation, and enhancement as the goals are being met.

The quality policy indicates the vision of the organization and its goals in conducting business. The document or statement must contain measurable indicators (see the example in form 4.5.3-1). All employees should know its contents and understand their role is this pursuit.

#### **Form 4.5.3-1 Example of Statement of Commitment to Quality**

The company, including its owners, managers, and staff, believe that quality is the primary means by which the company will succeed, and so have agreed to make it a critical priority. To this end, the company expects quality within the organization and from those organizations and individuals with which it does business.

Through meeting quality goals, the company expects to provide its customers with products that are of excellent quality, reliable, and cost-effective. These products will be delivered on time, and will be backed by a level of service that is second to none in the industry.

---

Managing Director

Date



## 2.2.4 Planning (Clause 5.4)

### 2.2.4.1 Quality Objectives (Clause 5.4.1)

The quality policy identifies the purpose of the organization. In order to fulfill this purpose, the senior management of the organization must develop a strategic plan and identify associated goals needed to achieve and improve its performance. For example, in a manufacturing company, reduction of scrap, reduced cycle time, and delivery on schedule are examples of goals that enhance the business performance and customer satisfaction. They are measurable and could be analyzed for trends and consistency of the performance.

Achievement of the goals or objectives of the organization can be hindered by noncompliance issues or products that limit the efficiency and effectiveness of the delivery of services or products, or both. These issues are usually identified through the management review process and through the customer satisfaction surveys. In order to improve (and sometimes to maintain) the quality level, it is necessary to establish goals and objectives for the specific functions or processes that are identified as the source of nonconformance. These objectives must be measurable and set up for a specific period. After that period, progress is evaluated by a management review and a new set of goals set up. It is important to recognize that quality improvements come in small steps, which steadily advance toward the top of performance.

Frequently the relevant processes are broken down into specific key objectives that are then improved to enhance the performance of the quality system. It is important to identify the resources and the skills of the operators required in order to avoid pitfalls during the implementation process of these changes. Management must monitor changes in processes very closely to ensure the integrity of the quality management system.

### 2.2.4.2 Quality Planning (Clause 5.4.2)

The supplier is responsible for ensuring that the products or services to be rendered are consistent with the specific customer requirements and statutory and regulatory requirements at all times. Therefore, on projects involving either standard or nonstandard products, a plan should be in place that assures that the final product meets all those requirements, as shown in form 5.4.2-1. A sample quality plan is included in appendix 2 as a typical document for a manufacturing company.

In addition, a strategic quality plan should be in place for the continuous evaluation of what is needed to maintain and improve the quality of products or services. The plan should include attention to both short-term and long-term quality goals. Short-term goals typically



- ✱ Ensure compatibility with present processes, equipment, procedures, inspections, tests, and so forth on new orders or projects for special products.
- ✱ Detail the action plan requirements for delivery. (Frequently several departments are necessary in the design, manufacture, and implementation of special products. An action plan is needed to assert the proper documentation and test requirements.)
- ✱ Verify project milestones in the schedule.
  - ❑ Clarify the needs and expectations of the customer and the acceptance criteria (including those requirements that may be subjective).
  - ❑ Evaluate how to meet all the statutory and regulatory requirements.
  - ❑ Document and maintain quality records and problem resolution procedures.

Long-term goals typically

- ✱ Identify responsibility and authority for the implementation of any process improvement plans.
- ✱ Identify the need to acquire controls, processes, or new equipment, including tools and fixtures needed to achieve the desired quality or performance.
- ✱ Identify the capability of state-of-the-art equipment and technology, and develop the skills required and training or technology development required prior to accepting orders that demand such skills.
- ✱ Update test equipment, inspection methods and techniques, and instrumentation and quality checks, as required.
- ✱ Identify operator training requirements through employee involvement and participation in the planning phase.
- ✱ Identify the cost and verify the product performance at various stages of the project.

In order to achieve these goals, the plan must address the following:

- ✱ **Senior executive leadership.** The management of the company must lead the effort to plan ahead to meet the company's short-term and long-term requirements. Significant investment may be called for new equipment, and financial analysis may be needed to justify certain courses of action. It is important to utilize



### Form 5.4.2-1 Quality Planning Checklist

The management representative and the quality team\* should engage in quality planning that considers the best way to:

- Prepare quality plans
- Identify and acquire any controls, processes, equipment (including inspection and test equipment), fixtures, resources, and skills that may be needed to achieve the required quality
- Ensure the compatibility of the design process, production process, installation, servicing, inspection, and test procedures and the applicable documentation
- Update, as necessary, quality control, inspection, and testing techniques, including the development of new instrumentation
- Identify any measurement requirement involving a capability that exceeds the known state of the art, in sufficient time for the needed capability to be developed
- Identify suitable verification at appropriate stages in the manufacturing process
- Clarify standards of acceptability for all features and requirements, including those that contain a subjective element
- Prepare quality records

\*A "quality team" is an organization's team of managers and staff responsible for developing and reviewing the organization's quality systems. It is a good way for the management representative to involve other employees in the planning process.

existing resources fully before considering requests for new ones. The goal of a good plan is not to add resources immediately, but rather to use all existing resources more effectively.

- ★ **Customer satisfaction, requirements or complaints.** The driving force in all decisions should be the customers and their needs and requirements. Customers might want improvements in quality, reductions in cost, improvement in performance or reliability, or changes in shipping methods and delivery time. Frequent surveys are one means of staying close to the customer and are an important source of input to the strategic plan.

## **2.2.5 Responsibility, Authority, and Communication (Clause 5.5)**

### ***2.2.5.1 Responsibility and Authority (Clause 5.5.1)***

This clause requires the identification of each employee's responsibility and level of authority. This is particularly important when analyzing nonconformance issues and implementing corrective or preventive actions. The duty of the operator and manager or process owner is to seek signatures of the authorized personnel to implement the changes required. The documentation shall identify such responsibility to maintain an orderly system of operation. This is applicable to a service or a manufacturing organization as well.

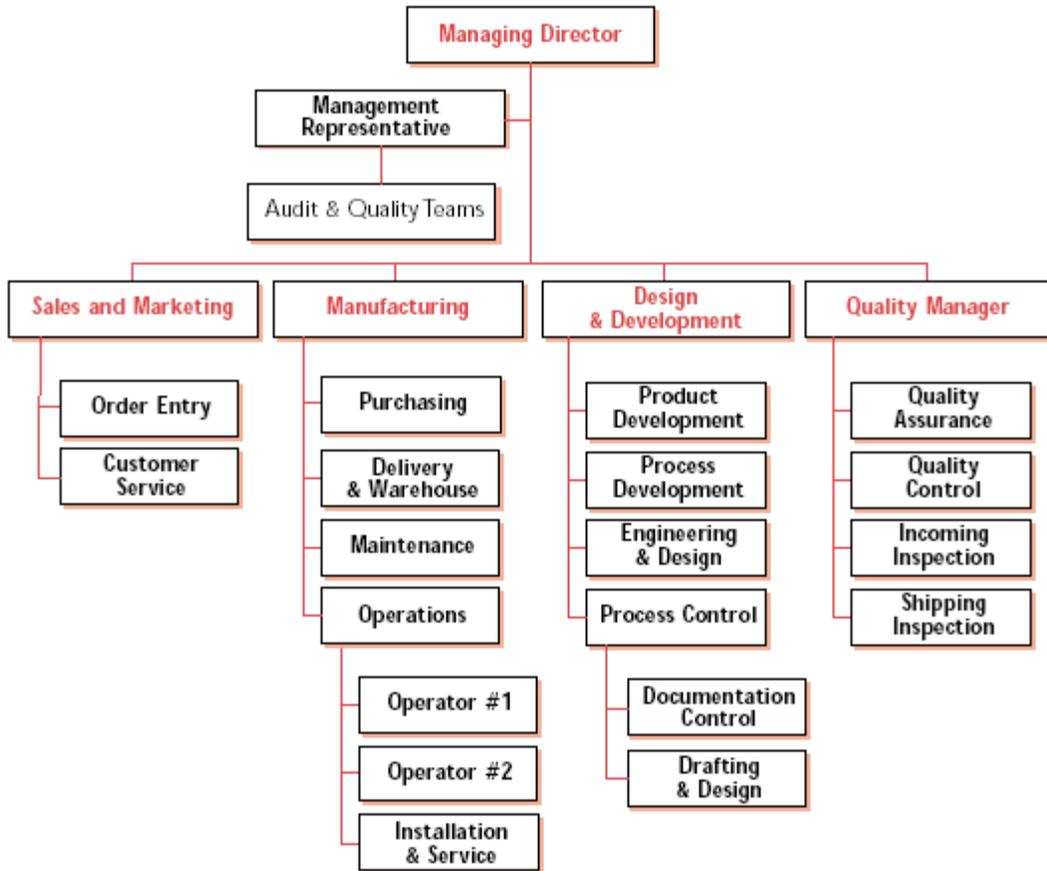
In order to identify the authority, the organization usually issues an organizational chart delineating the reporting authority throughout the organization. This chart is not mandatory for the ISO 9001:2000, but it is the most frequently used vehicle to achieve the goal. In very small organizations, it may not be necessary, but in intermediate and larger organizations, it is indispensable.

The chart shown in form 5.5.1-1 is an example of how an organization chart for a small manufacturer might look. A company using this manual should develop its own organizational chart, or use its existing organizational chart to identify the personnel, their positions, and the reporting structure.

In order to identify the responsibility within the quality system, the most frequently utilized vehicle is a job description form. This form is sometimes based on some specific operational requirements. It should also, however, incorporate the quality implications of the specific function and the expectations for such function, as shown in form 5.5.1-2. For example, a salesperson will be responsible for an accurate delivery schedule, and accurate description of the customer requirements, and communication to the manufacturing or service department of any special need that the customer has requested. The salesperson should be responsible for following up on the results after completion of the work and for ascertaining the level of customer satisfaction.



**Form 5.5.1-1 Sample Organization Chart**



## Form 5.5.1-2 Job Description

Job Title: \_\_\_\_\_

Employee Name: \_\_\_\_\_

Date Started on Job: \_\_\_\_\_

Description of Work: *Module manufacturing engineer*

**Description of Responsibilities:**

*Review and issue process specifications. Evaluate manufacturing needs to introduce new products. Issue and review materials specifications. Review all nonconforming products or materials. Request capital equipment required for manufacturing.*

**Description of Reporting Authority:**

*Reports to manufacturing manager and line manager. Functional support for engineering manager and process development.*

**List of Required Qualifications:**

*Bachelor degree in engineering. Mechanical know-how. Ability to program electronic controllers or computerized systems. Materials science background and experience.*

**List of Equipment Responsibilities:**

*Controllers, computers, laminators, automation units. Calibration of sun simulator. Capable of designing jigs and fixtures.*

**Training Completed:** (note: only personnel with appropriate training may perform some tasks)

*Direct training in troubleshooting electronic controllers and automation equipment.*

**How does your job function affect the quality of the products/services of the company?**

*My job maintains quality of the assembly and calibration of the module line. I am responsible to maintain yields equal or better than goals for the year. Training of new employees is very important. Evaluation of nonconforming products and corrective actions assures the quality of the company's products.*

If additional space is required, attach additional sheets.

These quality functions and feedback are elements that should appear in the salesperson's job description, along with clear indication of responsibility for achieving them.

### ***2.2.5.2 The Management Representative (Clause 5.5.2)***

Quality should be the concern of everyone in the company. At the same time, however, the design and day-to-day coordination of the quality system should be the responsibility of one clearly authorized **management representative**. In small organizations, the general manager or even the person with the highest authority may be the management representative. It is essential that the manager be able to carry out the responsibilities associated with the job. The greater the authority of the management representative is, the greater the commitment to quality will be throughout the company.

The company's quality goals should be posted, and the managing director should commit in writing to the goals of the program. **Form 4.5.3-1** is an example of a Statement of Commitment. The managing director may be the management representative, but in case this is not possible, he or she should name one. The management representative not only sets up and oversees the quality system within the company, but also is the company's representative to any auditors or standards bodies, such as the ISO or the IEC, under which the quality system will be certified.

The management representative is responsible for establishing quality goals. Quality goals should be realistic and achievable. Milestones should be set to measure and monitor progress; they are the basis for reporting how the program is helping to improve quality or for eliminating complaints from internal or external customers. The management representative stands for the involvement and commitment of the top management in the quality system of the organization. As original goals are achieved and confidence is developed, new and more challenging goals can be set. In this way, there can be continuous quality improvement.

It is important to recognize that small steps can improve quality and steadily advance the company to the top of its performance. All goals should be measurable. Employees who contribute to their enhanced quality may be rewarded for their efforts and their commitment. The management representative is responsible for frequent rewards and recognition of efforts, so that other employees understand that quality is a top concern of everyone in the business.

The management representative ensures that the responsibilities for carrying out the tasks related to accomplishing quality objectives are appropriately distributed throughout the company and that specific quality control tasks are carried out by those whose jobs are most directly involved with the corresponding part of the production process.



Once the individual quality job descriptions are completed, the management representative may find it useful to develop and post a master organizational chart that shows employees how their tasks fit into the larger quality system and that helps them understand better how their coworkers contribute to product quality. **(Form 5.5.1-1)**

Part of the management representative's role is to make sure that all employees see clearly how their work affects the quality of the product or service that the company provides and that they understand and commit to specific quality control actions. One of the tasks of the management representative or other designee is to document every employee's role and responsibilities in a quality job description. **(Form 5.5.1-2)**

The management representative should organize a quality team (or various teams from various departments or functions) that will assert that the quality goals are understood and maintained as a main objective of the company. These teams should have members from all levels of the company, should be cross-functional, and should be responsible for bringing the quality objectives to the operator level through the use of participative dialogue and feedback.

The establishment of system procedures may entail additional work for some individuals or may call for new skills for which training will be required. Management must identify training needs and allocate the resources needed to address them, such as equipment, added labor, jigs, and measuring equipment.

**Form 5.5.2-1** outlines the requirements and documentation that assure the integrity of the quality system and that need management implementation. It also outlines the authority and responsibility of the management representative.

The management representative is responsible for the operation and performance of the quality system, including the performance of subcontractors, documentation, and record-keeping of all quality processes, the verification and validation of quality, the quality audit process, the documentation of results, and the use of statistical analysis of data to facilitate a continuous improvement process.

In order to assure the continuous operation and success of the quality system, the management representative must conduct regular



### Form 5.5.2-1 Management Representative

The Management Representative has authority and responsibility for:

- ensuring that the quality system is developed, implemented, and maintained, in accordance with the requirements set out in this document;
- making sure that all customer needs and requirements are understood and satisfied
- reporting on the performance of the quality system to management;
- creating quality teams and internal audit teams to support the quality effort at all levels of the company; and
- conducting a constant review of the system effectiveness.

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Name of Management Representative

**management reviews.** A quorum should be established for such reviews. Their frequency is not fixed—it depends on the company—and could be weekly, biweekly, monthly, or quarterly. A standardized procedure and agenda should be used to study and evaluate the following:

- \* Overall system effectiveness.
- \* The system's conformance to the company's stated quality policy.
- \* Documentation and records.
- \* Problems encountered and corrective or preventive actions taken.
- \* Assurance that customer needs are communicated and understood.
- \* Customer complaints.
- \* Training needs, and equipment or maintenance problems.
- \* Subcontractor performance.
- \* Resource allocation for quality-related tasks.

Reviews should be aimed at assessing the effectiveness of the system. The purpose is not to present a lengthy report, but rather to summarize how the system is functioning to improve the customer satisfaction. **Form 5.6.3-1** can be used to assure that all elements are being reviewed and that reports are issued as needed.

The central part of any review should always be to evaluate all aspects of customer satisfaction related to product, performance, and supply, using the most relevant documentation and information. Once the quality policy is well known and accepted throughout the company, the focus of the management review should shift to reviewing information that best illuminates the factors that contribute to nonconforming products. This information typically includes documented failures, predominant problem areas, corrective actions taken, training needs, and equipment or maintenance problems. (**Form 5.5.2-2**)

Specifically, it is the responsibility of the management representative to set up a quality management system, based on this manual and the forms it contains, which will

- \* Assure that customer needs are identified and understood.
- \* Initiate actions that prevent defective product by reviewing the process, material, and quality system requirements.
- \* Identify and keep record of any problems found with the product, its process, or components.
- \* Initiate and recommend solutions by using the proper channels and authority as outlined in a documentation approval process.
- \* Verify that corrective action is being taken.
- \* Control the disposition of any nonconforming products.
- \* Monitor effectiveness of the system.



## Form 5.5.2-2 Management Representative Responsibility Checklist

Check off the items on the following list as each is completed.

### 1. QUALITY SYSTEM DEVELOPMENT

- Quality requirements of this manual
- Ask customers about their requirements and expectations and communicate internally
- Ask employees for input on improving/implementing quality processes
- Adapt sample manual to company specifics
- Adapt/develop appropriate reporting/tracking/auditing forms\*
- Adapted Quality Manual is reviewed and accepted by management

### 2. QUALITY SYSTEM IMPLEMENTATION

- Equipment is checked against the operating parameters specified in its documentation
- Internal communication methods and channels are established
- Employees receive training in job functions
- Employees receive training in quality program
- Documentation and audit materials are used to track quality
- Management receives product quality reports
- Quality audit and documentation filed and accessible

### 3. QUALITY SYSTEM MAINTENANCE

- Quarterly audit of quality procedures

### 4. REPORTING TO MANAGEMENT

- Quarterly report to management

### 5. REVIEW OF THE QUALITY SYSTEM

Review of the quality system and its impacts on the company and the company's products and customer relations by the management representative, the quality team (if one has been assembled), and company management, including

- Quality problems and actions taken
- Customer complaints
- How the quality system is working/if objectives are being met
- Quality audit reports (internal and external)
- Corrective action reports
- Areas for improvement/changes needed
- Outstanding actions
- Relevance of quality policy and objectives to current needs
- Training needs
- Vendor problems
- Equipment, working environment, and maintenance problems

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\*Remark: Sample forms are included in this manual.



### **2.2.5.3 Internal Communication (Clause 5.5.3)**

This internal communication requirement is new in ISO 9001:2000. Although it has always been recognized as a good method to achieve results, it was not postulated as an element in the previous issues of the standard. It does not require a special documentation, but records and the Quality Manual should indicate how the internal communications will take place and with what frequency.

In small companies, internal communications are generally easy because people interface more often. In medium-size and large companies, interface becomes more occasional. Therefore, a plan is usually made for assuring that important reports are communicated and the results of audits or management reviews of the quality system are followed up.

Meetings for departments, strategic discussions, nonconformance reviews, and the like are typical means of communicating. In many companies, quarterly or monthly meetings are organized to review with all employees the financial, marketing and sales, and quality issues for the month.

Typically, department reviews, design reviews, engineering meetings, and sales and marketing reviews are the best means to communicate the status of new projects, new products, and the performance of the organization and to discuss with the employees of the various departments their needs for training or equipment. Employee reviews offer excellent opportunities for suggestions and for analysis of quality problems and prevention of nonconformance.

Suggestion boxes and bulletin boards for posting news that affects the company in general can also facilitate internal communication.

Systematic information derived from the performance of various departments and the posting of quality results provide a continuous data flow, and are excellent ways to provide the information necessary to analyze trends and promote employee awareness of potential problems before they cause a nonconformance.

The most important communication is usually the customer requirements and, after delivery, any indications of customer satisfaction or complaint. Records should be kept of these data to gauge the level of customer satisfaction.

### **2.2.6 Management Review (Clause 5.6)**

#### **2.2.6.1 General (Clause 5.6.1)**

The organization's top management shall participate in the quality effort through a scheduled number of reviews during the year. Even though the top management has named a management representative for day-to-day executive decisions, the top managers



responsible for all functions must be involved in the operation of the quality system.

The management reviews are fundamentally directed at the performance of the quality management system, and to oversee it to ensure that it is effective and adequate for achieving customer satisfaction and seeking new opportunities for improvement. During the management reviews, the quality policy and the quality goals are evaluated and changed, if pertinent.

In order to perform the review, the top management and participants must rely on inputs from the various activities and then provide solutions or outputs for further action.

### **2.2.6.2 Review Input (Clause 5.6.2)**

The agenda for the management review should start with an analysis of the action items from previous review meetings and the results obtained. The second item on the agenda would be customer feedback and its assessment, positive or negative, of the quality system and its effectiveness.

The management review should also analyze the results of all quality audits. Quality audits should be conducted for internal or external purposes. They could encompass the review of the quality system, the process quality, or the product quality. They should not be confused with the quality surveillance and inspection process, which is part of the process control or product acceptance. Quality audits are often conducted by personnel not involved directly in the operation, together with and in cooperation with relevant personnel. The purpose of an audit is to evaluate and recommend changes that may be needed for improvement or corrective action. Form 5.5.2-2 can be used to report on the most critical areas of activity typically covered by a quality audit.

The status of preventive and corrective actions must be evaluated for the implementation of changes that could affect quality, with the goal of seeking improvements in the system.

In a manufacturing environment, the process performance and product conformity are key to achieving superior customer satisfaction.

### **2.2.6.3 Review Output (Clause 5.6.3)**

The findings of the management review should be recorded and reports filed of management involvement and recommendations. Follow-up action items for corrective actions or preventive actions should include measurable goals for further review at the next meeting.

The type of output desired from the management review is identification of negative performance areas and needed improvements for the system or processes. Identification of human



resource needs or equipment requirements is the direct output of these reviews.

Changes to update the quality goals or the quality policy statement, or both, are also examples of the management review output. A typical form for reporting is shown in form 5.6.3-1. As usual, fulfillment of the customer needs and requirements shall be the main goal from this review. Planning the resources required to achieve this is an effective outcome from the review.

## 2.3 Resource Management (Clause 6)

### 2.3.1 Provision of Resources (Clause 6.1)

This clause has been expanded in the present ISO 9001:2000 revision to include all types of resources needed to implement and improve the quality management system. The previous issue took for granted that facilities to meet the product existed and dealt with maintenance and training of the personnel at all levels. The requirements under this clause of ISO 9001:2000 cover all the human resources required by the company to fulfill and assure that the products delivered meet all customer requirements and also enhance customer satisfaction by improving the quality system. This applies to the total resources of the company, human resources, facilities, materials, supplies, instruments, software, transportation equipment, environmental issues and, most important, the time required to provide the services and improve the system.

This clause refers not only to the personnel involved in the provision of the service or manufacturing of the product, but also to the management personnel involved in the sales, finance, and the general management functions.

Resource availability should be evaluated at periodic intervals, for example, during management reviews or prior to accepting special contracts or new projects that increase the demands for time and skills. This process should be audited and documented to demonstrate that the company satisfies this requirement.

### 2.3.2 Human Resources (Clause 6.2)

#### 2.3.2.1 General (Clause 6.2.1)

All employees can affect the quality of service or the product that a large or small company provides its customer. Customer satisfaction can be impaired if sales personnel do not properly identify the customer requirements and also if the product does not comply with all its specifications. The purpose of this clause is to create a mechanism that the company can use to enhance the performance of its personnel.



The company should analyze the four competency aspects critical to the achievement of quality goals. They are the skills, experience, education, and training of all personnel in all levels of the organization, including the management personnel. This effort is partly satisfied using the job descriptions developed in a previous chapter.

### **2.3.2.2 Competence, Awareness and Training (Clause 6.2.2)**

The most valuable asset your company has is the knowledge and competence of its employees. The competence of all personnel is fundamental to the proper performance of all functions. This includes training for people at all levels of the organization, including management. The supplier should identify by internal audits or resource review the educational level, the skills requirements, and the training needs associated with each function or process. These needs should be documented; they can change or become more demanding as tasks change. A procedure shall be established to provide training to all personnel in positions that affect quality, as shown in form 6.2.2-1.

This can be achieved by creating the job descriptions, as detailed earlier in the manual, and analyzing the gap between job requirements and the actual skills and abilities available in the company. Adjustments can be made through reassignments of functions or by training. Training requires that all personnel be made aware of the importance of their function in the achievement of customer satisfaction and the improvement of the quality system.

The organization should keep records of all personnel trained, and these records should be continuously audited and updated. Continuously enhancing the training should be a high priority because it will result in better performance and enhance the abilities of all personnel.

The training of new operators in safety, health, and quality policies is recommended, even for small businesses. Employees should be trained in several operations, and records of each employee's certifications should be kept. Only certified operators should perform critical quality functions. The training records do not have to be very elaborate, but they should be designed to help demonstrate during an audit that only properly qualified personnel are performing the critical quality operations. A flow chart is shown in figure 2.3.

All employees should be required to undergo training in safety and health. They need to be aware of potential accidents that could take place in many areas. Training in chemical handling, fire drill procedures, and emergency management is essential to protect the welfare of employees at all times. Management should make clear



**Form 6.2.2-1 Training Plans and Documentation**

- A) Employee name \_\_\_\_\_
- B) Employee ID/designation \_\_\_\_\_
- C) Employee start date \_\_\_\_\_
- D) Employee job function \_\_\_\_\_
- E) Employee training record

<b>Training module</b>	<b>Date</b>		
New employee orientation	____	____	____
Employee safety training	____	____	____
Renewal of safety training	____	____	____
Quality training	____	____	____
Renewal of quality training	____	____	____
Skills/competency training			
Job function _____	____	____	____
Job function _____	____	____	____
Job function _____	____	____	____
Additional Training			
Training module _____	____	____	____
Training module _____	____	____	____
Training module _____	____	____	____

F) Trainer/training organization: Name: \_\_\_\_\_

Evaluation of effectiveness of training \_\_\_\_\_

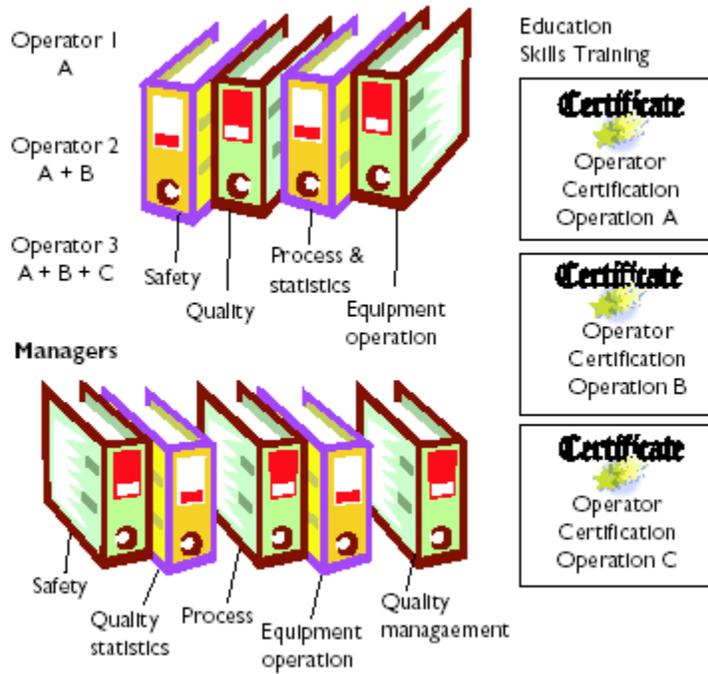
\_\_\_\_\_  
\_\_\_\_\_

Comments and corrective and improvement actions \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

G) Employee feedback: *(attach separate document)*

Figure 2.3 Training



that health and safety are not only in the employee's own best interest, but also in that of the company.

Training in quality and workmanship is particularly important. All employees must know what to do and how to do it as part of their training and certification for all operations. Employees must know at all times what is expected of them, how to operate equipment, how to follow setup parameters, how to conduct routine maintenance, and when to shut down an operation (for example, if the unit is out of calibration or the product is not within specifications).

It is important that the organization either contract for external training (which is sometimes more cost-effective) or develop a group of in-house trainers composed of personnel with the appropriate skills, knowledge, qualification, and experience needed to design and conduct training that meets the required needs. Whichever method is used, evaluation of training effectiveness is a necessary follow-up step so as to verify that the training has been understood, learned, and properly applied.

Based on the skill requirements of specific job categories, training and review shall be carried out on a regular basis to ensure familiarity with evolving procedures. Training will be relevant to job function, as well as to general company orientation, safety, and quality training. Company orientation and on-the-job safety training are required of all new employees. Safety training should be repeated periodically. Although safety training is not an ISO requirement, it is in every company's interest and is highly recommended.

Employees shall receive quality training within six months of starting with the company, or within six months after the quality training is instituted. Skills training, where applicable, shall take place before allowing an employee to begin work on an assigned job. Additional training may be required when indicated in audits of job performance, product quality, service quality, corrective action reviews, and preventive action reviews or other appropriate indicators. Employees shall also receive training on any new equipment before beginning work with the new equipment.

### **2.3.3 Infrastructure (Clause 6.3)**

This clause is also new for the ISO 9001:2000. Although the concept was implicit in the previous issue of the standard, this requirement has been highlighted because of its great importance in obtaining the desired results. Infrastructure refers to physical facilities, such as buildings, offices, warehouse, equipment, and instruments, which are essential to provide the service or product to the customer. This also includes office space, telephones, and support equipment. Without the required infrastructure, product quality will suffer, and work will not be performed as anticipated.



Infrastructure requirements are evaluated based on the availability of necessary resources that are required for the fulfillment of the customer needs. Some examples of infrastructure needs are an air-conditioned room to store materials, or a clean room for the assembly of a complex and sensitive product. Other infrastructure needs can be computer systems to maintain records or to control purchase orders and the statistical control of various parameters.

Management usually evaluates these needs during the management review or during quality evaluation of the system. They are normally subject to economic analysis and may require the renting or leasing of equipment or the acquisition of new facilities or equipment.

### **2.3.4 Work Environment (Clause 6.4)**

The work environment can be a critical factor in achieving adequate quality results. Several jobs require special protective equipment; others require ample cooling, because of the heat generated by a furnace or a special high-temperature device. These problems may affect the quality of the product, or they may affect the performance of the operator of the equipment and sometimes the equipment calibration.

This new ISO 9001:2000 clause could be erroneously viewed as solely focused on employee health and safety. Although employee health and safety are major concerns to be considered in any company, the intent of clause 6.4 is to prevent any environmental conditions that could curtail or diminish the capability of personnel or equipment to perform the function at the desired quality level.

The most important work environment considerations are usually the following:

- \* Heat.
- \* Noise.
- \* Light.
- \* Hygiene.
- \* Humidity.
- \* Vibration.
- \* Pollution.
- \* Airflow.
- \* Cleanliness.
- \* Ergonomic considerations.

The facility requirements should be identified and personnel trained to work in those areas and monitor requirements and record compliance. Compliance in the work environment should be a subject for the management review in order to assess the need for



improvements. The requirements are usually evaluated through the data obtained from the corrective and preventive action reviews.



## Homework Assignment—Day Two

YOUR NAME: \_\_\_\_\_

YOUR COMPANY: \_\_\_\_\_

Early in the process of designing for the first time or setting out to improve your company's quality system, it will be important to engage people throughout the company in taking stock of what policies, procedures, and attitudes toward quality currently exist. Today's homework assignment gets you started with this assessment process.

What quality goals and policies are currently in place in your company? How were they set and by whom? How often are they reviewed? How are they communicated throughout the company?

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On the back of this page or on a separate piece of paper, draw an organizational chart for your company. Include all its divisions, managers, and employees, and make it clear who reports to whom.

Does your company currently have a management representative responsible for the achievement of quality goals?

Yes

No

**(If yes)** What specific responsibilities and authority does this person have? Based on what you've learned at this training, do you

think this role is adequately defined and implemented in your company, or do you think it needs to be improved? (Be specific)

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**(If no)** Who in the company should be assigned to carry out this function and why? What specific steps need to be taken by what parties to formalize the appointment of someone to this position in the near future?

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What specific steps need to be taken and by whom in your company to ensure that every employee is clear about his or her role and responsibility in quality control? What kinds of resistance would you expect? How might such resistance be effectively overcome?

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Refer back to the flow chart you developed as part of your Day One Homework Assignment. Put a checkmark beside those steps for which you know a description of the operation or work instructions already exist and are adequate, or a plus (+) for where they exist but need improvement. Put a question mark (?) beside those where you are uncertain, along with the name of the person(s) who would know. Put an "x" next to those steps where you are certain no descriptions or instructions exist.

# Chapter 3. ISO 9001:2000 Standard—Clause 7



## 3.1 Product Realization (Clause 7)

This clause is one of the most important in the standard. It combines several requirements of the previous issue of the standard. The fundamental reason for the existence of the organization is to deliver a service or product. Therefore, product or service realization is the organization's most important business.

The organization shall demonstrate that it knows what it takes to make a product and therefore should plan all the activities required to realize the process from beginning to end. This clause dwells on the fundamental plan and execution requirements that will assist your company in assuring that your product or service conforms to all requirements, satisfies customer needs, and achieves improvements in the delivery process.

The basic concept of the ISO 9001:2000 is to establish a quality system through a process approach. Various steps are linked one to the next until product or service delivery is accomplished. In this sequence, each step can be considered to be performing an addition to the value of the product. Also, each step has an input and an output, a supplier, and a customer in a different terminology. Therefore, on each step we can have a measure of effectiveness and a value-added measurement. The quality of each step must be evaluated and improved to allow progress in the goal of customer satisfaction.

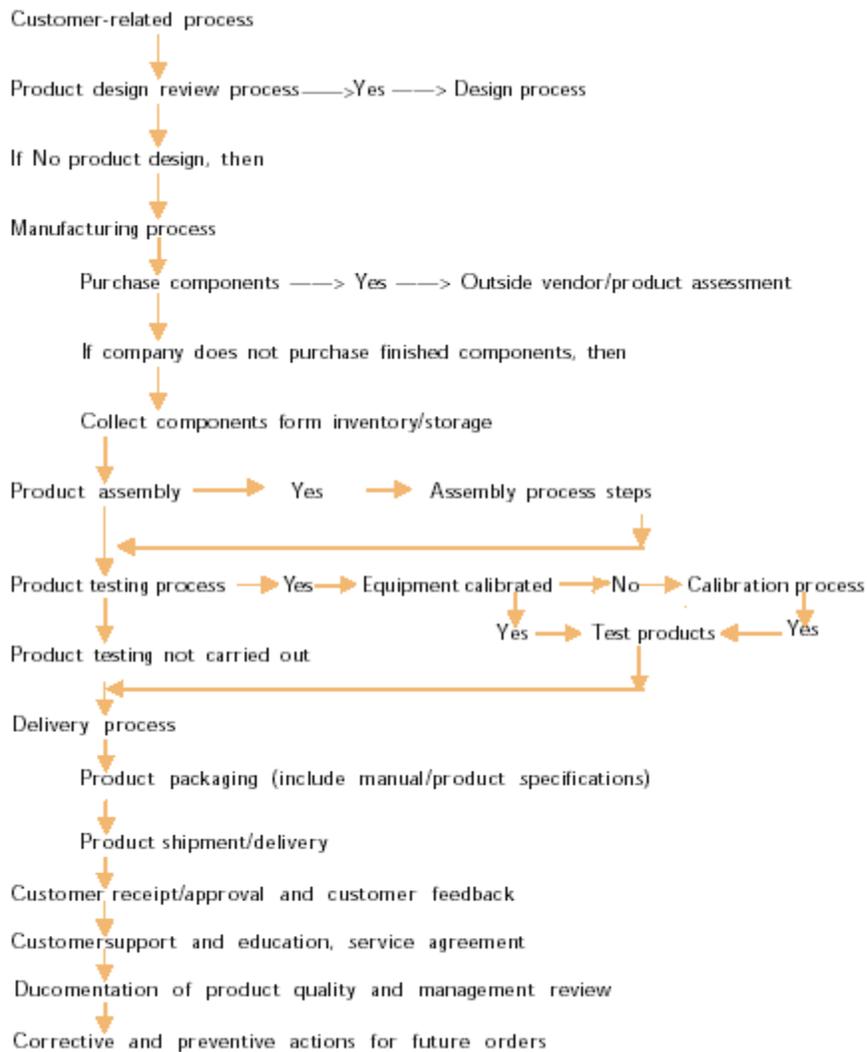
### 3.1.1 Planning of Product Realization (Clause 7.1)

The main objective of this clause is to define what is required to make the product, how this is going to be achieved, what documented procedures and processes are needed, and what resources are available and required in this regard. These objectives are usually known. Your organization must detail a plan to achieve them and document the process. Validation and verification of the activities must be recorded and the results stored.

The first task for your organization is to demonstrate that it knows what is required in the total process, from the initial customer requirement to the delivery and customer feedback.

These processes were presented in clause 4.1 in a simple flow diagram (form 4.1-1). For example, if you are manufacturing solar cells, the silicon wafers have to be within a certain range in resistivity, and the crystal should be of a specific type, monocrystalline "p" type or polycrystalline. All this information should be described in a purchasing document. The chemicals must

### Form 4.1-1 Work Flow Diagram



be of a certain quality. The process shall be performed in certain equipment with defined parameters, and so on. This list is part of the quality plan.

The resultant product should be able to meet certain specifications, reliability, and the like, as defined by the standards in use for that product with the additional customer requirements for the specific project.

This listing of documentation, specifications, and parameters are compiled into a quality plan that demonstrates that the product is made in such a way as to meet all needs. A typical example of a quality plan has been included in appendix 2.

The plan should also include which records are needed, and it shall be saved to demonstrate conformance, if requested by a customer or an inspector.

The ISO has issued Document ISO 10005, which has valuable guidelines for the creation of quality plans.

The quality plan must further define the quality goals and the objectives and requirements to be met by the product. Usually the organization has all the resources at hand to meet its quality plan. If there is a gap in either the equipment or the expertise of the human resources, the quality plan must contain a plan of action to fill this gap. The management of the organization must be familiar with the contents of the quality plan, its needs, and procedures in order to create the goals and objectives of the product realization process.

It is important that documentation is always kept up to date. All operators need to know the location of documentation for each process and the type of records they should maintain. Each employee could sign a form, as is attached in form 7.1-2, to demonstrate his or her awareness of the requirements for the job.



### Form 7.1-1 Sample Documentation of the Steps in the Work Flow Process

- Customer order
- Product design
  - Design process steps
  - Final design quality assurance approval
- Purchase components
  - Outside vendor/product assessment
- Collect components from inventory/storage
- Manufacture/assembly process steps
- Product testing
  - Equipment calibrated
  - Calibration process
  - Test products
- Product packaging
- Product shipment/delivery
- Customer receipt/approval
- Customer education
- Service agreement
- Documentation of product quality

Marketing and sales	Manufacturing supervisor	Customer
Date	Date	Date

## 3.2 Customer-Related Processes (Clause 7.2)

The organization shall have a procedure for contract review and documentation, in order to assure that all commitments are adequately defined in writing and that the organization has the capability to deliver and meet all the contractual requirements. Many contracts require complex systems that need new design or assembly configuration. Therefore, a project review, schedule, and documentation are necessary to fully evaluate the contract.

The contract review should cover all aspects of the contract—the product to be delivered, performance specifications, product design (if necessary), design reviews, terms of customer acceptance, shipping schedule, method of shipment, payment schedule, installation instructions, training, and anticipated reliability, service, and warranty.

### 3.2.1 Determination of Requirements Related to the Product (Clause 7.2.1)

One of the most common problems encountered with contracts is a misunderstanding of what was ordered or a misinterpretation of the customer expectations. A good communication and clarification process with the customer is essential for the good execution of the contract. A complete record of all communications is also very valuable, in case of conflict. The person taking an order over a telephone should read back what has been written to confirm a good understanding of all the details of the order. All contacts, discussions, memos, and correspondence should be properly documented and filed. If the order is received electronically, a fax acceptance or an electronic record of the requirement shall be sent to the customer to verify the customer need.

The new ISO 9001:2000 has explicitly incorporated four different types of requirements:



#### Form 7.1-2 Instructions for the Use of the Quality System Procedures

The use of quality system procedures involves an understanding of the specific quality standards, through training and familiarizing employees with the concepts of quality systems and the specific procedures and documentation requirements of each step in the process for which an employee is responsible.

#### Instructions on Where to Find Information on the Quality Procedures

Information on where to find information on the quality procedures is available in *(location)* of this document. In addition, information is available from *(name of the management representative)*, and additional documents are on file in the office of the *(name of office)*. Finally, information on specific quality procedures is available at the applicable workstations.

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Operator

Date

- \* Customer-specified requirements.
- \* Necessary requirements, which are not specifically stated, but are understood for the application.
- \* Regulatory requirements.
- \* Additional requirements characteristic of the organization.

Any modifications or changes between the contract and the original tender (or bid) documents should be clarified and recorded in writing. All parties affected by the changes shall be notified in writing, and they should approve the changes in writing, if called for in the contract. If the contract is changed in scope or content at any time, a written record should be made and all the supplier's departments involved in the contract should be notified in writing to avoid confusion that could lead to an erroneous delivery of a product.

For example, after an order for a system is received, a layout and a drawing for the configuration are commonly submitted to the customer for approval. These might not be acceptable, and changes in configuration may be requested at that time. Because the manufacturing and ordering of components could be taking place simultaneously, prompt and accurate feedback is needed to avoid purchase of the wrong components or assemblies and subsequent delay of delivery. Communications and rapid feedback are essential for proper workflow and delivery.

### **3.2.2 Review of Requirements Related to the Product (Clause 7.2.2)**

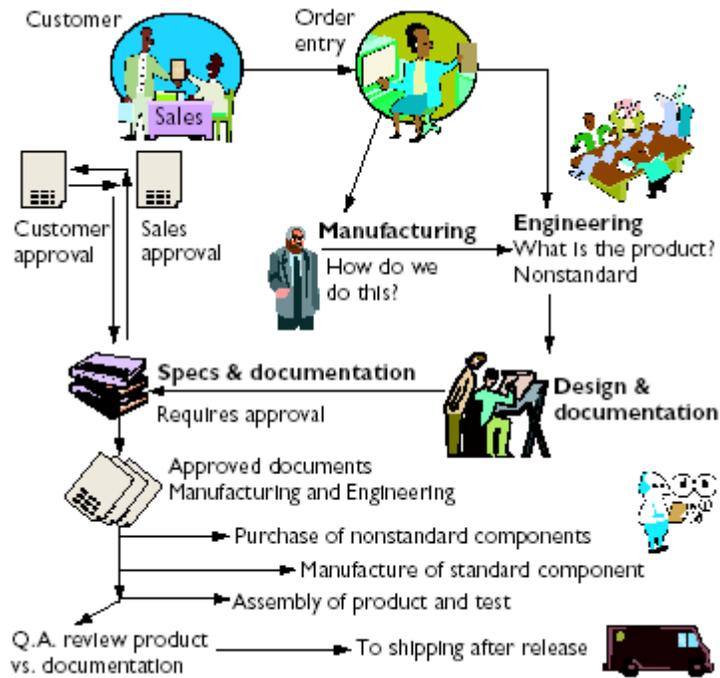
Product requirements have been discussed above. It is very important that your organization review the requirements against the performance of its products or services. In the case of a distributor or a contract for off-the-shelf items, this is a simple review that some experienced personnel can conduct. In the case of a small company, the manager can make a quick decision. The problem starts when the product is part of a system that has to operate in diverse conditions, sometimes unknown. In such a case, it is important to review the requirements with the engineering or development personnel to avoid mistakes.

A documented procedure is the most convenient and expeditious way to prevent these situations. The acceptance authority should be clarified and the customer requirements meticulously analyzed. An example of the procedure is noted in figure 3.1.

Important aspects of this clause are first to confirm the requirements (product, delivery, and installation, if needed), second to review the requirements against the product and capability of your organization and make a plan to fill the gaps if any are found, and third to provide the required resources. If your organization does not have these resources or the product is a state-of-the-art



**Figure 3.1 Nonstandard Products Purchase Order Procedure**



product, the customer and the key people in your company must know the risks associated with the order.

### **3.2.3 Customer Communication (Clause 7.2.3)**

To satisfy the customer, it is imperative to understand all the customer requests and to pass them on to those in charge of delivering the product or service. After delivery, follow-up with the customer is important to determine customer satisfaction and acceptance of the product. This follow-up exercise applies not only to product quality, but also to delivery, invoicing, details of the instructions, and the like.

A file for the contract should be established. All paperwork, quality records, and documentation should be filed and kept for future reference or use. Many contracts specify a minimum period during which the supplier must keep records proving that the quality process was fulfilled during the execution of the contract. All contract documentation or orders are quality records and should be handled according to the ISO requirements in clause 4.2.4 (see form 7.2.1-1). The retention of records is very important for future reviews and verification of compliance. An established record-keeping cycle is recommended to avoid storing records forever. The storage time should be pre-established as part of your Quality Manual. If your customer or contract requires longer storage, this should be specified when the contract or order is received and approved.

## **3.3 Design and Development (Clause 7.3)**

The design and development process applies only to companies that provide design and development services or that design new products. The intent of the process is to provide a documented procedure that will explain the organization of the design effort. It should not be very elaborate, or limit or restrict the creativity and ingenuity of the designer.

### **3.3.1 Design and Development Planning (Clause 7.3.1)**

The process starts by defining the intent of the design. This includes identifying any specifications for performance, appearance, and reliability, along with any changes or new developments in shape or form. Once the intent is defined, the company shall identify the resources needed to achieve the design goal, assign qualified personnel, and commit resources. This will generate a design plan and schedule that should be reviewed periodically to monitor progress, address difficulties, or add new requirements, as needed. The plan should outline the interfaces between the design and manufacturing functions and develop a



**Form 7.2.1-1 Contract Order, Review, Verification, and Validation**

Customer: \_\_\_\_\_

Customer contact information (phone, etc.) \_\_\_\_\_

Product name: \_\_\_\_\_

Unique product identification: \_\_\_\_\_

Order date: \_\_\_\_\_

Due/delivery date: \_\_\_\_\_

Delivery requirements/pickup requirements: \_\_\_\_\_

Special requests: \_\_\_\_\_

Quoted cost: \_\_\_\_\_

Quoted constraints: \_\_\_\_\_

Contract review: \_\_\_\_\_

Employee/group assigned work: \_\_\_\_\_

Manager responsible: \_\_\_\_\_

Initial product specification review Yes/No \_\_\_\_\_ Date

    Requirements Yes/No \_\_\_\_\_ Date

    Estimated cost Yes/No \_\_\_\_\_ Date

    Delivery schedule Yes/No \_\_\_\_\_ Date

    Special requirements Yes/No \_\_\_\_\_ Date

    Contact person(s) Yes/No \_\_\_\_\_ Date

Design/engineering meeting (if appropriate) Yes/No \_\_\_\_\_ Date

Initial product design/progress review (if appropriate) Yes/No \_\_\_\_\_ Date

Interim product design/progress review (if appropriate) Yes/No \_\_\_\_\_ Date

Prototype review (if appropriate) Yes/No \_\_\_\_\_ Date

Final design review Yes/No \_\_\_\_\_ Date

Order/contract modifications: \_\_\_\_\_

phased-in production process, so that there is a smooth transition between the functions.

A well-defined goal for performance and reliability must be set-up at the beginning of the design effort. Regular progress reviews help the team involved in the design focus on problem areas, seek support from other areas of the company, and keep the customer aware of any difficulties or delays in the completion of the design. Effective communications are indispensable for an effective design plan. The documentation of all calculations or any appropriate data is important for the contracted design, as well as for input to any future design effort. Flow charts and Gantt or Pert charts are effective visual aids and graphical tools that show the status and progress of the design effort and the indicators of proper or defective planning.

The elements of the suggested process for establishing the desired control are given in forms 7.3.1-1 and 7.3.1-2:

1. The aim of the design is to
  - Define clearly the desired outcome.
  - Establish a simple flow chart of how to get there.
  - Assign responsibility for various steps.
  - Establish design reviews, and verification and validation activities.

### Form 7.3.1-1 Form for Quality Control of Design Procedures

#### Description of the Company's Design Process

\_\_\_\_\_ Customer order  
\_\_\_\_\_ Customer requirements  
\_\_\_\_\_ Purchasing specifications for material/component  
\_\_\_\_\_ Assess cost and price  
\_\_\_\_\_ Confirmation of order, requirements, and price  
\_\_\_\_\_ Assignment to appropriate staff  
\_\_\_\_\_ Document requirements and schedule with staff  
\_\_\_\_\_ Preliminary design  
\_\_\_\_\_ Design review  
\_\_\_\_\_ Review design with customer  
\_\_\_\_\_ Finalize design  
\_\_\_\_\_ Final design review  
\_\_\_\_\_ Customer review  
\_\_\_\_\_ Approve design



## Form 7.3.1-2 Design Review, Verification, and Validation Form

Product name: \_\_\_\_\_

Unique product identification: \_\_\_\_\_

\_\_\_\_\_

Product customer: \_\_\_\_\_

Product design requested by: \_\_\_\_\_

Date of product design initial request: \_\_\_\_\_

Date product design expected: \_\_\_\_\_

Manager responsible for product design: \_\_\_\_\_

Product design assigned to: \_\_\_\_\_

Date design assigned to staff: \_\_\_\_\_

Date/initials

- Initial product specification review \_\_\_\_\_
  - Requirements \_\_\_\_\_
  - Estimated cost \_\_\_\_\_
  - Delivery schedule \_\_\_\_\_
  - Special requirements \_\_\_\_\_
  - Contact person(s) \_\_\_\_\_
- Initial product design meeting \_\_\_\_\_
- Design/engineering meeting \_\_\_\_\_
- Initial product design/progress review \_\_\_\_\_
- Interim product design/progress review \_\_\_\_\_
- Prototype review \_\_\_\_\_
- Final design review \_\_\_\_\_

Ideally it will be possible to compare the new design to previous designs as the first step in identifying the changes required. In this case, the calculation of the new design can be derived from a basic known product and its performance, and can simply be expanded or changed to achieve the new design. The creation of a schedule and a Gantt or milestone chart are very helpful for planning and resource issues.

2. Procedures and responsibilities include the following:

- ❑ Assigning technical support requirements.
- ❑ Determining other related efforts and support.
- ❑ Specifying the needed documentation and purchasing support.
- ❑ Defining communication with and review by all related parties.

The responsibility for carrying out the design effort must be made clear. All resource needs should be anticipated and addressed, in order to allow for a smooth project schedule. It is likely that other departments, such as manufacturing, purchasing, and sales and marketing, will be involved in the outcome of the design. Subcontractors and the customer may also be involved. All concerned parties should participate, as appropriate, throughout the process. Their support at critical times may be indispensable to timely and satisfactory completion of the design process. Regardless of the nature and extent of their participation, however, each party should always be kept aware of the status of the design.

### **3.3.2 Design and Development Inputs (Clause 7.3.2)**

Design requirements are sometimes confusing or not well defined. Communications are of prime importance to avoid an effort that could lead to an unwanted product. A clear outline of needs calls for links among sales, the customer, and the designer. There should be no conflicting goals. Common examples of nonstated requirements are high-voltage performance, operating environment, corrosion resistance, and reliability test conditions.

Information requirements:

- ✱ Review and clarify all input requirements with customers and marketing.
- ✱ Review all statutory and regulatory requirements.
- ✱ Take into consideration all contract reviews and needs.
- ✱ Clarify conflicting requirements with customer or marketing needs.
- ✱ Review lists of "nonstated requirements," such as legal requirements, patents, safety, industry practice, and standards.



- ✦ Use all previous design and development data and pertinent requirements of existing products.

### **3.3.3 Design and Development Outputs (Clause 7.3.3)**

Once the design is completed, a performance test is calculated, based on the parameters that have been changed or a prototype is commonly made. It is important to evaluate whether the new design introduces any negative environmental effects that would violate regulatory norms. For example, the new design may require use of a different chemical that has special disposal requirements or a new metal that emits gases as it is processed. Also, problems can be associated with handling or storage, as in the case of batteries that may be in storage for a long time and that may require recharging or specific storage conditions. Some materials for assembly have limited shelf life and can only be stored for a limited amount of time under certain conditions of humidity and temperature. All these details must be part of the design effort, including a plan for the disposal of the product at the end of its life (for example, batteries).

Design output (outcome):

- ✦ Review the desired outcome of the design effort.
- ✦ Verify that the design meets all the intended requirements of the input.
- ✦ Consider how the design is going to be used and any pertinent regulations.
- ✦ Document all aspects of the design and its components or the raw materials needed to provide the service or produce.
- ✦ Review the acceptance criteria of the finished product and also of the materials and subassemblies.
- ✦ Identify factors that could be critical to customer satisfaction during operation or use (such as storage, handling, maintenance, or disposal).
- ✦ Demonstrate that the product will not perform unwanted functions or have unwanted failures.

### **3.3.4 Design and Development Review (Clause 7.3.4)**

The design review is a vital instrument for the proper outcome of the design. Sometimes, if the design is very small, initial and final reviews are all that is required. However, for a new design effort or for an elaborate product or service, multiple reviews involving all the departments, such as sales, marketing, and manufacturing, in addition to engineering and service, are generally involved and can provide a great benefit. These general reviews are highly recommended. These reviews could include the customer and some

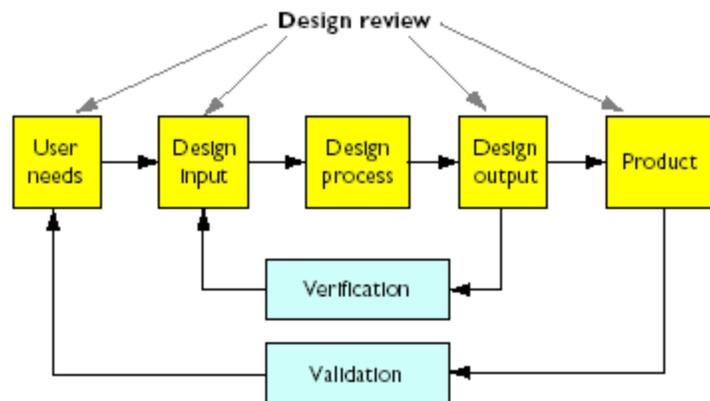


outside contractors, as required. Documentation of any changes is a critical item to be controlled. The design review process is shown in figure 3.2.

Design review details:

- ✦ Establish intermediate reviews to measure progress.
- ✦ Allow a review of the plan, updating of the schedule, and use of additional resources, if needed. New people can be assigned to the project.
- ✦ Review all needs, internal and external, to assure success.
- ✦ Seek all involved departments' inputs into the discussion, that is, marketing, manufacturing, management, engineering, maintenance, service, installers, and so forth.
- ✦ Check scheduling of purchase of components or subassemblies and setup of inventory requirements.
- ✦ Enable customer or contractor participation.
- ✦ Assure that the product meets all specified requirements.
- ✦ Secure suppliers' or subcontractors' assurances that their products meet requirements.
- ✦ Reduce cost of fabrication by involving proper manufacturing people.
- ✦ Assure a timely release of new products.
- ✦ Provides records and documentation of all steps and decisions. Allow follow-up of action items, and list all the issues and their solutions.
- ✦ Allow greater customer satisfaction through participation in the design effort.

Figure 3.2 Design Review



### 3.3.5 Design and Development Verification (Clause 7.3.5)

The verification process should be defined in the Quality Manual. Verification of the design typically takes place after the process is defined and the design is completed or initial units are made. It is a valuable step for producing a reliable product. Several tests are usually needed to confirm that the design meets all the desired parameters and specifications, such as the international standards or regulatory functions.

**Design verification:**

- ✱ Use an established verification plan to confirm that the design meets the outcome desired.
- ✱ Perform alternative comparisons to existing products or calculations based on available products.
- ✱ Undertake demonstrations and tests according to existing standards.
- ✱ Review the status of documentation and its completeness.
- ✱ Involve the customer in the evaluation of results.

### 3.3.6 Design and Development Validation (Clause 7.3.6)

The ideal reliability test is usually a life test under normal use. In the case of PV products that have a life expectancy of 10–25 years, the use of accelerated tests have been well established, and they provide stress in the designs similar to those of actual life. These tests should be repeated as many times as required for practical purposes.

#### Design validation:

- ✱ Follows verification, after completion of a finished product.
- ✱ Usually requires a functional test under normal operating (field) conditions.
- ✱ Should involve customer or intended user.
- ✱ Must meet the environmental and reliability goals for the product and be tested under established standard test conditions.

### 3.3.7 Design and Development Changes (Clause 7.3.7)

Records and documentation, as part of the product design function, are valuable tools in the event of a redesign process. Products are redesigned for varying reasons. The verification and validation of the product should be made when changes are implemented to understand the effect of the changes in the design. This effort is greatly simplified if good records have been kept during the initial design process.

#### Future design modifications and changes:

- ✱ Products usually require changes and modifications during their market life.
- ✱ All changes should be recorded, documented, and **approved** by authorized management representative.
- ✱ The quality system must have formal requirements for documentation and control of changes.
- ✱ Design changes may require design review, verification, and validation.
- ✱ Changes may affect contracts or customers who therefore should be notified prior to implementation.



### 3.3.8 Procedures to Control and Verify the Design of Products

For each design process step above, the parties involved (for example, manager, designer, and customer) should keep a record of all the appropriate comments and, after reviewing the new changes, initial and date the documented change. All documentation for each product design should be kept together in a dedicated file. A simple form listing all the steps in form 7.3.1-1 can be used. It should be modified, as necessary, for your company's process, with the appropriate space for comments, as a checklist form.

Very often, a company may select a number of managers from various departments, including marketing, manufacturing, design engineering, process engineering, quality assurance, and purchasing to create a product review board. This board signs off on any new product or on any products where changes in the design of existing products were made. The review board is useful for making sure that all involved parties are aware of any changes before they are implemented. Form 7.3.1-2 can be used to document the stages in the design review, verification, and validation process.

## Case Study No. 1

### CONTRACT CONTROL

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The contract review process should be performed with extensive analysis of the requirements of a contract and the customer needs prior to acceptance.

Sometimes in the process of doing business, contracts are signed either to gain a customer or to enter into a new market. Every contract should be properly analyzed prior to acceptance with the aim of fully understanding the risks entailed and the investments required.

For example, a PV system manufacturer was determined to win a contract to build a PV-powered irrigation system in Southern Egypt. This was a great opportunity to establish an oasis in the middle of a desert. A group of managers worked very hard for weeks to develop the contract proposal. Their efforts were rewarded when they did, indeed, win the contract.

However, it wasn't long after starting work on the project that the manufacturer discovered a major problem. The contract called for the delivery and installation of a water tank as part of the irrigation system. The customer anticipated getting a steel water tank sitting on a pad of concrete. It turned out that the managers had not understood the formidable engineering challenge of installing a heavy tank in a remote region where there were no accessible roads. It soon became clear that the tank would cost more than the company had estimated for the entire cost of the project. The management failure to consult adequately with the company's engineers as part of the process of drafting the contract had created a seemingly inescapable dilemma.



As it turned out, after several negotiations and reviews, the manufacturer was able to avoid going deeply into the red by a stroke of luck. This was possible only because of an equally lax contract control on the customer's part. Although the customer had wanted a metal water tank on a concrete base, the contract had not specified what the tank needed to be made of. This gave the supplier the opening to utilize an easy-to-transport plastic bladder tank that served the performance specifications of the irrigation system and honored the letter of the contract at a substantially reduced cost.

Although this case study had a happy ending, the outcome could easily have been disastrous. The situation illustrates how the absence of formal contract review and procedures can easily lead to costly oversights and mistakes. It also illustrates how detailed contract negotiation with the customer can create cost-saving opportunities for an alert company.

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### 3.4 Purchasing (Clause 7.4)

Clause 7.4 of ISO 9001:2000 requires a documented procedure to make sure that any products purchased from vendors, retailers, or distributors conform to desired specifications and functions, especially those that affect the quality of the product. The intent is to assure that your company gets what it needs, wants, and expects without incurring costly errors or delays.

#### 3.4.1 Purchasing Process (Clause 7.4.1)

It is important that the purchase order for any product describe in detail your company's requirements, including the type, class, grade, and other pertinent information. When purchasing materials, costly errors can be avoided by specifying technical data and the materials' intended use.

The vendor should be required to certify that the product meets its specific performance rating, either by identification of a catalogue number (standard product) or by providing evidence of testing prior to delivery. Your company should identify the title, description, or quality system standard to be applied. If the purchased product or material is of a critical nature for the finished product, you should remember that the responsibility for the quality of the material that you purchased is yours. You have to assure that what you receive is what you need.

All purchasing transactions or subsequent changes should be presented in writing. Even when agreement is reached over the telephone, proper documentation of the changes or agreements should be written up and kept for the records. All documents should contain all the relevant details of the items purchased, including part numbers, special requirements, or markings needed to handle the product. Provisions should be made for settlement of any quality disputes.



A performance record should be kept on each subcontractor that documents product quality, delivery performance, and subcontractor reliability in supplying quality information.

In some cases, it is advisable for your company to visit the vendor's production site, possibly accompanied by the customer. These visits will help ensure timely deliveries and proper quality. Site visit requirements should be part of the purchase document and coordinated with the subcontractor personnel.

### **3.4.1.1 Evaluation of Suppliers**

In order to assure that suppliers are acceptable, you must establish and document the answers to the following questions regarding each of your critical vendors (form 7.4.1-1):

1. *How reliable is the vendor?*  
Many suppliers or vendors overlook tolerances or quality requirements. You must establish with the vendor the specification of the products or materials that you are purchasing and make the vendor's managers aware of the impact on your product that a missed parameter can cause.
2. *Can they deliver what you want?*  
The vendor should have the equipment and the capability to deliver the products without significant trouble. Otherwise, your manufacturing schedule can be at risk and, by extension, your delivery to the customer. A plant inspection should be made to assure that the supplier or vendor has adequate capability.
3. *Is their quality acceptable? Do they have a quality system?*  
Ideally, the vendor will have ISO 9000 certification for its manufacturing plant. This will assure you that it has the proper quality system in place and that it will work together with you to maintain the required quality level. If the vendor does not have such certification, you must explain in painstaking detail what they must do to guarantee that the product they deliver to you is adequately tested.
4. *Is the quoted delivery and price adequate?*  
Price and delivery considerations are always important, but they should not replace quality considerations as the primary guideline for a purchase. You must stress that poor quality at a low price results in higher cost because of the increased amount of nonconforming product.
5. *Does the vendor have a good reputation, and have you done business before?*  
Previously known suppliers are usually preferred vendors. You should establish a list of preferred vendors for each of the materials or products purchased, based on delivery



**Form 7.4.1-1 Form for Qualifying Outside Vendors/Products and Tracking and Verification**

**Name of Vendor** \_\_\_\_\_

**1) Is Vendor Certified to ISO 9000 Quality Standards, or Equivalent?**

Yes

No

**2) Previously Purchased Products from This Vendor?**

Yes (if Yes, answer Questions 3 and 4)

No (if No, skip to Question 5)

**3) Experience with Previously Purchased Products**

Parts previously supplied: \_\_\_\_\_

Quantities of parts previously supplied: \_\_\_\_\_

Audits previously performed: \_\_\_\_\_

Failure rate and acceptance testing: \_\_\_\_\_

**4) Comments on Business Practices of Vendor** (service, delivery, warranty, etc.)

**5) Information Gathered from Other Organizations That Have Used This Vendor**

**6) References on Vendor** (Better Business Bureau, etc.)

**7) Documentation from Vendor** (warranty, service agreement, references, product specifications, etc.)

experience. Timeliness and quality should be measured and recorded for future buys.

6. *Does the vendor have adequate equipment, resources, and personnel?*  
Adequacy of equipment is imperative for holding the desired tolerances. For example, if you buy a frame, the subcontractor should have adequate machine tools to maintain squareness during the assembly process. Trained personnel make it easier to obtain good products. For example, in the case of installation services, a trained technician can avoid costly mistakes in the installation of the battery, regulator, and the release of the system after checkout.
7. *Is the product off the shelf? Does it have a shelf life? How well does the supplier handle the product?*

Many products are common to several suppliers of different industries. A distributor can handle these products, and they may be on their shelf for a long time. This is significant when a product has a limited shelf life. For example, if your product needs a primer, be aware that most primers have a limited shelf life. If you use a battery, keep in mind that most batteries self-discharge and should be maintained or delivered dry to avoid plate corrosion. Also, many of the silver pastes used for printing cell contacts have limited life and require specific temperatures for storage. Failure of a vendor to handle products adequately can result in future failures for your products.

#### **3.4.1.2 Inventory Control**

The purchase of materials or components for manufacturing is a very important matter, not only with regard to the quality of the materials, but also with regard to delivery schedule and the service received from vendors.

Maintaining a basic inventory of standard materials, parts, and components is advisable to be able to respond to nonscheduled demands. Usually the level of inventory is strongly dependent on the lead times required and the turnover rates for the product. In general, an on-time delivery system from the vendors or subcontractors is favored over maintaining costly in-house inventories of materials.

The cost of inventory is a significant investment for many industries and can be particularly high for a small manufacturing company. Therefore, inventory should be kept to a minimum without unduly affecting the day-to-day operations. Timely delivery fulfillment is critical. Late or irregular delivery of materials or subassemblies can prove very expensive for your company because they force you to carry a higher inventory level.



### **3.4.1.3 Vendor Evaluation**

Records of the performance of all vendors shall be maintained to develop a list of approved suppliers. These suppliers are selected by the performance in the acceptability of their products and the timely fulfillment of the delivery, as described above. These records are part of the documentation requirements by the inspectors for the ISO evaluation of your system.

### **3.4.2 Purchasing Information (Clause 7.4.2)**

The process of purchasing depends strongly on the importance of the materials involved. If the material is an off the shelf item and it is not used for a critical assembly or application, the description should be simple and would require only a catalogue number. Approval procedures for purchase usually consist of a checkmark or some simple note or signature.

This clause focuses instead on the purchase of critical parts. They require a very detailed description of what is required, and written information that leaves no doubt of what is needed. The information shall list all pertinent details and clearly state how the material or product will be accepted. This also includes the description of the acceptance process at your plant or at the vendor's plant. The purchase documents should be very specific as to details of inspection accuracy to satisfy your needs.

An inadequate documentation process is the most frequent reason for failure or rejection of materials or worse. If the product is not caught at the receiving platform, it will result in defective products and warranty claims in the future, thereby creating a liability.

The purchasing documentation is an important element in the evaluation of the quality process. Again, the responsibility for the adequate quality of materials used is yours.

All purchase orders for critical parts are to be approved by various managers prior to release. Care shall be taken that the documentation is kept current and that the parts ordered have not been changed, as was discussed in the design change section of the manual. Records of the purchase orders for materials are maintained and performance of the vendors analyzed frequently to promote improvement in the process.

### **3.4.3 Verification of Purchased Product (Clause 7.4.3)**

This step is very important to ensure and maintain quality control in your company. The type of inspection or verification depends on the nature of the material received and the record of its supplier. The intent is to assure that all materials received are in conformity with requirements.



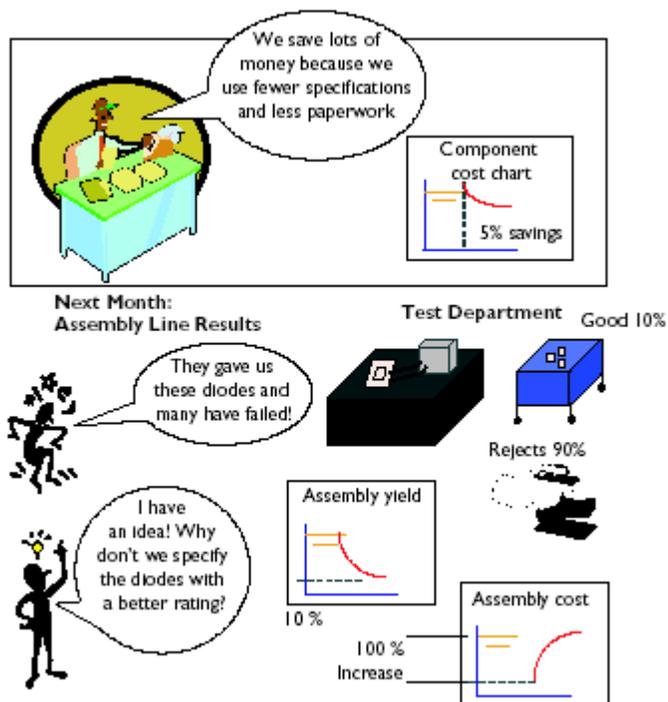
In the case of office supplies, a very simple procedure can verify that the product is what was ordered. In the case of manufacturing materials, it is important to follow the specific instructions of the purchase order and its level of inspection and verification. The activities shall be planned in advance. They could be of a variety of levels, such as the following:

- ✱ Conventional sampling techniques.
- ✱ One hundred percent inspection and measurement.
- ✱ Certification of material quality by the supplier.
- ✱ Verification of operating quality at the supplier's facility.
- ✱ Hiring an independent inspector.
- ✱ A combination of all these strategies.

The end result of these efforts should be objective evidence that the requirements are being met (see figure 3.3).

Products received from a vendor could require tracking after receipt in order to verify quality, quantity, or performance. These data should be part of vendor or subcontractor records and should help in future purchases of a similar product. This is especially important for suppliers of complete systems that buy most components of the system in a completed assembly, because there are limited ways to verify actual performance until the components are integrated in the final system. A failure at this point could cause major delays or expense, resulting in the need to disassemble all the other components in the factory or at the field installation.

**Figure 3.3 Why Use Purchasing Specifications?**



## Case Study No. 2

### PURCHASING CONTROL OF SUBCONTRACTOR QUALIFICATIONS

Design process controls, including substantial testing of new designs, are essential to ensuring that products will meet customer expectations for performance and reliability. However, product quality can also be greatly affected by post-design factors. For example, lax implementation methods or sloppy workmanship can jeopardize the outcome of the assembly process. Likewise, procedures for procuring components or assemblies can have a major impact on the quality of the final product.

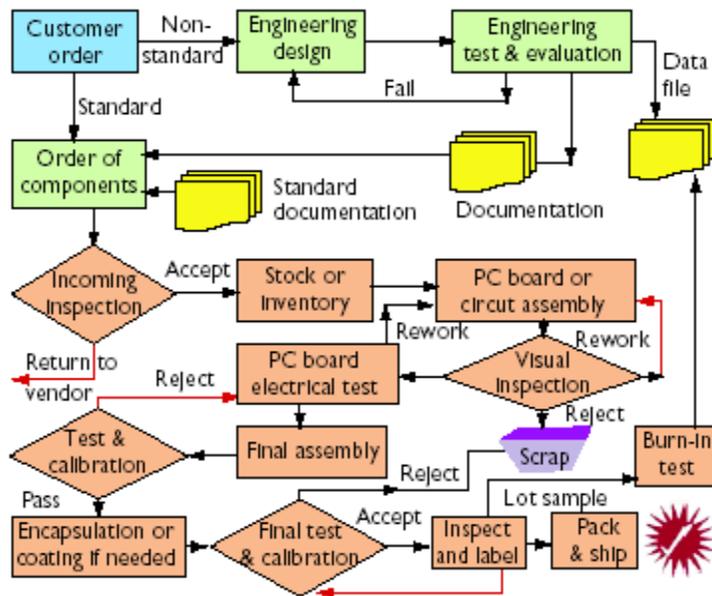
In fact, the ultimate success or defeat of a company's quality efforts can hinge on the proper selection and qualification of its vendors' quality systems. As the following example shows, the acquisition of components or, in the case of solar cells, materials for use in the manufacturing process are situations in which vendor performance can become a critical issue (see figure 3.4).

A new controller was designed for solar home systems with a maximum capacity of 12 amperes for either 12-volt or 24-volt systems. The functional parameter for this unit was its ability to control the charging capacity with a switching, shunt-type circuitry, but with low power dissipation. As a result, it did not require a large heat sink. This performance was the result of a variable pulse design, which lowered the voltage to a level close to the short-circuit current and therefore dissipated very low power levels. The frequency of the pulse varied with the state of charge of the battery—zero at a low state of charge, allowing a full charge, and faster as the battery voltage progressed towards full charge. The advantage of the system was that the battery received short pulses of charge even when the voltage was full, thereby preventing problems related to lack of charging when the system was fully charged and in a float condition.

As with all shunt systems, the performance of the unit depended on the protection afforded by the blocking diode placed between the solar and the battery. Special care was taken to select a Schottky diode characterized by low leakage and low forward voltage drop, in order to avoid losses and ensure enough voltage during system operation.

The design parameters produced by the engineering team were excellent and successfully withstood extensive environmental testing, including

Figure 3.4 Sample Controller Flow Chart



temperature and humidity tests typically performed on solar modules. This was necessary, because one of the design requirements called for the controller to be fitted in the module junction box. Therefore, it would have to be able to endure the same type of environmental conditions.

Once the design was completed, several manufacturing lots were made with a successful yield and performance after burn-in of a sample taken from each lot. A substantial order was received and, after thorough analysis of the plant assembly capacity, the decision was made to go with an outside supplier rather than to expand internal capacity. The purchasing department led the effort, and a vendor was selected based upon its experience with this type of assembly. A set of components was delivered to assess workmanship and successful product assembly. Next, the production lot was released to the selected vendor.

Samples of the production lots were tested for performance, and the lots were accepted and shipped to customers until a field failure was noticed. Repeated environmental tests indicated a deviation from the original design. The nonconforming product was analyzed and it was soon found that, after the high temperature test, the leakage and the voltage drop across the diode were drifting with temperatures higher than what was allowable within normal parameters. Room temperature tests were not affected. Further investigation showed that the blocking diode was at fault. Because the diode was a critical component, the engineering department had specified the exact type of diode to be used. Further inquiries of the vendor revealed that its purchasing department had decided to use an "equivalent" unit, without noticing that the drift and leakage of the alternate unit differed from the original design. A vendor has no authority to change components without prior approval from the contractor. Any vendor should have the same quality system level as the contracting company to assure the proper results. Also, no changes should be made or "equivalent" supplies used without testing the consequences of the change, however minor their anticipated impact on performance.

Further problems developed in a subsequent delivery because of the encapsulation process. All the terminals and connections were encapsulated to prevent corrosion of the controller from humidity. The location of a calibration potentiometer was such that it allowed the adjustment of the set points after encapsulation. A batch of units went to stock before it was noticed that the level of encapsulation was below the specified mark. This allowed water penetration and accumulation with the resulting corrosion and failure of the terminals of the adjustment device. Although the system did not fail outright, the battery ran unprotected for several weeks before the defect was noticed.

Tighter control of the encapsulation process and inspection was necessary to avoid further recurrence of the problem. The drawings needed to be clarified because, although properly dimensioned, they did not warn the manufacturer of the danger of not meeting the proper level of encapsulation.

The performance of the unit after these initial hurdles has been excellent, with returns of less than 0.1% in the last 12 years.



## 3.5 Production and Service Provision (Clause 7.5)

This important clause deals with the product or service the company provides to its customers, which is the main goal of the business. Whatever is provided must be of good quality and must satisfy all the requirements of the customer. This clause also deals with the delivery and post-delivery activities, which are also critical in maintaining customer satisfaction.

### 3.5.1 Control of Production and Service Provision (Clause 7.5.1)

This requirement addresses the need for controlling the processes that critically affect product or service quality. The standard that deals with the need for planning to ensure constant controlled conditions was discussed in section 2.2.4. There is no specific requirement for operations that involve no risk to the quality of the end product or service. In such noncritical operations, adequate training of a nonskilled operator or a brief description of the steps in the process will suffice. This is usually summarized in simple work instructions.

In order to determine which operations are critical, you must have a full knowledge of the requirements and specifications that the product or service must fulfill. After a design or development function, as described previously, is completed or, based on previous experience, a documentation package is presented with interim specifications that can be your current procedures. The critical areas are those that contribute more strongly to noncompliance conditions if they are not performed properly and those that have higher complexity.

To control critical processes satisfactorily, your company must take the following steps: For all critical operations, written specifications and process procedures are required. They must detail clearly what to do, how to do it, and the equipment required together with the set-up parameters for its use. Only equipment that has been approved for the task should be used. To avoid costly errors, fully qualified and certified operators shall carry out these operations. The operator should know the reason for the requirements and the operation's impact on the quality of the product. All critical operations should be monitored, measured, and reported for compliance, and the measurement equipment properly maintained and calibrated.

(a) Information, documentation, and work instructions:

- ❑ Document work instructions and the sequence of processes.
- ❑ Provide updated process specifications accessible to all operators.

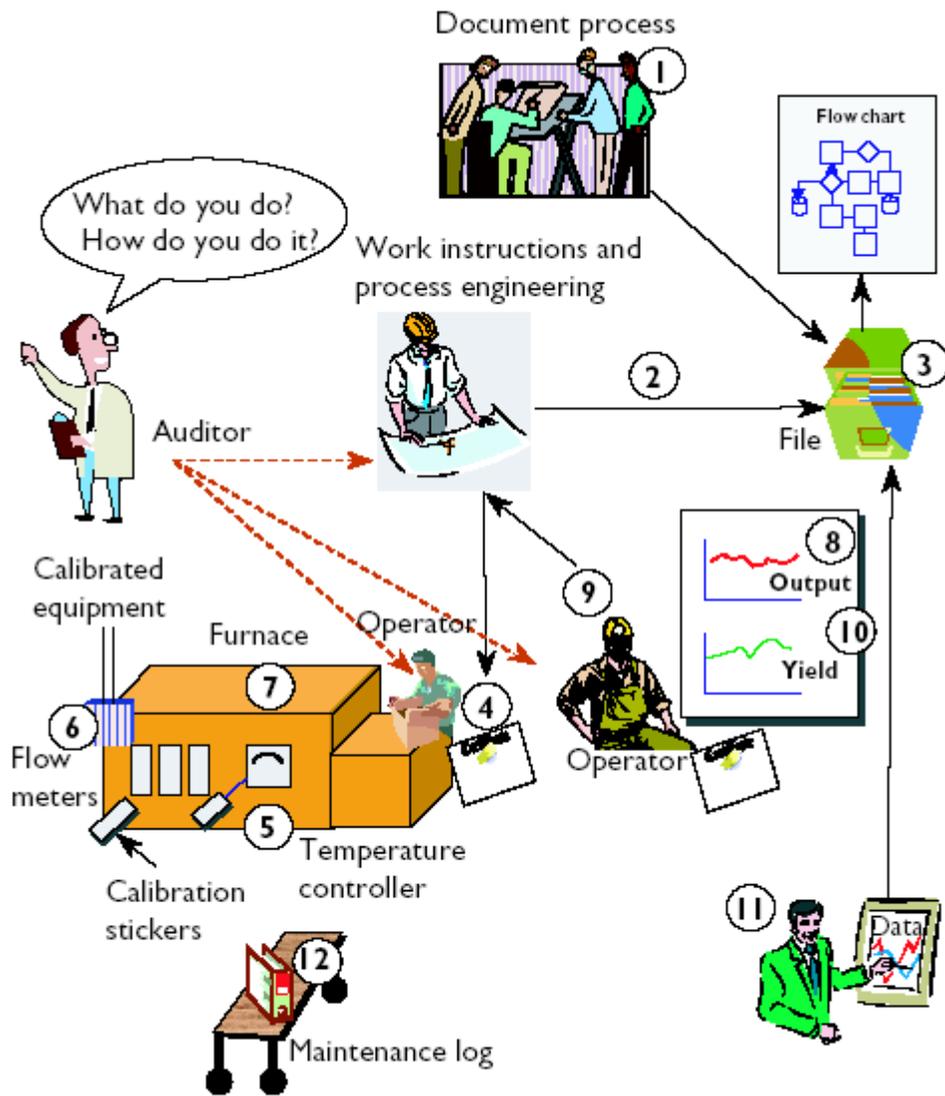


- ❑ Monitor and frequently audit documented procedures to assure inclusion of the latest approved revisions or changes (form 7.5.1-1).
  - ❑ Evaluate and document the impact of any process change on quality.
- (b) Equipment-related issues:
- ❑ Use suitable equipment.
  - ❑ Use only equipment that has been approved for manufacturing.
  - ❑ Monitor and control all process parameters.
  - ❑ Review and list all necessary equipment compliance with codes, standards, quality plans, and documented procedures.
- (c) Monitoring and measurement:
- ❑ Monitor maintenance and proper operation of equipment.
  - ❑ Establish a clear workmanship standard and representative expectation for the output in a measurable form of data, shape, color, and the like, with the aid of test equipment or color charts and similar tools.
  - ❑ Provide statistical data to show in measurable terms that the operation is under control conditions. Data should be displayed whenever possible.
  - ❑ Provide training, as necessary, to maintain qualified operators in all critical steps at all times.
- (d) Implementation and record-keeping:
- ❑ Generate a system to maintain quality records.
  - ❑ Set up maintenance records that document scheduled maintenance requirements.
  - ❑ Keep records of all critical parameters and calibrations.
  - ❑ Keep records of all unplanned maintenance requirements and their downtime effects or losses.
  - ❑ Try to maintain a simple and clear system.

Process control is a basic requirement that originates from the knowledge of the requirements and specifications (see figure 3.5). The processes to obtain the product or service are based on the experience on what is critical for the product to meet all requirements. This is usually demonstrated through the verification and validation process, which shows the inputs and outputs required from each step in the provision of the product. The need for training and assistance for the operators is based on these experiences. The auditors rely on these records to be able to verify that the processes are under control at all times. **REMEMBER:** The aim of the ISO standard is to maintain the process and quality under controlled conditions. The sole purpose of paperwork is to verify



Figure 3.5 Process Control



**Form 7.5.1-1 Process Control**

Date: \_\_\_\_\_

Revision level: \_\_\_\_\_

■ Process/operation: \_\_\_\_\_

■ Work instructions (attach, if necessary): \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

■ Process input: \_\_\_\_\_

■ Staff requirements: \_\_\_\_\_

■ Training requirements: \_\_\_\_\_

\_\_\_\_\_

■ Equipment requirements: \_\_\_\_\_

■ Quality monitoring/testing: \_\_\_\_\_

\_\_\_\_\_

■ Storage/handling requirements \_\_\_\_\_

\_\_\_\_\_

■ Process output: \_\_\_\_\_

\_\_\_\_\_

that the controls are in place, and that the specifications and process documentation are up-to-date and accessible to the operators.



### ***3.5.1.1 Inspection and Testing***

This clause also requires establishment and maintenance of procedures for inspection and testing activities to assure that the product manufactured meets performance requirements. The quality system should spell out all the inspections and tests that are to be conducted and documented before, during, and after the manufacturing process begins, along with the steps that are necessary for the release of the product to shipment. (Forms 7.5.1-2 and 7.5.1-3)

The inspection process can be divided into three stages: incoming materials or receiving inspection, in-process inspection, and final inspection and test. Each stage of inspection and its requirements shall be identified in the quality plan and shall be performed on all materials and parameters that could affect quality to guarantee that the end product will meet customer requirements. The testing requirements and how they will be carried out are to be clearly defined. The operators responsible for the inspection or testing must be given the appropriate equipment and training.

### ***3.5.1.2 Incoming Inspection***

- ✦ The supplier should have written specifications for all raw materials used, or detailed acceptance criteria in the purchase order.
- ✦ The quality plan and documented procedures should address any specific requirements not covered in the material specifications.
- ✦ No material should be released for use before incoming inspection.
- ✦ If an emergency release of material is required, the material should be positively identified to allow for recall of the finished product, in case a subsequent problem is found with the quality of the original material after the product is finished. Examples could be the absence of a UV inhibitor, or an unknown change in plastic formulation.

Consideration should be given to the certification and inspection of the subcontractor and its past quality performance and audit of its established quality system. The need for incoming inspection could be waived in such circumstances; but should be identified previously in the quality plan and documented accordingly.

### ***3.5.1.3 In-Process Inspection and Testing***

- ✦ The product should be tested or inspected to verify that it meets the required quality procedures as described in the quality plan

**Form 7.5.1-2 Form for Monitoring Production Process**

1) **Name/designation of product** \_\_\_\_\_

2) **Unique assigned tracking ID** (alpha/numeric) \_\_\_\_\_

3) **Procedures and instructions for quality functions**

Review procedures for production quality system for your company (sections)

- (iv) Quality system procedures
- (ix) Control of customer-supplied materials
- (x) Product tracking

4) **Attach original documentation on equipment used in each step**

5) **Monitoring of process conditions**

Process step: \_\_\_\_\_

	Acceptable range	Current measure	Date
Temperature	_____	_____	_____
Humidity	_____	_____	_____
Barometric pressure	_____	_____	_____
Cleanliness	_____	_____	_____

Process step: \_\_\_\_\_

	Acceptable range	Current measure	Date
Temperature	_____	_____	_____
Humidity	_____	_____	_____
Barometric pressure	_____	_____	_____
Cleanliness	_____	_____	_____

Process step: \_\_\_\_\_

	Acceptable range	Current measure	Date
Temperature	_____	_____	_____
Humidity	_____	_____	_____
Barometric pressure	_____	_____	_____
Cleanliness	_____	_____	_____

5) **Monitoring of product**

(Use form 7.5.3-1 in this manual, "Product Tracking and Verification.")



before further processing, for example, testing the resistivity of diffused layer of wafers prior to further processing.

- ✱ The product should be held until the required inspection and tests are completed. If the product is released before acceptance under established procedures, it should be marked appropriately so that it can be recalled and can preclude shipment of a nonconforming product.
- ✱ All nonconforming materials should be treated according to the nonconforming material procedures and marked appropriately, as well as removed from the production line.
  - Individual operators may be responsible for checking their own work. This flexibility is essential for small businesses where duplication of efforts is to be avoided.
  - Records should confirm that operators or inspectors have performed the necessary tests at the intermediate process steps.

#### ***3.5.1.4 Final Inspection and Testing***

Final inspection is your company's last opportunity to assure that all specifications and parameters are met. This process should be documented to the customer's satisfaction, as shown in form 7.5.1-4. It is also important to verify that all the inspections, tests, and paperwork have been performed on the product before it is released. This could be achieved by a simple, but consistent methodology. A checkmark in a routing slip is all that is necessary to verify compliance.

The final inspection and test could be specified within any of the following:

- ✱ A quality plan.
- ✱ A sampling plan.
- ✱ A procedure.
- ✱ An instruction.
- ✱ An inspection and test plan.
- ✱ The customer's order.

An inspection authority should be empowered to make sure that all the contract details are fulfilled. Records should indicate when the product is released. All documentation shall be kept to demonstrate that the quality plan has been satisfied.

A contract or special order may also have specific shipping requirements. A responsible authority must be sure that all shipping-related paperwork, packaging, markings, and identification of product conform to the contract. All records related to the contract should be kept for a specified time and be made available for customer review upon request.



**Form 7.5.1-4 Documentation for Receiving, In-Process, and Final Inspection and Testing**

1) **Name/designation of product** \_\_\_\_\_

2) **Unique assigned tracking ID** (alpha/numeric) \_\_\_\_\_

RECEIVING

3) **Product receipt** By (initials) \_\_\_\_\_ Date/time \_\_\_\_\_

**Visual inspection**

Accepted \_\_\_\_\_

Rejected \_\_\_\_\_

Reason for Rejection and Disposition of the Product: \_\_\_\_\_

4) **In-process** By (initials) \_\_\_\_\_ Date/time \_\_\_\_\_

**Quality test**

Pass performance check \_\_\_\_\_

Pass quality check \_\_\_\_\_

Rejected \_\_\_\_\_

Reason for rejection and disposition of the product: \_\_\_\_\_

5) **Final** By (initials) \_\_\_\_\_ Date/time \_\_\_\_\_

**Quality test**

Pass performance check \_\_\_\_\_

Pass quality check \_\_\_\_\_

Rejected \_\_\_\_\_

Reason for rejection and disposition of the product: \_\_\_\_\_

6) **Positive recall** (when products are released prior to verification: e.g., urgent release)

Reason for release prior to verification (customer request, etc.) \_\_\_\_\_

Identification and documentation of product/customer \_\_\_\_\_

Nonconformity event/date of recall \_\_\_\_\_

\_\_\_\_\_

### ***3.5.1.5 Servicing***

Servicing, also part of this clause, includes delivery and post-delivery activities. This section requires that the supplier establish and maintain documented procedures for performing the servicing function and verifying that it meets specified requirements.

Suppliers frequently offer installation services for their products. Also, the supplier may offer additional services, such as maintenance, or may agree to conduct a performance test of the installed equipment. In such cases, procedures should be in place to document the result of these services. **(Form 7.5.1-5)**

For example, a supplier may commit to testing a solar system after installation for power output, orientation, potential shadows, proper wiring, status of the storage battery system, and the like. A document should be filed and a report issued with the findings and any correction made to the installation. A similar case occurs when a servicing organization is responsible for verification of the performance and soundness of the system after it has been in use for a long period. This inspection can help detect corrosion issues, early module or equipment failures, water penetration, and problems with the encapsulant in the modules.

In cases where a warranty claim is involved, a written record and report are indispensable to back the claim to the supplier and to get the system back into proper working order.

### ***3.5.1.6 Planning and Scheduling Servicing Activities***

The plan depends on the type of arrangement between the supplier and the customer, for example, on whether the supplier is a service-only (installation and repair) organization or whether it is also the provider of the product to be serviced.

### ***3.5.1.7 Spare Parts Availability and Management***

This is a very important issue, especially if the system is installed at a remote site where access to the end user involves a long and inconvenient journey. The points where batteries are exchanged are often useful points of access for service and maintenance.

### ***3.5.1.8 Post-Delivery Activities—Instructions and Records***

Good record-keeping is especially important in case warranty claims or complaints about product performance arise. One example is when the interconnects in a module fail. This limits the power output of the module, but it is not a catastrophic failure. Previous measurements are critical to being able to detect the type of failure mode. Therefore, good records and adequate instructions on what measurements to take are essential for early detection, and they can prevent the supplier from having to replace the entire module.



**Form 7.5.1-5 Servicing Documentation Form**

1) Customer name \_\_\_\_\_

2) Customer location \_\_\_\_\_

3) Product name \_\_\_\_\_

4) Product unique ID \_\_\_\_\_

5) Date product purchased/installed \_\_\_\_\_

6) Sold by/installed by \_\_\_\_\_

7) Servicing information/education provided to customer?  No  Yes

**8) Servicing history**

**Scheduled servicing** (*attach agreement and schedule*)

Date: \_\_\_\_\_ Technician: \_\_\_\_\_

Date: \_\_\_\_\_ Technician: \_\_\_\_\_

Date: \_\_\_\_\_ Technician: \_\_\_\_\_

**Unscheduled servicing**

Date: \_\_\_\_\_ Technician: \_\_\_\_\_

Problem: \_\_\_\_\_

Resolution: \_\_\_\_\_

Customer acceptance (*signature & date*) \_\_\_\_\_

Date: \_\_\_\_\_ Technician: \_\_\_\_\_

Problem: \_\_\_\_\_

Resolution: \_\_\_\_\_

Customer acceptance (*signature & date*) \_\_\_\_\_

*(If product is replaced, document the date and new unique product ID.)*

**9) Report and documentation filed with service and quality managers** \_\_\_\_\_

Service manager \_\_\_\_\_ Date \_\_\_\_\_

Quality manager \_\_\_\_\_ Date \_\_\_\_\_

The basic tools needed to control the quality of servicing are the following:

- ✱ Personnel education and training.
- ✱ Records of product failures and nonconformance.
- ✱ Instrumentation and proper instrument calibration.
- ✱ Audits of services and reports to management.

The service department must be organized to issue reports of their findings that become part of the quality record.

### **3.5.2 Validation of Processes for Production and Service Provision (Clause 7.5.2)**

Tests are made to materials in progress in the manufacturing area, as we discussed in the previous section. The idea is to eliminate from the manufacturing cycle those products that do not meet the requirements previously designated as necessary to generate a product that meets the specifications desired. These tests consist basically of analysis by inspection or testing of the output of certain critical processes.

The problem with testing some products is that sometimes either the test is destructive or it cannot be performed in real time. These defects may affect product reliability later in life, several months after installation. Although the final factory tests may be satisfactory, they cannot not reveal the latent defect.

The purpose of this clause is to deal with what to do when it is not possible to monitor or inspect a problem. The solution is to qualify the procedure by validation of the process. The emphasis is to analyze all the parameters that surround the process, that is, the equipment, its parameters, the materials, the qualifications of the personnel, the environmental conditions, and the procedures and preservation of the product.

Once all these parameters are optimized by test and validated from results, the process is documented and the inspection is performed about the future conditions that should be the same as those validated. If the conditions change, for example, a new piece of equipment is introduced, the process must be revalidated.

This type of problem is readily visible in the interconnects for solar cells and their degree of reliability under extreme temperature cycling. This also applies to the performance and reliability of the metallization of the solar cells and the variables surrounding the interconnect attachments.

In other industries, the results of a weld and the strength of a concrete slab after casting are prime examples of processes that require controls on process, because products cannot be tested without destroying the pieces. Testing the interconnects and the solar cell bond strength are also destructive tests.



Thus, the records of the process used in these examples are very important to demonstrate that the process was under control. In the case of the solar cell interconnects, the problem was detected four years after deployment in the field. The records and design parameters were used to find the solution to the problem and to reduce the stress that promoted those early failures.

### **3.5.3 Identification and Traceability (Clause 7.5.3)**

The need for product identification is common in manufacturing. The supplier should establish a system that can identify the product and aspects of its status that are essential to maintaining quality and avoiding costly mistakes. This identification system should also identify changes in documentation and revision levels. You can use **form 7.5.3-1 or 7.5.3-2**, depending on whether your company provides installation services.

For example, in a solar cell factory, cleaned wafers must be identifiable from new, uncleaned wafers and also from diffused wafers. This is usually achieved by some combination of the following:

- ✱ Job card entries.
- ✱ Tagging.
- ✱ Computer tracking.
- ✱ Batch numbers.

Some contracts may require further traceability of the raw materials used in the final product. In this case, the supplier shall establish procedures to document the flow of the product and identify the materials used. This identification can be achieved through the use of the following:

- ✱ Material tags with identification numbers of lots or quality.
- ✱ Batch processing data.
- ✱ Individual data in computerized form.
- ✱ Visual inspection data.

Other important details should be taken into account in product identification and traceability, such as the following:

- ✱ How to segregate nonconforming materials and mark them properly.
- ✱ How to be able to demonstrate that only approved material is permitted to progress from one operation to the next.
- ✱ How to record and maintain unique identification numbers for products.
- ✱ How to maintain quality records and tracking records, as required by the customer contract.



**Form 7.5.3-1 Product Tracking and Verification  
(Copy to Remain with Product/Shipment)**

1) Name/designation of product \_\_\_\_\_

2) Unique assigned tracking ID (alpha/numeric) \_\_\_\_\_

Product tracking

3) Location <i>(ex. Receiving)</i>	Received By <i>(initials)</i>	Date/Time <i>(ex. 99-10-01, 08:35)</i>	Documented <i>(ex. signed receipt)</i>
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Product verification

4) Product receipt	By (initials)	Date/time
A) Visual inspection		
<input type="checkbox"/> Accepted (go to B)	_____	_____
<input type="checkbox"/> Rejected	_____	_____
Reason for rejection:		
B) Check order		
<input type="checkbox"/> Product matches order/accepted (go to C)	_____	_____
<input type="checkbox"/> Product does not match order/rejected	_____	_____
C) Quality test		
<input type="checkbox"/> Pass performance check	_____	_____
<input type="checkbox"/> Pass quality check	_____	_____
<input type="checkbox"/> Rejected	_____	_____

Reason for rejection: \_\_\_\_\_

**Form 7.5.3-2 Product Tracking**  
**(ID Shall be Permanently Affixed to the Product)**

- 1) Name/designation of product \_\_\_\_\_  
 2) Unique assigned tracking ID (alpha/numeric) \_\_\_\_\_

Product tracking

Product development

3) Location <i>(ex. Warehouse)</i>	Accepted by <i>(initials)</i>	Date/time <i>(ex. 99-10-01. 08:35)</i>	Documented <i>(ex. initialed form)</i>
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Product delivery

- 4) Product description \_\_\_\_\_  
 5) Delivery from/location \_\_\_\_\_  
 6) Delivery to/location \_\_\_\_\_  
 7) A) Delivery agent \_\_\_\_\_  
     B) Pickup date/time \_\_\_\_\_  
 8) A) Received by \_\_\_\_\_  
     B) Receipt date/time \_\_\_\_\_  
     C) Documentation/manuals/installation instructions \_\_\_\_\_  
     D) Delivery of safety information/instructions \_\_\_\_\_

Installation

- 9) A) Installed by \_\_\_\_\_  
     B) Installation date/time \_\_\_\_\_  
 10) Installation test  Pass  Fail  
 11) Client acceptance: Signature/date \_\_\_\_\_

Note: This form is for companies that provide installation services.

The supplier should identify meaningful parameters and traceability requirements and evaluate what is truly important for the quality of the product. This section does not require tracing and identifying everything, unless the contract spells out this need. Paperwork and data should be kept to a minimum and limited to significant information. What is "significant" should be established during the design phase of the product or service.

Figure 3.6 gives examples of the types of tags, identifiers, routing slips, and process records that are typical for a manufacturing process.

**Figure 3.6 Sample Tags and Labels**



**Nonconforming Product**

Reason for rejection \_\_\_\_\_

Engineering disposition \_\_\_\_\_

Corrective action \_\_\_\_\_

**Routing Sheet**

Lot # \_\_\_\_\_ Date \_\_\_\_\_

	Receive	Passed	Reject
Step 1	_____	_____	_____
Step 2	_____	_____	_____
Step 3	_____	_____	_____
Data Step 1	_____	_____	_____
Data Step 2	_____	_____	_____
Data Step 3	_____	_____	_____

Date \_\_\_\_\_ Operator \_\_\_\_\_ Time \_\_\_\_\_

Next Step \_\_\_\_\_

Received by \_\_\_\_\_

**Test Record**

Module # \_\_\_\_\_

Recorded Data

Voltage Peak \_\_\_\_\_ V

Current Peak \_\_\_\_\_ A

Peak Power \_\_\_\_\_ W

Power at NOTC \_\_\_\_\_ W

Operator \_\_\_\_\_

Date \_\_\_\_\_

**Calibration Record**

Unit \_\_\_\_\_

Date \_\_\_\_\_

Operator \_\_\_\_\_

Deviation \_\_\_\_\_

### 3.5.3.1 Inspection and Test Status

Most businesses have some method of identifying the status of products or services provided. The ISO 9001:2000 standard requires that suppliers implement the following controls:

- ✱ Establish a quality system for identification of the inspection status of a product during all stages of manufacture. **(Form 7.5.3-1)**
- ✱ Classify the product as follows:
  - Not inspected.
  - Inspected and approved (by a previously described criterion).
  - Inspected and rejected.
  - Inspected and rejected and put on hold for further action.
  - Inspected and released under authorized concession.
- ✱ Establish procedures for maintaining records of inspection and the individuals responsible for releasing the conforming product for further action.
- ✱ Be able to demonstrate that only products that meet the specific quality requirements have been released at the various stages of manufacture.
- ✱ Establish a recording and reporting system for the critical parameters of the product. Data should be posted so that all operators and managers become aware of the performance and control of these parameters. The statistical section of this manual shows ways you can chart average parameters, as well as deviations or drifts, or both, in the manufacturing process. These data are essential to keeping the process under control or implementing product improvements.

### 3.5.4 Customer Property (Clause 7.5.4)

On many occasions, the customer supplies a product to the supplier as part of the end product to be provided. The supplier shall maintain documented procedures for the verification, control, storage, maintenance, and handling of the customer-supplied product. If any damage or failure occurs with the product, it should be recorded, and the customer should be advised of the problem.

**(See form 7.5.4-1.)**

An example of this could be customer-supplied batteries for use in a finished system. The batteries should be kept properly in a vented area, with adequate temperature control, and charged as required during the time of storage. Failure to do so would result in premature battery failure after the finished products are delivered.

The product supplied by the customer should be inspected for quality, and a relevant procedure submitted to the customer before delivery. The supply of an acceptable product is the responsibility of



**Form 7.5.4-1 Customer-Supplied Product Tracking and Verification**

**(Copy to remain in customer file)**

- 1) Customer name \_\_\_\_\_
- 2) Name/designation of product \_\_\_\_\_
- 3) Product/order for which this is designated \_\_\_\_\_
- 4) Unique assigned tracking ID (alpha/numeric) \_\_\_\_\_

Product Tracking

5) Location <i>(ex. Receiving)</i>	Received by <i>(initials)</i>	Date/time <i>(ex. 99-10-01, 08:35)</i>	Documented <i>(ex. signed receipt)</i>
_____	_____	_____	_____

Product verification

6) Product receipt	By (initials)	Date/time
A) <b>Visual inspection</b>		
<input type="checkbox"/> Accepted as is (go to B)	_____	_____
<input type="checkbox"/> Not accepted	_____	_____
<u>Note problems:</u>		
B) <b>Check order</b>		
<input type="checkbox"/> Product matches order/accepted	_____	_____
<input type="checkbox"/> Product does not match order/not accepted	_____	_____
<input type="checkbox"/> Not accepted	_____	_____
C) <b>Quality test</b>		
<input type="checkbox"/> Pass performance check	_____	_____
<input type="checkbox"/> Pass quality check	_____	_____
<input type="checkbox"/> Rejected	_____	_____

Reason for rejection: \_\_\_\_\_

- 7) Special conditions for storage and/or handling \_\_\_\_\_
- 8) Report to customer any product that is lost, damaged, or unsuitable for use

the customer, even if the product has been accepted and verified by the supplier.

The product should be identified by serial numbers and controlled storage conditions to avoid mixing them with similar product in the supplier's warehouse or with material supplied by other customers.

Similarly, your company might use a service provided by the customer. In one instance, a customer purchased a system for a radar beacon in Alaska. The supplier provided details of sizing, installation, battery enclosure, depth burial to avoid freezing, and the like, but the site preparation was left up to the customer. After a few months of operation, the system was in trouble, and the customer called the supplier. After several hours of telephone exchange, the supplier realized that, although the system had been installed in a forest reserve with trees 16 meters tall, the system was installed at a height of only 9 meters. In the month of December, the sun in Alaska barely clears the horizon, so the system was not getting enough sunlight to generate energy adequate to sustain the load. Changing the height of the system the next year resolved the installation problem. In this case the customer's installation was clearly defective and caused the system to fail. Better communications resolved the problem in this case, which arose because of customer-supplied service.

Similarly the intellectual property of the customer must be protected and verified as useful for a service or an application of equipment. All data shall be evaluated and protected to preserve customer confidentiality.

### **3.5.5 Preservation of Product (Clause 7.5.5)**

This ISO clause requires that the commercial functions of product handling, storage, packaging, preservation, and delivery be controlled by documented procedures to avoid problems in these areas and to identify requirements that will eliminate error in the performance of these functions.

#### **3.5.5.1 Handling**

Many products require specific procedures to avoid risk, damage, or problems in the handling of raw materials, the handling of the product throughout the manufacturing process, or the handling of the final product in the stockroom prior to shipping.

Examples of such problems include the improper handling of semiconductors sensitive to electrostatic discharges, the storage of electrical or electronic equipment in high humidity or dusty environments, overstocking products to the extent that the weight could damage the shape or boxes, mishandling acids or liquids of corrosive nature, handling metals with improper equipment.



Handling procedures shall be simple and clearly explained. They should describe the method of handling, tools, or precautions required during the handling and movement of the product through the plant or, after completion acceptance, through storage and shipment.

### **3.5.5.2 Storage**

Many products have specific storage requirements before use or shipment of the finished product. A good example is the storage of batteries in a systems integration operation. Batteries require periodic recharging to prevent plate corrosion. The room the batteries are stored in requires ventilation, because of the corrosive liquids involved. Furthermore, specific temperature ranges must be maintained in order to avoid rapid deterioration of the units.

Problems that can arise in the location of different chemicals should be taken into account in the layout of the storage facility. Attention to temperature needs is also necessary for safe storage of volatile and sensitive products. As another example, most plastics or laminating materials used in manufacturing PV modules have shelf lives that cannot be exceeded if a quality product is desired. Sometimes a cycle of "first in, first out" is required for perishable materials, or order quantities have to be restricted and delivery schedules carefully set so as to avoid shelf life problems.

The manufacturer should issue norms for storing raw materials and finished products to avoid any damage to products or injury to employees because of improper storage conditions.

### **3.5.5.3 Packaging**

The packaging of finished products is of great relevance for the manufacturer of PV products. Regulators are semiconductor-based units that are sensitive to humidity and electrostatic problems. Batteries are highly corrosive devices. There are rules and regulations for their handling during the shipping process, including special crating and labeling. For example, sometimes when shipping batteries, the electrolyte must even be shipped separately in glass containers.

PV products are sometimes fragile, as is the case with cells and wafers. In other cases, PV products are heavy, so that crating should incorporate protection against mechanical damage from other metal components—for example, when a system containing several modules in an assembly is shipped together with metal hardware.

In all cases, procedures should be established for shipping and marking the products to avoid costly mistakes from breakage, damage, or product deterioration.



### 3.5.5.4 Preservation

Quality control methods are required for the preservation of the product during storage or use in the factory. In the case of chemicals, the segregation of acids from bases during storage is very important. And again, the handling and storage of batteries and laminating materials requires special preservation, such as temperature control and cycling of use to prevent damage.

### 3.5.5.5 Delivery

This includes the proper labeling and insurance of the product for delivery to the customer and the necessary written instructions on the proper method of shipment. Other requirements were discussed in the previous sections on handling.

The container used for normal delivery should be an approved and tested container that protects the product from damage en route, such as rough handling by the shipping company. Markings are important to identify dangerous or fragile products.

## Case Study No. 3

### BATTERY REQUIREMENTS FOR STAND-ALONE OR AUTONOMOUS SYSTEMS

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All stand-alone PV systems require a device that stores the energy produced during the day, so that it can be used when needed. This is particularly important in the case of rural home systems that are used at night or transmission systems that must be available at all times.

There are various types of storage devices. The most common is a set of batteries designed to be able to hold energy for many days, so that the system can function even during winter periods when the amount of solar energy received is very low. Storage capacity can vary, depending on the anticipated usage charge and usage conditions and on how critical the system is. The cost of batteries—the most short-lived component of a solar system—is also an important factor.

Storage times range from 30 days, in the case of navigational aids such as marine buoys, to 3 days in the case of remote home systems. Telecommunication systems typically have a storage time of up to seven days, depending on the location site and the criticality of the operation.

The type of battery most frequently used is the lead acid battery. The following two examples illustrate battery-related issues of concern for suppliers and system integrators.

#### EXAMPLE 1: TRANSPORTATION REQUIREMENTS

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The location of the system should be a major concern for the system installer or integrator, especially in the case of large telecommunication



systems in which the battery size demands the use of a liquid electrolyte. A few years ago, several sets of such systems were sold that were to be located on mountaintops. The lack of attention to their location had a negative impact on the performance of the systems.

The customer failed to mention that there was no access to the locations by road. The supplier simply assumed such access. The supplier did not know that the equipment was to be transported up the mountains on the backs of donkeys. No special preparation was made for the transport of the large batteries, which were shipped filled with acid, instead of shipped dry-charged with the electrolyte kept in separate containers. Several instances of lost electrolyte went unnoticed and the batteries went into service at sub-par conditions, diminishing the life of the systems. In other instances, the electrolyte spilled and burned animals and operators handling the cargo, which created a safety concern for the system integrator.

## EXAMPLE 2: STORAGE OF BATTERY SYSTEMS

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Many applications involve multiple systems that are installed over a lengthy period and that require the storage of systems that have been delivered ready to be installed. In such situations, a strong warning is warranted, because the storage of battery systems is limited to a few weeks at a time. After a few weeks, the electrolyte—liquid or gel—starts to sulfate the plates of the battery, and a film develops that affects future life and capacity. In one case, a group of 50 navigational aid systems was shipped to a customer in the Middle East. After deployment, several problems developed with the charge retention (capacity) of the batteries. Several trips were made to analyze the solar system size, the controller operation, and settings, as well as the installation. It was subsequently discovered that the systems had been kept in a warehouse for more than six months, awaiting the arrival of other equipment. The temperature of the warehouse and, consequently, of the batteries rose as high as 50° C. These temperatures accelerated the self-discharge and activity of the electrolyte.

The customer did not pay attention to the warning labels that were placed on the systems and in the manuals, which specifically instructed that batteries be recharged during extensive periods of storage, especially when exposed to high temperatures.

The lesson to be learned here is that, in order to deliver a sound system, the designer should not only take into consideration the insulation and weather for the area, but also the transport, handling, and storage of the units from the time they are delivered through the actual time of commissioning by the customer. See form 7.5.5-1, for example.

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**Form 7.5.5-1 Sample Component or Product Handling Form**

1) Product name: \_\_\_\_\_  
2) Unique ID: \_\_\_\_\_

<b>Activity</b>	<b>Procedure</b>	<b>Conditions</b>
<b>Handling</b>	<i>(e.g., use gloves when handling)</i>	<i>(e.g., minimize vibration)</i>
	_____	_____
	_____	_____
<b>Storage</b>	<i>(e.g., do not stack)</i>	<i>(e.g., maintain temp. 10–35°C)</i>
	_____	_____
	_____	_____
<b>Packaging</b>	<i>(e.g., use biodegradable pkg)</i>	<i>(e.g., minimize dust in packing area)</i>
	_____	_____
	_____	_____
<b>Delivery</b>	<i>(e.g., customer education)</i>	<i>(e.g., verify operating environment)</i>
	_____	_____
	_____	_____

\_\_\_\_\_  
Signature of reviewing/inspecting manager

\_\_\_\_\_  
Date

### 3.6 Control of Monitoring and Measuring Devices (Clause 7.6)



Throughout the production process, the supplier uses equipment for inspection, testing, and measurement. In order to assure that the product meets its requirements, it is necessary to establish and maintain calibration and maintenance schedules for all measuring and test equipment. This ensures that the measurements are correct and within acceptable accuracy requirements. A record of this process should be kept in a file for future reference. **(Form 7.6-1)**

The use of equipment requires that any measurement uncertainty be known and consistent with requirements. Any hardware and software used to test the product should be checked regularly to verify the accuracy and repeatability of their test results. Records should be kept of this process.

The standard requires that the calibration be performed at specified intervals, that the equipment be adjusted as necessary, that the equipment not be readjusted by unauthorized personnel, and that the equipment be kept and operated within an environment adequate to achieve accurate measurements.

#### Form 7.6-1 Procedures for Quality Control of Measurement and Test Equipment

- 1) Equipment designation: \_\_\_\_\_
- 2) Date of calibration: \_\_\_\_\_
- 3) Employee/contractor performing the action: \_\_\_\_\_
- 4) What is the item used to test/measu? \_\_\_\_\_
- 5) What is the measurement tolerance for the process? \_\_\_\_\_
- 6) What is the measurement uncertainty? \_\_\_\_\_
- 7) Number of tests/cycles since last calibration: \_\_\_\_\_
- 8) Return of the item to its stored capacity?  Yes  No
- 9) Date item returned to storage: \_\_\_\_\_
- 10) Location of item storage: \_\_\_\_\_

Note: This form is only applicable to those businesses where measuring or testing equipment is used to check that what they are providing meets the customers' needs. Also, this applies only to equipment that can affect quality.

### 3.6.1 Control Procedure

Following are steps to take in the control procedure:

1. Identify the equipment that needs to be calibrated. Only equipment that controls critical parameters or measurements required by the product specifications needs to be calibrated.
2. Establish and maintain a list of each piece of equipment that requires calibration.
3. Demonstrate the calibration status of each piece of critical equipment. Records should be kept on when equipment was calibrated, who did it, what the acceptance criteria were, what the result was and, if it was acceptable, what the next date for calibration will be.
4. Identify and document the accuracy of required measurements and the accuracy of the equipment in use to perform those measurements. Demonstrate that the equipment in use has better accuracy or that it at least meets the accuracy requirement.
5. Establish calibration methods traceable to a certifiable standard to maintain the accuracy of tests and measurements. Establish frequency of calibration, and monitor records of calibration. Equipment or meters shall not be used beyond the effective calibration date.
6. Set up a certificate of calibration, and tag each unit or equipment with the date that recalibration is due, the accuracy of the calibration, and the conditions of operation.
7. Make sure that the conditions of operation are within the environmental conditions of the calibration. Otherwise, correction factors must be utilized, or the equipment must be calibrated under the anticipated usage conditions (for example, in the case of high temperature or high humidity beyond the range of the calibration).
8. Use secondary standards, as necessary, which is permissible when the measurement requires less accuracy than that provided by the unit calibrated to a certifiable standard.
9. If any test equipment is found to be operating outside the calibration or accuracy required by the product, an effort must be made to find when the unit went out of calibration, and how the product shipped during that period could be affected. The product should be listed as potentially noncompliant to the specification. A nonconforming product review must be done to decide what action should be taken.
10. Provide adequate storage and handling of calibration equipment so that accuracy and fitness for use can be maintained.



The calibration process can be expensive. Every effort should be made to minimize the number of units that require external calibration with traceable references, because they may not be readily available in all locations. You may use a subcontractor that has this capability or cooperate with other companies that have the same requirements to share the expense. Neither expense nor difficulty waives the need for accuracy in testing, but the accuracy should not be overstated beyond the need or the capability of the available equipment.

The process of calibration requires proper documentation procedures and maintenance of records for backing up the measurements performed at the company or in the field. Auditors are particularly sensitive about the calibration process. All records can become critical for demonstrating that specifications and requirements have been met.

## Homework Assignment—Day Three

YOUR NAME: \_\_\_\_\_

YOUR COMPANY: \_\_\_\_\_

Today's homework assignment is intended to help you think about a plausible quality management situation in your own company and about what you will do when you return to your company after this training to promote the adoption of a quality management system to qualify for the PV GAP Mark or Seal.

1. Describe the key elements of a quality system you would set up to deal with customer complaints about one of your company's products? (The complaints might have to do with the product's performance, with its condition upon receipt after shipping, or with after-sale service).
2. If the quality system you described in no. 1 were in place, how would your company benefit, and what advantages would the system give your company relative to its competitors?
3. What are the key messages you will take back to your company from this training? What specific things will you do in the next 30 days to communicate what you have learned here with others in your company and start the process of change?



# Chapter 4. ISO 9001:2000 Standard—Clause 8



## 4.1 General Concepts (Clause 8.1)

Although this clause is new in the ISO 9001:2000, it involves several concepts and factors that were implicit in the previous issue of the standard. The main purpose of this clause is to establish a plan to review requirements and to check the performance of the execution of clauses 4.1 and 7.0, that is, documentation control and product realization processes. This clause requires that the data be collected, measured, analyzed, and presented to the management of the company. The management is committed to a formal follow-up on the progress and failures of the quality system, as well as a review of customer satisfaction and continuous improvement.

The main concept is to have management reviews, establish preventive and corrective actions, and instill the quality improvement goals throughout the organization. This also opens the forum for review of the resources, training, and infrastructure that may be necessary to meet customer requirements.

Measurements are best presented through statistical methods and graphs, although many other types of analysis are also applicable. In order to present the available statistical methods most commonly used, the ISO TC 176 offers a standard, ISO/TR 10017:1999, which is still applicable, although it was developed for ISO 9001:1994.

Although the standard does not discuss the statistical methods, we include below a brief explanation of those most commonly used.

### 4.1.1 Statistical Data Analysis

Quality improvements require measures of status and comparisons after corrective action is taken. This is usually achieved through comparison of data collected from the company's various activities. The data collection process is the first step for any analysis. Receipt of materials, processing steps, equipment malfunctions, testing of the product, and handling at the shipping dock—all these activities produce some sort of data that should be collected systematically to obtain a clear picture of what's going on.

The personnel doing this frontline work usually gather the data—for example, a sales person who gets feedback from the customers, a customer service clerk who observes the promised versus actual shipping dates, or operators on the manufacturing line who handle the product at various stages in the manufacturing process. Gathering data is an important function of each employee. Subsequent data analysis can take various forms and be carried out

through a variety of methods, but the management representative is usually responsible for making sure that the responsible managers or process engineers analyze the data.

If there are nonconforming products or results, data should indicate increased activity in rejects or rework. These data should be analyzed and the cause of the problem investigated. Several methods of analysis can be used to form a decision about how best to resolve the problem. Continued reworking or sorting only perpetuates quality losses. Optimally, data collection and analysis can yield a basis for preventive actions that prevent defects from occurring. Analyzing the data using statistical methods is indispensable in correlating the corrective actions taken and the resolution of the root causes.

Some non-numerical methods commonly used to determine the best course of action to be taken include the following:

- \* Benchmarking.
- \* Brainstorming.
- \* Cause-and-effect diagrams.
- \* Flow chart or process descriptions.

In addition, various numerical methods are available for analyzing the data. The techniques most frequently used for numerical analysis are the following:

- \* Pareto charts.
- \* Histograms.
- \* Scatter diagrams.
- \* Control charts.
- \* Run charts.
- \* Percentage charts.

#### ***4.1.1.1 Description of Non-Numerical Methods***

Several non-numerical methods that are used to determine the best course of action are discussed below.

##### **Benchmarking**

This technique compares the company's processes and performance to those of other companies that are recognized as leaders in the same field or other similar fields. The optimal comparison is to the best in class in your own area. This could lead to goals and plans that will affect your marketing strategies. For example, one might compare field life performance to warranty and find that a marketing advantage could be obtained if you offered a better warranty.

However, data on process yield or data on plant equipment performance and uptime of specialized equipment are more sensitive and less likely to be shared among competing companies. For this reason, benchmarking may be used to compare your



performance against companies in other industries that use similar technologies. For example, in solar cell manufacturing, it is common to benchmark against semiconductor companies because of similarities in materials, processes, and equipment.

This technique could be used to evaluate the merits and costs of new technologies and how they have been implemented in other companies, as well as to evaluate the benefits and costs (for example, for maintenance and training) of acquiring new equipment used in other industries.

### Brainstorming

This process is useful when a team needs to resolve a problem and there is no clear initial understanding of the problems or issues involved. The team gets together with a facilitator with the aim of generating as many ideas as possible in a sequential manner from all participants (see box 4.1). One person's idea can stimulate ideas from others. The process is open, with no criticism of the ideas. The purpose is to generate as many ideas as possible. The ideas are posted for everyone to see and evaluate. When there are no more ideas or suggestions, critical evaluation begins. Ideas are clarified and discussed, and a selection of the best is made for future action.

This technique is often used to discuss potential project needs for a company, to prioritize the implementation sequence, or to review the impact of new personnel policies on employees.

### Cause-and-Effect Diagram

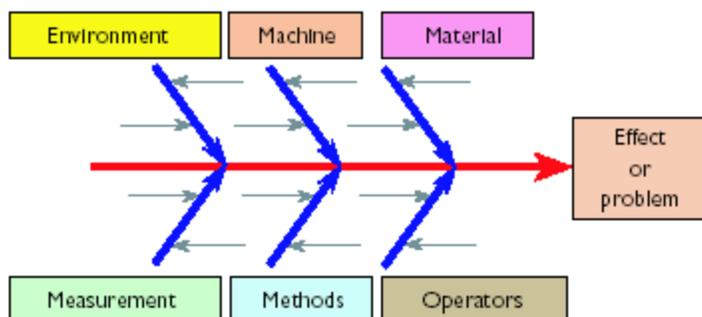
This diagram is also called a "fishbone chart" (see figure 4.1) Defining the problem starts the process. Next, several causes are identified that could influence quality results, for example, operator skills, machine repairs, materials used, and plant environment. For each cause, one or more contributing factors are listed (for example, under plant environment, such factors as ambient temperature, humidity, and dirt might be identified.)



#### Box 4.1 Rules for Brainstorming

- Generate a large number of ideas.
- Unbridle the imagination.
- Don't criticize.
- Make sure everyone participates.
- Record all ideas.
- Let ideas incubate.

Figure 4.1 Cause-and-Effect Diagram



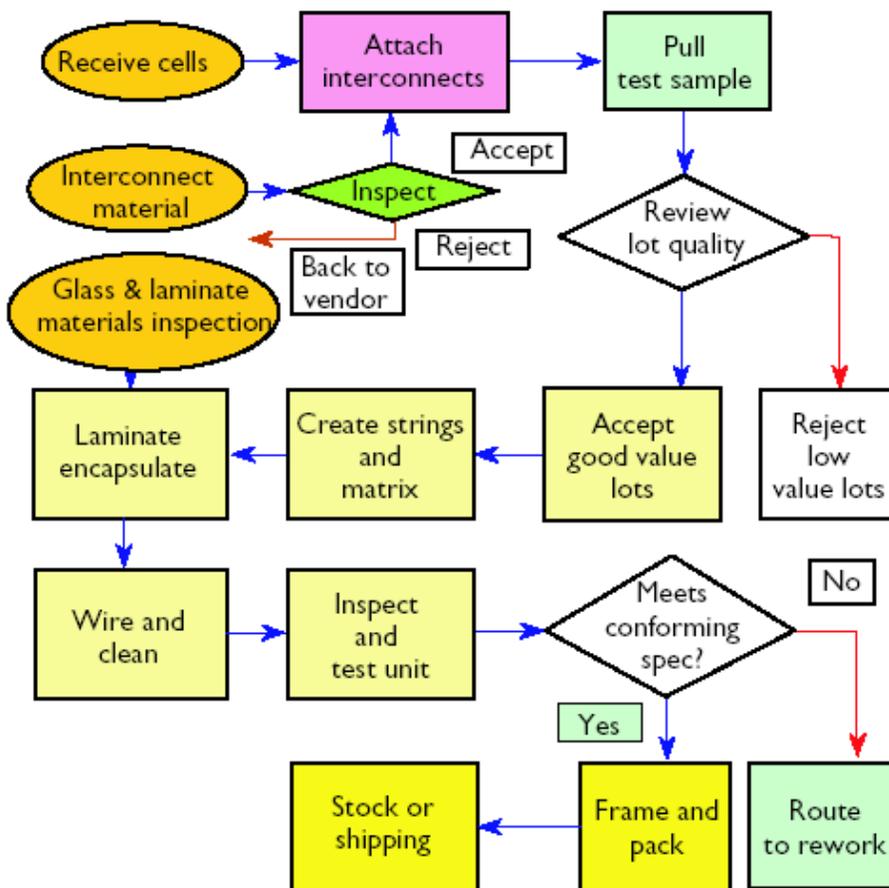
The impacts of these factors are then analyzed. Those known to have stronger influence are selected for future action and problem resolution.

### Flow Chart and Process Description

A flow chart is a pictorial description of the steps in a process. The benefit of using a flow chart is to be able to identify each step and to determine at what exact point it is most likely that a problem is occurring. A new process or changes in the flow may remove the problem and improve the quality of the product. Once a thorough analysis is made, a new flow chart is created. ISO requirements for documentation and process change should be met.

Flow charts are very often used to review the effect on the work process of a proposed new method or change in work sequence. Sometimes a change in vendor means that new materials control procedures need to be phased in. See the sample flow chart in figure 4.2.

Figure 4.2 Sample Flow Chart



### 4.1.1.2 Description of Numerical Methods

Several numerical methods that are used to determine the best course of action are discussed below.

#### Pareto Charts

Pareto charts are used to present data or conditions related to the type of failure occurring. For example, in the manufacture of solar cells, you may have a large number of rejects. The data should indicate what type of rejects you have (for example, broken cells, chipped cells, or electrical rejects).

If your process is under control, an increase in broken wafers indicates that the quality of silicon wafers may be affecting the process, or that some process has gone out of control unnoticed.

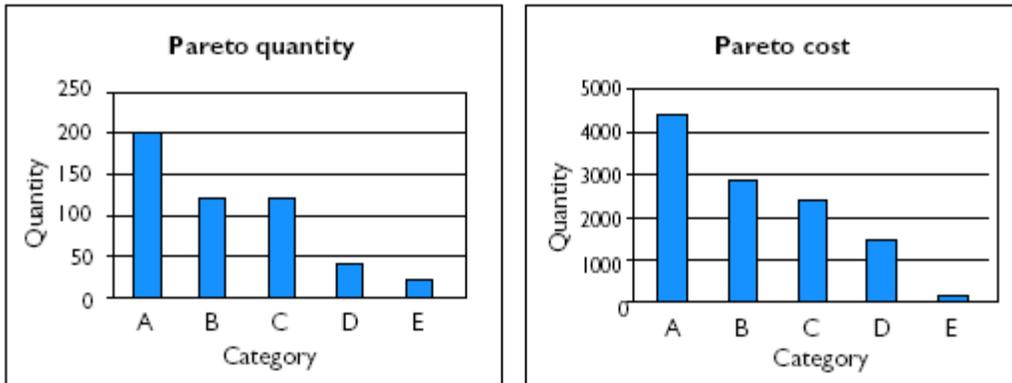
A Pareto chart can be used to analyze not only the type and number of failures, but also their cost implications. Losses of cells at attaching interconnects might be higher in numbers than losses at the module level, if the interconnect pull strength is not good. Analysis, however, might reveal that failure of one unit at the module level is more expensive than a loss at the beginning of the line.

Table 4.1 indicates that, although failure mode B occurs with greater frequency, category D and C failure modes are more critical because the cost of these failures is higher. The discrepancy values for a module line might look like those in table 4.1. The applicable Pareto charts are shown in figure 4.3.

**Table 4.1 Discrepancy Values for a Module Line**

Legend	Rate of discrepancy (%)	Type of discrepancy	Quantity	Unit Cost	Total Cost
A	40	Lamination defects	200	22	4,400
B	24	Junction box defects	120	1.4	168
C	24	Cell alignment	120	20	2,400
D	8	Matrix alignment	40	72	2,880
E	4	Glass defect	20	72	1,440

**Figure 4.3 Sample Pareto Charts**



### Histograms

The histogram is used to review process patterns or variations. Test results in solar cell manufacturing are usually good data to plot in histogram form. Such results should be near a normal distribution, but in general, they skew to the left if plotted against efficiency. On occasion, the results could show a bimodal distribution. In solar cell test results, this could indicate an anomaly in the process (for example, a difference in temperature between tubes in a diffusion furnace, or a nonuniform condition across a belt in a belt furnace). Bimodal distributions will be representative of a mixed distribution or two distributions superimposed. Maintaining such data is a good way to improve quality in a manufacturing line.

Figure 4.4 contains examples of several types of distribution plotted in histogram format.

### Performance Charts

Bar chart graphics are frequently used to present the past and present performance of a unit or of factory output and to compare it with expected performance. Charts are made based on experience (in our example, more than three years) and the anticipated goals for the manufacturing step or department. The charts in figure 4.5 show month-to-month actual performance during the last three years for the cell line and the module assembly. These charts can give plant management a quick overview of the degree to which performance is or is not measuring up to expectations. Corrective action may be necessary if performance is not adequate.

### Scatter Diagrams

Scatter diagrams are used to find the correlation between two different sets of data. The data seem like a cloud of points. Sometimes they are scattered throughout the page and do not show any relationship, but on many occasions they show a marked trend and statistical correlation. This can be used to optimize process parameters by changing some of the parameters and observing the

Figure 4.4 Sample Histograms

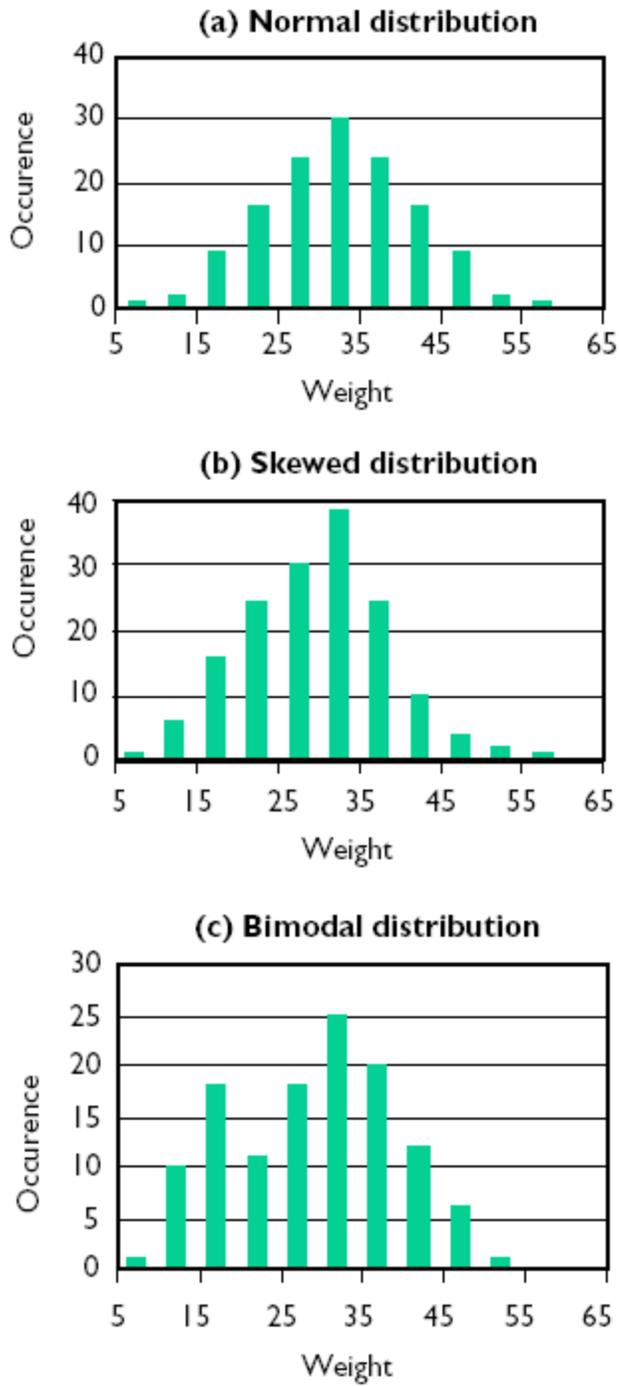
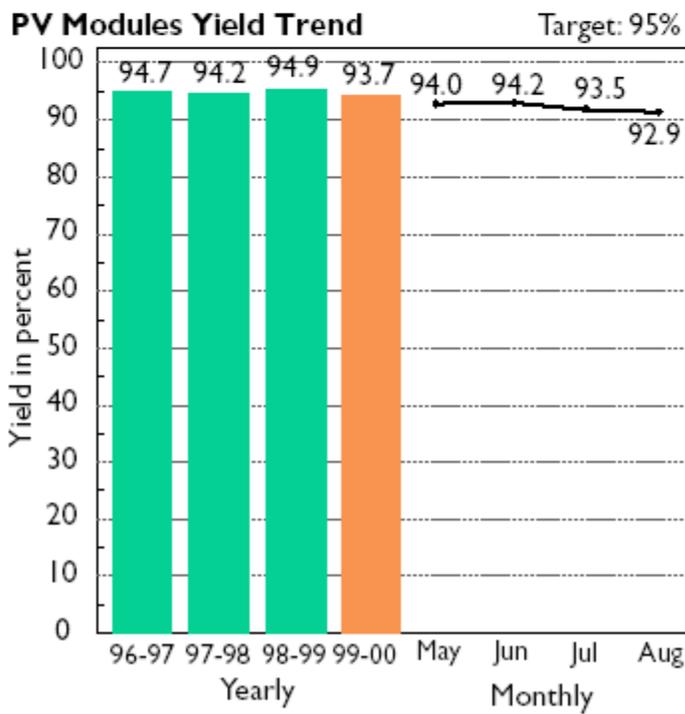
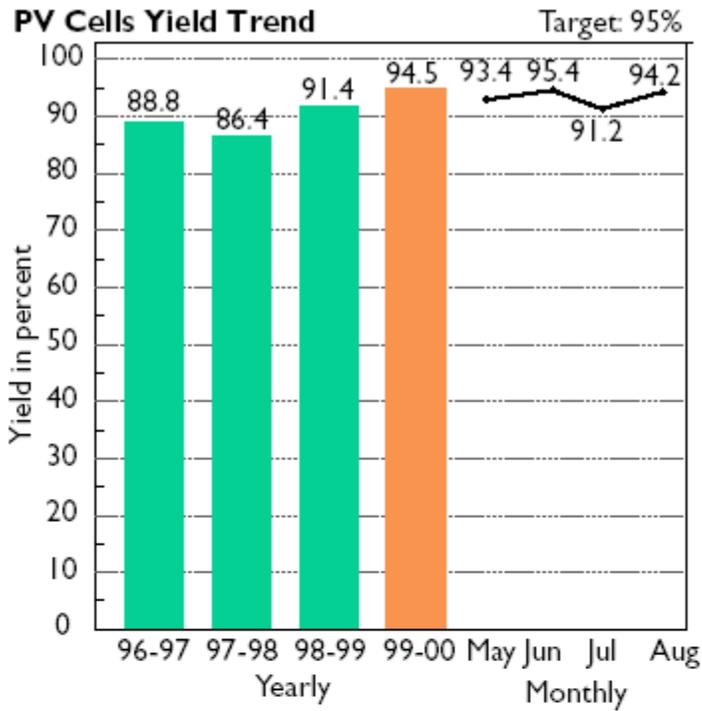


Figure 4.5 Performance charts



outcome data. One example could be the correlation between furnace temperature and the sheet resistivity of the junction formed. Another might be the correlation between contact series resistance and firing temperatures.

The relationships can be negative slope, positive slope, or curvilinear. The numerical correlation can be strong or weak, depending on the scatter around a trend line in the data points. Several examples are shown in figure 4.6.

Scatter diagrams are valuable tools for process improvement. The engineering department typically uses them to analyze data during proposed process changes. If one variable ( $x$ ) is changed, the performance of variable ( $y$ ) can be analyzed. Experiments are usually designed around more than two variables, requiring more complex analysis.

### **Control Charts**

The use of histograms opens the door for the normal distribution curve and the statistical control of data. Data are usually organized so that the process average is calculated. The data are then monitored on a daily basis and the averages of the data plotted in a continuous chart. This chart will indicate the variation around the average and how much the daily averages deviate from the established mean. After a number of days of plotting daily actuals, the upper limit and the lower limit of the average daily data can be found. This is indicative of the amount of deviation that the process has for the particular parameter or attribute being plotted.

This type of plot indicates the status of the process and whether it is improving or deteriorating over time. The smaller the variance, the better will be the control. Another feature is the indication of trends in manufacturing, either by shifting the average or by increasing or decreasing the deviation.

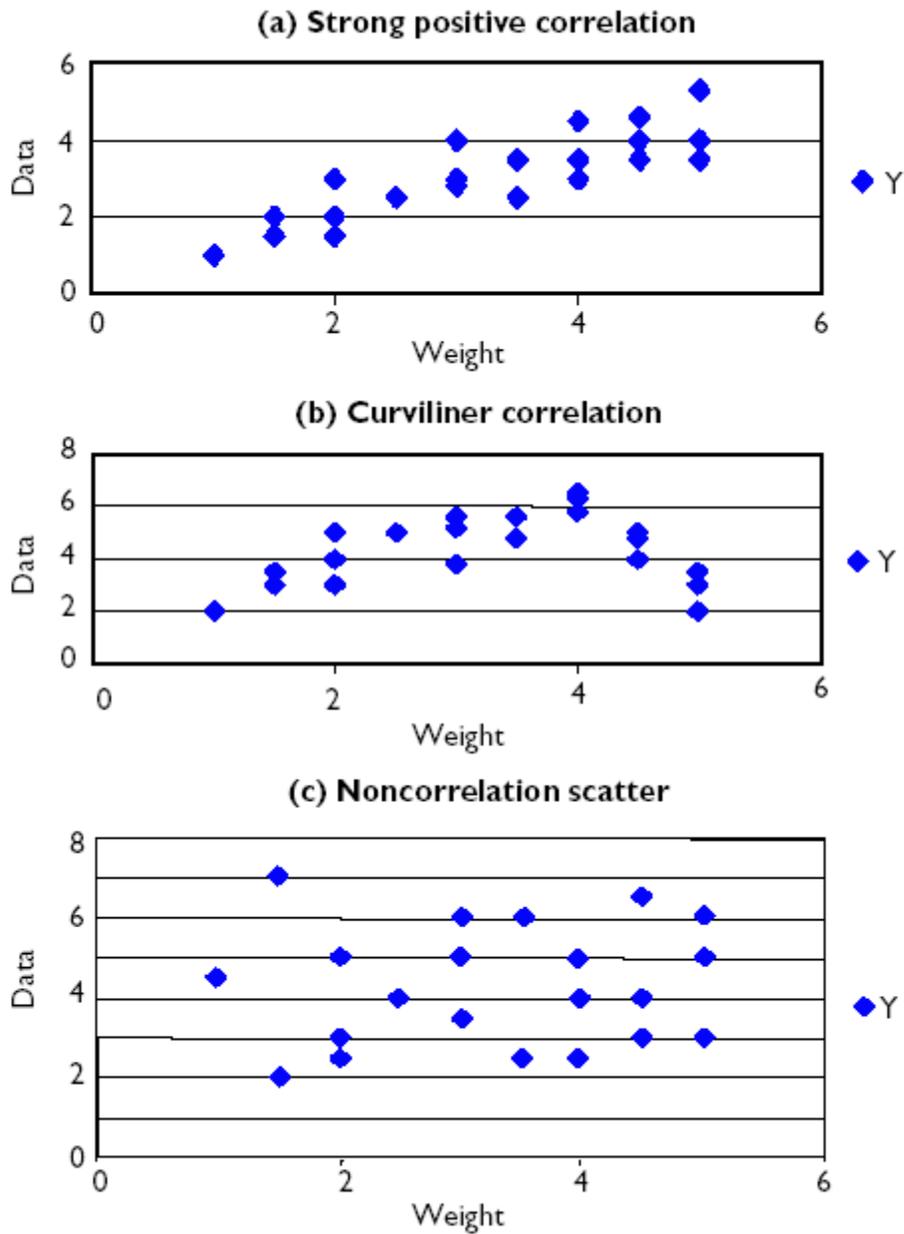
The ideal case is when the deviation is less than a few points and the average remains unchanged, when no changes are introduced into the process. If an improvement is introduced, its impact should improve the average or narrow the upper and lower limits for the parameter.

You can use this tool to demonstrate that the process is under control, or to gauge the capability of the process and evaluate the improvements introduced in the line.

The use of control charts is usually the duty of the operators. They gather the data and immediately generate the control chart, a very graphical analysis that enables them to observe whether the process is under control (within control limits) or not. If the process departs from its normal range, the issue is brought to the attention of the operation managers and engineers, and its resolution is achieved in a shorter time than would occur in the absence of such a statistical tool. See table 4.2, which describes the steps to make a



Figure 4.6 Scatter Diagrams



control chart, and figure 4.7, which shows examples of control charts.

In summary, all the above methods are part of an effort called statistical process control (SPC). Sampling plans are usually used instead of the 100% inspection used in many operations. The size of the sample and the analysis of product failure rate could be indicative of the correctness of the sampling plan. The ideal plan would detect all failures, but this may not be a realistic expectation. Therefore, the sampling plan is usually verified against the final test and acceptance test and, ultimately, against customer complaints and field returns. The objective is to conduct a systematic review to determine the proper level of sampling, in combination with verification against other information, to achieve the required quality.

Statistical analysis goals and procedures should be updated whenever new or improved data become available. Other business activities that benefit from the applications of statistical processes are as follows:

- \* Market research.
- \* Product design.
- \* Process optimization by design of experiments.
- \* Stock and inventory controls.

In conclusion, SPC is a very valuable tool that must be used in every area targeted for improvement in your company's quality plan. (Figure 4.8 contains suitable statistical tools that can be used in the various problem-solving steps.)

## 4.2 Monitoring and Measurement (Clause 8.2)

This clause concerns the collection of data for different areas of interest, such as customer satisfaction, processes, products, and all the other functions associated with the operation of your business. The note includes monitoring first as a less intense effort, and then measurement for numerical data, which can be compared over time to evaluate progress made with the quality system.

### 4.2.1 Customer Satisfaction (Clause 8.2.1)

This is the main thrust of the ISO 9001:2000 standard. The customer is the direct recipient of your product or your services. Your company survives because it has customers. It is everyone's desire that the customer be satisfied with the product you have delivered. The problem arises because it is often difficult to find out what perception the customer has. Thus, it is important to ask the customer or to make surveys to find out possible weaknesses in your company.



**Table 4.2 Steps to Make a Control Chart**

- 
1. Gather and convert data
  2. Calculate average control limits
  3. Determine chart scale
  4. Plot chart
  5. Analyze and interpret
-

Figure 4.7 Control Charts

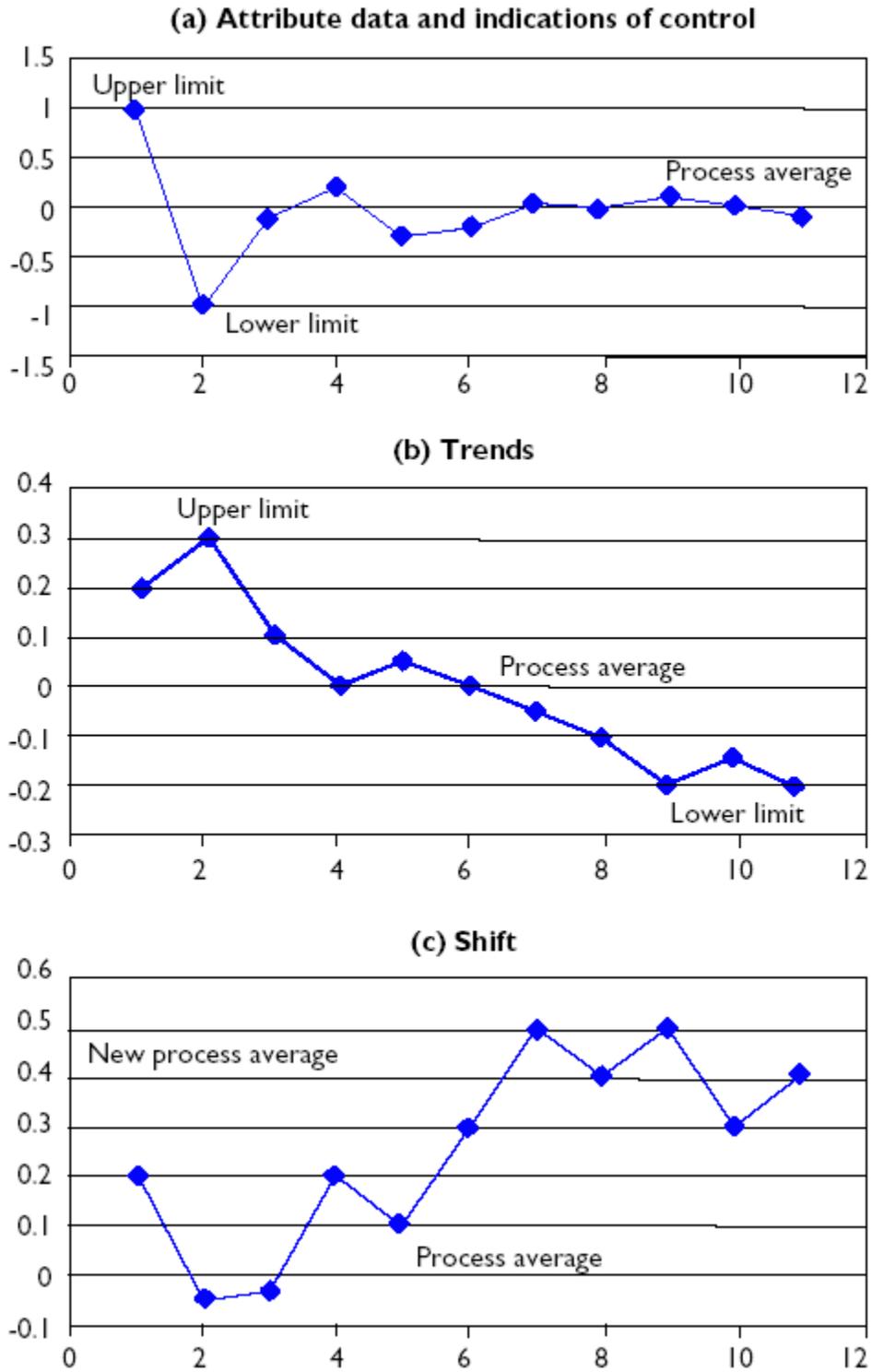
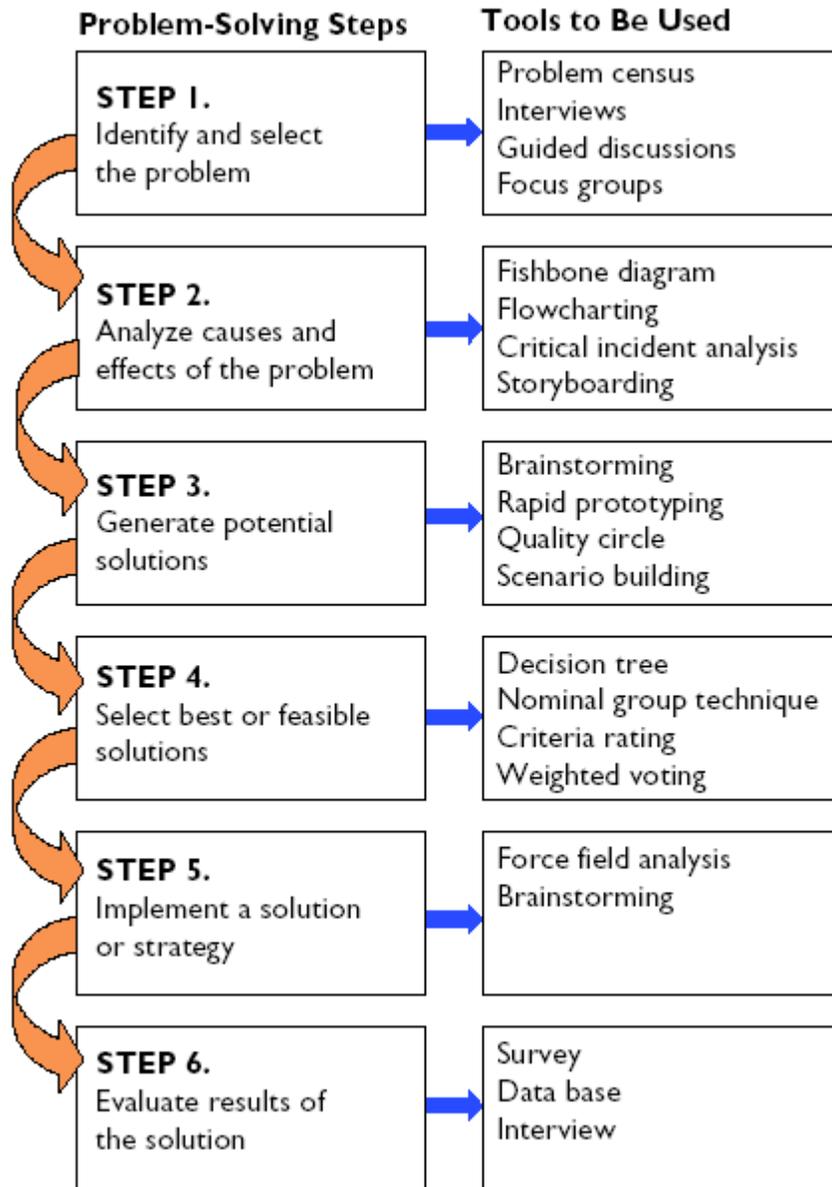


Figure 4.8 Statistical Tools for Problem-Solving



Many times, information received is misused, or nothing is done about it. We often treat the "status quo" as all we can do. The purpose of this clause is to eliminate that feeling, help you organize and plan activities to obtain direct or indirect customer feedback, analyze the information, and make an action plan to resolve issues. As a top company priority, management reviews shall devote considerable time to analyzing customer satisfaction and the necessary action to resolve these problems.

Various methods exist for gauging customer satisfaction. Some data sources are as follows:

- \* Customer complaints.
- \* Customer returns.
- \* Questionnaires or surveys.
- \* Warranty claims.
- \* Direct customer contact.
- \* Benchmarking data.
- \* Industry reports or studies.
- \* Consumer organizations.

Statistical analysis of the data is very important. Usually it helps to select some large customers and work together with them on major issues. Follow-up and attention to complaints until their resolution helps eliminate a large percentage of complaints and also allows the customers to feel more closely related to your company.

The action plan and the management review provide documents that shall be recorded, which will be audited by the ISO inspector during your official audit report. The ISO standard requires two types of audits—internal and external.

## **4.2.2 Internal Audit (Clause 8.2.2)**

The purpose of this clause is to verify through "quality audits" that the procedures for planning and implementing your quality system are being followed and planned results achieved. These audits are also necessary to determine the effectiveness of the quality system. If the planned results are not achieved, the activities should be corrected and improved. The process of implementing a quality system is a long one and involves hard work on the part of many people. If the system is implemented without periodic checking, procedures will tend to be changed, abandoned, and soon forgotten. Quality management requires that an auditing method be in place to verify that procedures continue to be kept up-to-date and followed.

### **4.2.2.1 The Internal Audit**

An internal audit is your company's self-audit. Internal audits should be organized and planned by the quality organization, and properly documented to show that they have been carried out in a



systematic fashion and that reports have been issued for review by the management team. Audits are generally implemented by personnel who do not work in the operation being audited. The audit consists of the following activities:

1. Select the process to be reviewed.
  - Review process flow and activities.
  - Plan which part of the process will be audited.
  - Recognize the input and the output typical of the process.
  - Recognize the responsibility and authority of all members.
2. Plan and execute activities.
  - Review procedures.
  - Observe whether procedures are being followed.
  - Talk with and observe the people carrying out these procedures.
  - Look at the actual records of the operation contrasted with the requirements.
3. Check the process performance and achievement of goals.
4. Report and take corrective or preventive action, if necessary. A report should be written for the area manager and the management review. **(Clause 5.6.2)**

**Form 8.2-1** is useful for planning an audit. Refer to the self-audit exercise in box 4.2 to see the most commonly asked questions in an internal audit. The results of the audit will be brought to the attention of the responsible manager for the operation being audited. If corrective action is required, the responsible manager should initiate this in a timely manner, update the procedures to reflect new knowledge and best practices, or train personnel if they are not following the procedures properly.

The goal of the audit is to confirm, in an objective manner, that the processes are being followed correctly and that everyone is doing what ought to be done. The auditor should also review whether employees have adequate training and understanding to perform their jobs well. Corrective or preventive action is a normal outcome of an audit (see figure 4.9).

The audit should be recorded on a form similar to form 8.2-2. To avoid a conflict of interest, people not involved in the operation ideally should perform the audit. Many alternatives should be tried, even using personnel from a different company to obtain objectivity in the review. The frequency of auditing shall be planned and related to the importance of the operation being audited and the company's experience with problems in that area, as shown by previous audits.

The audit report should include a review of the operation to assure that the previous corrective actions were made and that improvements in the operation have been properly documented.



**Form 8.2-1 Audit Planning**

1) Name of Management Representative responsible for internal audits:

\_\_\_\_\_

*(Note: Auditor must be independent from the function being audited.)*

2) Schedule of internal quality audits

Audit period	1st quarter	2nd quarter	3rd quarter	4th quarter
Contracts	_____	_____	_____	_____
Procurement	_____	_____	_____	_____
Receiving	_____	_____	_____	_____
Design	_____	_____	_____	_____
Manufacturing	_____	_____	_____	_____
Testing	_____	_____	_____	_____
Packing/warehouse	_____	_____	_____	_____
Shipping	_____	_____	_____	_____
Installation	_____	_____	_____	_____
Service	_____	_____	_____	_____
Records	_____	_____	_____	_____

Year: \_\_\_\_\_

3) Audits performed and reviewed

Auditor	Group	Group manager
_____	Contracts _____	_____
_____	Procurement _____	_____
_____	Receiving _____	_____
_____	Design _____	_____
_____	Manufacturing _____	_____
_____	Testing _____	_____
_____	Packing/warehouse _____	_____
_____	Shipping _____	_____
_____	Installation _____	_____
_____	Service _____	_____
_____	Records _____	_____

4) Results of individual audits should be appended to these records and copies should be filed with the permanent quality records

## Box 4.2 Self-Audit Exercise

### Documentation:

1. Is your quality management system documented?
  - Quality manual.
  - Flow charts.
  - Standard operating procedure.
2. Does your documentation system prevent the use of obsolete procedures or processes?
3. Do you keep quality records? Are they legible, identifiable, and easy to access?
4. Do you have a documentation control system to keep all documents and specifications up-to-date?

### Purchasing, materials, and supplies:

1. Do you have a formal process to select and evaluate suppliers?
2. Do you have a list of approved vendors?
3. Do you ensure that key services and materials are purchased only from approved sources?
4. Do you have specifications for your materials, and are they updated?
5. Do you have a control procedure for the release of purchase orders and their content?
6. Do you have control of incoming materials and their conformance with the specification and delivery schedule?
7. Do you keep records and statistics on the performance of each vendor with regard to quality and delivery expectations?

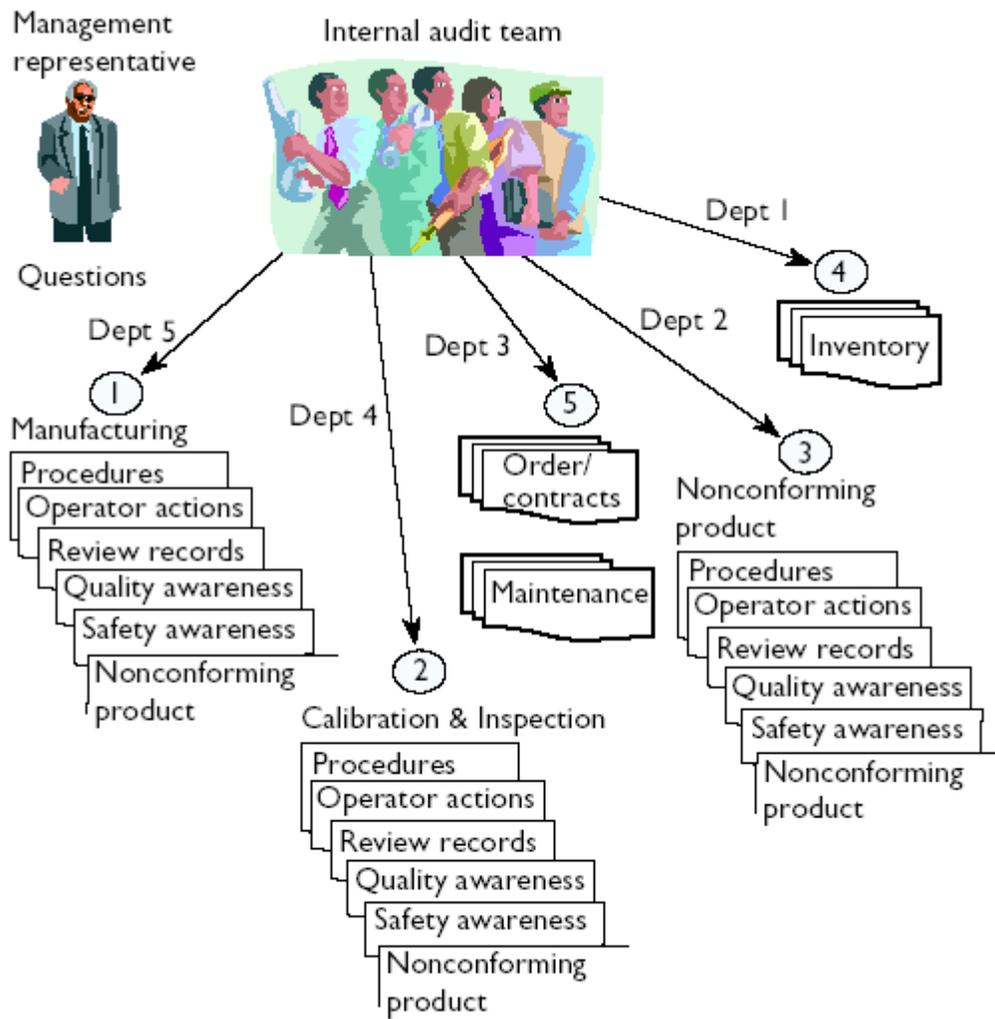
### Manufacturing:

1. Is there a procedure to establish and document new manufacturing processes?
2. Do you have written instructions or charts to cover all operations, especially those critical to quality?
3. Do you have a formal training program?
4. Do all operators performing a task receive training and have knowledge of the task and its impact on the quality of the product?
5. Do you keep records of quality at different stages and plot deviations of parameters critical for each operation?
6. Does each employee know equipment operating parameters and preventive maintenance requirements?
7. Does the operator know where to find the documentation for the processes?

### Nonconforming material or product:

1. Does each operator know the procedure and records needed for the disposition of nonconforming products?
2. Is the nonconforming product identified properly and isolated from standard products?
3. Is the operator aware of the notification process, and does he or she issue reports on nonconforming products immediately?
4. Are repairs and rework documentation completed and the product re-inspected before release?
5. Is a procedure in place for investigation of nonconformance, and is corrective action taken?

Figure 4.9 Internal Audits



**Form 8.2-2 Internal Audit Report**

Internal audit number _____	Date _____
Auditor _____	Department audited _____
	Process audited _____

Operator talked to: \_\_\_\_\_ Date: \_\_\_\_\_

Department \_\_\_\_\_

Reports to: \_\_\_\_\_

Department manager: \_\_\_\_\_

Operation/activity audited: \_\_\_\_\_

Document/specification/process number: \_\_\_\_\_

Observation found: \_\_\_\_\_

Compliance Status:  Satisfactory  Concern  Noncompliance  Not Available

Are documented instructions available?  Yes  No

Has the operator been trained for this activity?  Yes  No

Are the instructions been followed?  Yes  No

Has previous corrective action been taken?  Yes  No

Is documentation available up to date (revision level)?  Yes  No

Has the operation manager been advised of status?  Yes  No

Manager's signature: \_\_\_\_\_ Date \_\_\_\_\_

Auditor's signature: \_\_\_\_\_ Date \_\_\_\_\_

Comments \_\_\_\_\_

Corrective action requested \_\_\_\_\_

Preventive action requested \_\_\_\_\_

Internal audits should include procurement and inventory reviews. Internal audit records are reviewed carefully during external quality audits and the certification process.

#### **4.2.2.2 Noncompliance**

The most common reasons for noncompliance during audits are shown in figure 4.10.

##### **Procedure for Corrective or Preventive Action Required**

1. Notify findings and identify nonconformity.
2. Analyze of nonconformity by statistical means.
3. Clarify the section responsible for nonconformance.
4. Investigate the root cause of nonconformity.
5. Evaluate and plan corrective action.
6. Implement corrective action.
7. Record results of corrective action.
8. Evaluate results and confirm effectiveness of action taken.
9. If the action was not effective, repeat the process until nonconformity is resolved.

#### **4.2.3 Monitoring and Measurement of Processes (Clause 8.2.3)**

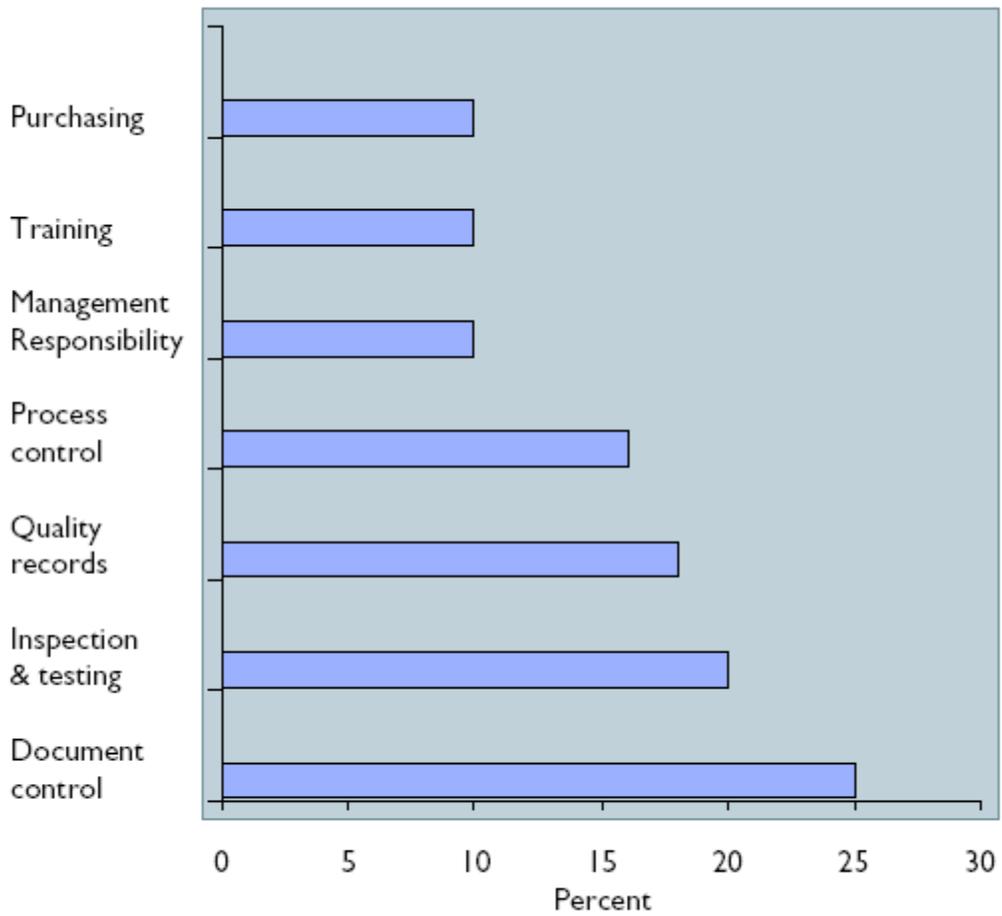
This clause is new and should not be confused with the effort of monitoring and measuring parameters in a manufacturing line for the product realization. Instead, this clause goes beyond such an effort and includes the need to monitor and measure the manufacturing parameters.

The whole standard is based on a sequence of processes that were explained in paragraph 1.5.3 of this manual. This clause attempts to monitor and measure the success or failure of the sequence of processes that integrates the organization. Several processes cannot be measured in the commonly known parameters, but they can be monitored and evaluated by the degree of failures to achieve goals. One example can be the failure to deliver a product at the date promised by the sales department to the customer. This can be caused by deficiencies in the manufacturing (product realization) cycle or could be the result of a wishful plan from the salesperson in order to obtain the order. If this condition repeats itself, the process of booking the orders must be reviewed and a realistic schedule proposed.

The most typical interpretation of the monitoring and measurement activity corresponds to the design effort and the product realization effort. A plan must be developed to provide management with key measures that indicates the health of specific efforts that are critical to the success of the organization. Usually you can identify hundreds of parameters and data that could be of



**Figure 4.10 Most Common Reasons for Noncompliance**



Source: *Computer Technology Review*, September 1992.

relative importance. The challenge is to select the important parameters for key processes that limit the ability to satisfy customer requirements.

The use of statistical techniques helps to provide these measurements and analyze the monitoring details. The relevant procedure(s) should be identified and incorporated into the Quality Manual and into the items in the management review process. If some of the data or monitoring is found to be irrelevant to the goal of controlling and improving the processes efficiency, they should be discontinued; but any modifications to the monitoring and measurement procedure in the manual should be made only after approval by the proper authority.

#### **4.2.4 Monitoring and Measurement of Product (Clause 8.2.4)**

The measurement and monitoring of product characteristics at various stages in the manufacturing cycle or product realization were discussed at length in chapter 3 of this Manual.

The intent of the present clause is to monitor the products or services, ensure that all critical parameters listed in the quality plan are adhered to, and ensure that recorded evidence exists that the monitoring and measurement took place for all products or services. The various steps in the process are to be monitored to assert the fulfillment of the quality plan. The purchased components, their incoming inspection and certification, and the necessary output parameters characteristic of all steps in the realization process all have to be listed and the method of acceptance documented. Sometimes a dedicated person monitors the process to ensure that the adequate steps and measurements have been taken. Often, the next operator in line is the one that performs that function. Whichever procedure your company adopts as the most adequate and practical shall be listed in the Quality Manual and monitored for the responsibility of accepting the materials.

The identity of the person charged with monitoring shall be noted in a routing ticket or an acceptance document. For intermediate steps, this could also imply that if materials are accepted for further processing before all the required acceptance procedures have been completed, the materials must be identified for potential removal if the specified parameters are not met.

The most critical step for monitoring and measurement takes place at the final test and inspection of the product. This is the last stage where you have control of the product before its release to the customer. Records of all tests made and the parameters observed are part of the records that show that the product meets the customer requirements. An authorized management representative or a



designated person is usually responsible for the final release of the product; this person exercises the release authority.

Sometimes the results of the final test are not yet available when the product needs to be released. In these cases, the product can be released with the customer authority and under conditions of a recall if further testing and adjustments are needed or if a failure to meet the specifications is detected. This can happen when a voltage regulator unit is released without a final burn-in process, and it is later found that some components show instability in the output voltage that requires adjustments.

The main requirement of this clause is to maintain positive records that the product has met all the specified requirements during the manufacturing cycle and before final release.

### 4.3 Control of Nonconforming Product (Clause 8.3)

There will be times when things don't work as planned and some quality problems arise. At such times, actions should be taken to identify and address these problems as soon as possible. In the interim, however, some product may be nonconforming and may not meet intended specifications or performance parameters. **(Form 8.3-1)**

This section of the standard requires that procedures be established for handling and identifying corrective action and for the handling and disposition of nonconforming products. Information about product deviation, corrective actions, and proper disposition of the product should be recorded. The customer and other affected parties, internal or external, should be notified. A flow chart for handling the nonconforming product is shown in figure 4.11.

This section emphasizes the necessity of first identifying the nonconforming product. This may be accomplished by inspection or testing—either during manufacturing or during the final test. It might also happen as a result of a customer complaint or a warranty claim.

Second, your company must segregate the nonconforming product and identify it by means of labels or tags or by placing it in a separate physical location. This will prevent errors caused by mixing this product with good materials. While awaiting disposition, nonconforming products should be stored apart from the area where good materials are being handled.

The materials or products should be reviewed. The decision about their disposition should be made by the management representative, together with others with responsibility and authority to make this decision. In some cases, the customer must be notified and will participate in this decision.



**Form 8.3-1 Form for Product Status, Disposition, and Corrective/Preventive Action**

1) **Product name:** \_\_\_\_\_

2) **Unique ID:** \_\_\_\_\_

3) **Tracking product status**  Pass  Fail (If status is "fail," complete No. 4 below)

Location	Received By	Date/Time	Status
_____	_____	_____	_____
_____	_____	_____	_____
<i>(ex., Receiving)</i>	<i>(Name or Initials)</i>	<i>(ex., 99-10-01, 8:35)</i>	<i>(ex., pass/fail)</i>

4)  **Product nonconformity**  
Reason for nonconformity \_\_\_\_\_  
Product removed to *(Location)* \_\_\_\_\_

Disposition of nonconforming product:

- Reworked to meet specifications  Accepted with or without repair by concession  
 Re graded for alternative applications  Rejected or scrapped

5) **Authorized signature:** \_\_\_\_\_ **Date** \_\_\_\_\_

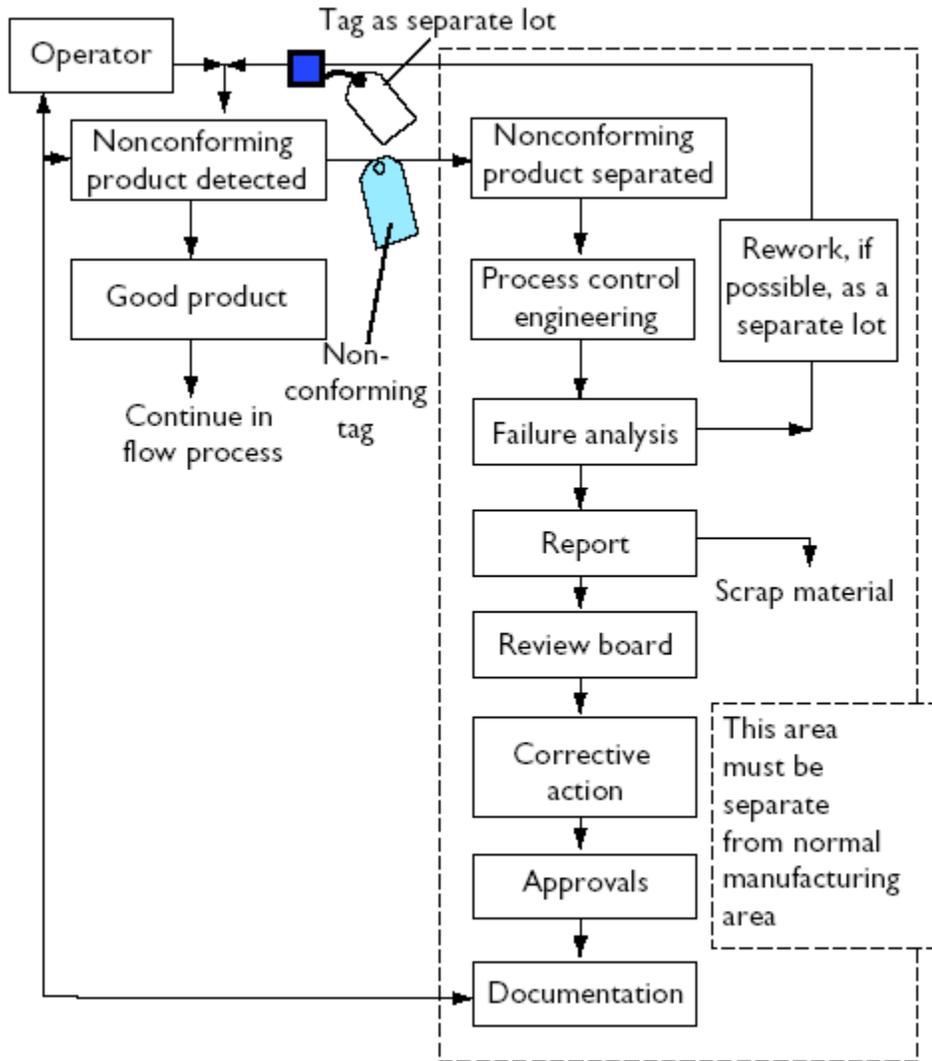
6) **Corrective action**  
 Handling customer complaints or product nonconformities  
 Investigation of the cause of product nonconformities and documenting the results  
 Determine corrective action  
 Apply controls to ensure that action is taken and is effective

7) **Authorized signature:** \_\_\_\_\_ **Date** \_\_\_\_\_

8) **Preventive action**  
 Assess and use information from process audits, customers, records, service  
 Determine steps needed to deal with any problem requiring preventive action  
 Initiate preventive action and application of controls to ensure effectiveness  
 Submit management reviews, documentation of actions

9) **Authorized signature:** \_\_\_\_\_ **Date** \_\_\_\_\_

Figure 4.11 Handling a Nonconforming Product



The nonconforming product can be disposed of in various ways, for example, as follows:

- \* Rejection or scrapping.
- \* Acceptance and use as is, with some concession from the customer or user.
- \* Use as is for another application of a lower grade.
- \* Reworking or repair by an acceptable procedure with retesting and inspection after repair.

Whatever decision is made, records should be kept. A logbook note or some identification sign shall be kept for future records, in order to recall the actions taken in case similar problems arise in the future.

## 4.4 Analysis of Data (Clause 8.4)

Data analysis is one of the most useful activities of your quality system. It is noted as one of the basic quality principles from which is derived the ISO 9000:2000 quality process.

Data-gathering is a normal technique in the discussion of various sections of this standard, but data are meaningless unless they are analyzed, interpreted, and utilized to provide future corrective or preventive actions.

Although the standard mentions four critical areas of action, they shall be interpreted as a minimum. Other areas of activity should also use data to benefit in their pursuit of improvements. One clear example is the product development area. Decisions on the type and characteristics of a product should be based on marketing and competitor data, which indicate what customers want and need.

An additional goal of data analysis is to determine, by objective and measurable means, the effectiveness and performance of your quality system and to identify areas for improvement.

The specific four areas that the standard singles out for data analysis are as follows:

- \* Customer satisfaction.
- \* Conformity to product requirements.
- \* Characteristics and trends of processes and products, and possible improvements.
- \* Suppliers.

Customer satisfaction has been differentiated from conformity to product requirements so as to focus on and analyze what the customer wants or desires. The customer may be knowledgeable as to the characteristics of the specifications and the requirements, but may want to see a different product, even if it does not meet those requirements. This usually offers an opportunity to design a new product and gain a new market area, although it may not be for a product that meets existing norms. A good example is the



development of a marine module for the United States Coast Guard, which had very specific requirements that no other module could meet, even though the other modules met normal specifications for a photovoltaic module.

Data analyses can help evaluate the following:

- \* Product performance deviations.
- \* Training effectiveness.
- \* New processes.
- \* Evaluating customer complaints.
- \* Missed delivery dates.
- \* Customer satisfaction levels.
- \* Critical process performance.
- \* Supplier selection and materials improvement.

Statistical methods, such as those described earlier, offer important tools for analyzing data. Different methods can be applied, depending on the type of data, but the results of analysis must be oriented toward elimination of nonconforming product or product improvement. Achieving both these objectives will improve customer satisfaction, as well as the operational performance of your company.

There cannot be continuous improvement without continuous data analysis.

## 4.5 Improvement (Clause 8.5)

### 4.5.1 Continual Improvement (Clause 8.5.1)

The quality management system may not always be perfect in its implementation. Many loopholes and problems can develop, which can lead to nonconforming products that demand corrective actions. Many of these problems are caused by defective training that can be avoided if your organization has better training or a different type of training. Some are related to product issues that result in customer complaints or lack of satisfaction. Many of these issues can be approached by preventive actions, which are discussed below in section 4.5.3.

In order to enhance the effectiveness of your quality system, the management of the organization has to analyze the goals of the quality plan, continuously monitor progress towards these goals and adjust goals as needed. This cannot be viewed as an arbitrary goal setting exercise. It is a serious undertaking coming out of the Management Review for which resources will be made available. The continuous enhancement of goals requires continuous review and data analysis to assess progress made throughout the year. Achievement of small steps in the quest for improvements is the basic principle on which this effort is based.



The quality system must be perfected to eliminate nonconformance through use of corrective and preventive actions. The intent to continually improve the System should be part of your company's quality policy.

#### **4.5.2 Corrective Action (Clause 8.5.2)**

Corrective action is a useful tool in all quality systems. The need for change arises when products are not meeting the desired performance of a service or manufacturing organization. The corrective action called for in the standard goes beyond product or service analysis. It encompasses all the processes of the organization, starting in sales and marketing and ending at analyzing customer satisfaction with the delivery. For example, a delayed shipping date can make for a very unhappy customer, even though your product meets all requirements and is in conformance with contract specifications.

Corrective action processes are usually undertaken when a condition of nonconformity occurs with certain frequency. An occasional event does not usually trigger corrective action. This is why data use and analysis are important first steps prior to initiating such action. Usually the need for corrective action arises from internal nonconformity, warranty claims, product returns, customer complaints, internal audits, or problems encountered with a supplier.

A documented procedure shall be part of the Quality Manual to indicate how to implement and carry out corrective actions, and how to approve the resultant requests for action. The first step is to determine the root cause of the nonconformance and the underlying source that creates the problem. Data analysis can indicate the following root causes:

- ✱ Inadequate procedures or documentation.
- ✱ Inadequate process control.
- ✱ Defective or inaccurate equipment controls.
- ✱ Poor scheduling.
- ✱ Insufficient training or human resources.
- ✱ Inaccurate facilities and working conditions.

Data can be obtained from the following sources:

- ✱ Inspection records of product and raw materials.
- ✱ Operator observation during monitoring.
- ✱ Internal audits.
- ✱ Customer complaints about the product or service.
- ✱ Supplier changes or problems with existing ones.
- ✱ Management review of quality goals.

A corrective action process requires that you identify the root cause of the problem, as well as various trials for its correction.



Analysis of the results of these trials will indicate whether the root cause has been clearly identified and corrected, and will thus justify the recommended course of action. A typical technique used is the design of experiments. This technique is valuable for complex problems where several variables can affect the results; it is frequently used to optimize process variables. Care should be taken to avoid solving one problem and generating another one further along in the process.

The analysis of the verification shall be used to assert whether the solution is appropriate to the problem and whether action is warranted. The necessary action should be recorded for future audits and potential correction in the future. One example is the need to replace a large piece of equipment that requires capital investment and for which no capital is presently available. The corrective action results can be an important means of justifying the proposed investment.

If the corrective action requires changes in your company's Quality Manual, process documentation, or changes in the procurement specifications, they shall be approved by authorized personnel and taken in accordance with the documentation procedures described in clause 4.2.3 (section 2.1.3). Once corrective action is implemented, a validation process concerning the actions taken is needed. Records should be established to confirm that these actions were effective.

All these actions should be part of the management review process and part of the record of its activities. If the corrective action originated from a customer complaint, the customer should also be notified of the action and a follow-up procedure established to confirm the solution of the problem and to reestablish the customer satisfaction.

### **4.5.3 Preventive Action (Clause 8.5.3)**

Preventive action is frequently confused with corrective action. Both deal with the same issues: avoidance of nonconformance and improvement of customer satisfaction. The difference is the point of departure for these two actions. Corrective action is taken after the fact; that is, it takes place as a result of a recognized problem. Preventive action is an action taken prior to a problem to prevent the problem from occurring. A simple and useful comparison is the difference between fire prevention and putting out fires.

Quality improvement activity is usually enhanced by preventive actions. This requires a thorough knowledge of the processes and the product, a vision of what could go wrong, and what should be done to prevent this from happening. Several techniques help prevent problems. Most of them are based on analysis of failures and their consequence. A clear example is offered by the automotive industry, which has various types of tires and limits on the



capability of their use for specific vehicles. Accidents can be prevented when proper tire size and quality are used, although this might be more expensive.

The most common preventive action technique is the failure mode effect analysis (FMEA). This technique, used in aerospace and the automotive industry, evaluates the potential consequence of a failure and compares its relevance to the effectiveness of a change to prevent the failure.

The preventive action procedure shall be documented in your Quality Manual and form part of the management review process. Resources are usually needed and must be provided, whenever justified by the data. Verification and validation of the results are also needed, and records must be kept of these results.

Some of the preventive actions that require continuous attention are the following:

- ✱ Planned preventive maintenance of equipment.
- ✱ Improved control equipment.
- ✱ Improved training of operators.
- ✱ Monitoring of operator activities to prevent mistakes.
- ✱ Systematic improvement of facilities to allow easier operating conditions.
- ✱ Review of schedule and plant capacity to allow upgrades before demands increase.
- ✱ Implementation of new products and technology to satisfy new customer needs.

The continuous improvement process is best achieved through preventive action, which is more in tune with the main goal of ISO 9001:2000: "Complete Customer Satisfaction"



# Chapter 5. Photovoltaic Standards



## 5.1. Existing Standards and Specifications

### 5.1.1 What Is a Standard?

A standard is a norm that all interested parties have agreed upon, such as the width of a railway track, the spelling of a word, the size of a golf ball, the way a CD-ROM disc goes around, or the way a PV installation should perform.

There should be a standard for your PV system. Moreover, there should be standards for the components and materials used in the PV system, from the PV module itself, the charge-controller, and the battery right down to the wiring, junction boxes, and wall fixing screws. There should be standards, too, for all the loads you are likely to power with the system, beginning with the lights and water pumps.

A technical standard is a document that describes a material (for example, glass), component (for example, charge controller), or system (for example, solar home system). It consists of the following:

- ✦ Test items (for example, appearance, labels, and each of the important functions of the product. In the case of a charge controller, test items might include set points, a high-voltage disconnect, temperature compensation, and the like).
- ✦ Technical requirements (for each test item).
- ✦ Test methods (for each test item).
- ✦ Sampling procedures.
- ✦ Quality assurance (for each test item, for example, procedures for test failures and repeat testing).

### 5.1.2 Why Are Standards Needed?

A need can arise to standardize a material, a product, or a system because of the manufacturers' desire to have interchangeable products, or because of the public or government. Standards are needed to define the product technically, and to define the various characteristics (length, width, weight, and the various measures of its performance). Standards also define how these characteristics should be measured.

## Case Study No. 5

### PV STANDARDS

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Early in the history of the terrestrial utilization of PV, it was realized that product reliability would be an extremely important matter for the acceptance of PV as a viable energy source for the future. The very first step in defining a benchmark for PV product reliability was taken by the Jet Propulsion Laboratory of the California Institute of Technology (JPL).

At that time, JPL was the U.S. leader in promoting PV development. In order to further production of PV modules, JPL initiated a program in 1975 to buy a large quantity or "block" of PV modules from manufacturers. "Large quantity" in those days meant 2–10 kWp.

In the tender (bid) to buy the PV modules, JPL established quality control methods and acceptance test criteria for the purchased modules. This was the first time terrestrial PV modules had ever been subjected to any kind of quality control and acceptance test procedures. Until JPL established its criteria, manufacturers tested their modules to internal procedures. Those manufacturers who wanted to sell to JPL had to accept JPL's test requirements and allow a JPL inspector to observe the performance of their modules during the tests.

To the great surprise of practically all the manufacturers under contract to produce modules under this JPL program, their modules failed. Some of the companies succeeded in identifying and solving the problem and salvaging their contracts, as in the following examples:

- ☼ In one case, a module failed during humidity testing. The company found out that the cause was that the plastic coating to protect the cells repelled water, but not humidity. Therefore, the solar metallization was corroding. The company had to develop a cell metallization process that would not corrode in humidity. After the process was changed, the module was successfully tested and accepted by JPL.
- ☼ In another case, a module failed during temperature cycling. The company found that the temperature coefficient of the used materials was too great. As a result, the entire design of the module had to be changed before it could pass the test.

After this first "Block I," JPL repeated the purchasing process four more times. In those Blocks (II–V), requirements for acceptance testing became even more stringent, based on the experiences of the previous blocks. The JPL testing specifications became the "standard" that other buyers of PV modules started to use. Ultimately, a modified version of the Block V specification became the IEC standard for crystalline PV modules.

JPL established quality control methods and, in successive purchases, enforced higher and higher quality specifications. As a result, PV modules now come with a 20–25 year warranty. If JPL had not established these specifications, there would be no PV industry today. What can be learned from this story?



- ✿ Any standard (test specifications) is better than having none. The standard is a benchmark against which every manufacturer can measure its product quality.
- ✿ Standards should be updated based on what is learned through their application.
- ✿ Utilizing standards will result in superior products.

## 5.2 How Are Standards (Specifications) Established?

### 5.2.1 National or Regional Standards

National or regional standards are established within a country or region. Many countries have a national standards organization, which is usually a government agency. In Europe, standardization occurs at the national level, although in the European Union, the standardization body, which has the authority for PV, is called CENELEC (European Committee for Electrotechnical Standardization). In the United States, the situation is more complex. There is no one government agency responsible for standardization. Many public and private organizations develop standards. In the field of photovoltaics, the safety standards are established by Underwriters Laboratories (UL). Other U.S. standards organizations relevant to photovoltaics are the Institute of Electrical and Electronics Engineers (IEEE) and the American Society for Testing Material (ASTM). Both are private, nonprofit organizations.

Despite such national and regional differences, in general, the process used to establish a standard is similar:

1. Standards are developed based on the knowledge and experience of many experts. Typically, products or materials are tested in the laboratory and also under field conditions. The experts, who may be working for the government, a manufacturer, or a customer form a committee and establish an initial draft.
2. After an initial draft of the standard is written, the passing of a standard requires a consensus of the experts.

National and regional standards have limitations in an international economy. A manufacturer producing a PV product in a particular country should test the product according to the pertinent national standard. If the product is sold in another country or region, however, the PV product has to be retested according to the standard of that country or region. This may require the modification of the product or, at a minimum, the expense of retesting.



## 5.2.2 International Standards for PV (IEC Standards)

The IEC issues the internationally accepted standards for PV. The IEC's principal activity is developing and publishing international standards and technical reports. These international standards serve as references when drafting international tenders and contracts. Box 5.1 describes the advantages of having an international standard in place.

The IEC is a worldwide federation of national standards bodies (IEC member bodies). The work of preparing international standards is normally carried out through IEC technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, as well as governmental and nongovernmental bodies also take part in the work.

The IEC has recognized the need to develop international standards based on market demand. The standards work of the IEC is carried out by technical committees, subcommittees, and working groups. IEC standards prepared by the technical committees are then submitted to the full member national committees (IEC members) for a vote with a view to their approval as international standards. Publication as an international IEC standard requires the approval by at least two-thirds of the member bodies. Because of this approval procedure, the completion time for IEC standards takes at least two to four years.

The IEC has already approved module standards, but it is still working on the standards required for all other system components—such as controllers, batteries, inverters—as well as the standards for the reliability, sizing, and performance of the totally integrated solar home system.



### Box 5.1 Advantages of Having a Global Standard

Bad example: TV is a prime example of the problems that can arise, if national or regional standards are used for a global product. Several TV standards were established and adopted by different countries.

European countries, for example, use three or four different TV standards. As a result, anyone who wants to see TV programs from another country, must purchase a more expensive TV set, that is equipped with circuitry capable of receiving and processing the signals utilizing different standards. To make things more complicated, the same problem exists with VCRs. If one wants to tape a program and take it to another country, a VCR in that country may not be able to play it, unless one has a special VCR and also a special TV with the ability to handle multiple systems.

Good example: Fax technology is a good example of the advantages of global standards. Fax machines were initially manufactured in Japan. Their use spread too quickly for development of either national or regional standards. Thus, fax machines can communicate with each other all over the world. This has helped the global market for fax machines to grow very quickly.

Good example: The compact disk (CD) was the joint development of a Netherlands and a Japanese company. Only one standard exists, even though one might assume that there would be at least two, corresponding to the nationalities of the two companies in the venture.

The fax and CD examples show the distinct advantage of having global standards, instead of national standards. This is especially important for photovoltaics because photovoltaics is already a global business. Components and systems are manufactured in numerous countries. Therefore, the best scenario is to unify all standards activities into a global or international standard

## 5.2.3 The Two Categories of IEC Standards for Photovoltaics

### 5.2.3.1 Standards Developed Specifically for PV Applications

IEC standards originate from a request to write a standard for a certain product or system. The request becomes a "new work item" assigned to one of IEC's technical committees (TC). The IEC TC 82 handles PV. Within IEC TC 82, photovoltaics becomes a work item for one of the working groups (WGs).

Technical Committee No. 82, Solar Photovoltaic Energy Systems, has at the moment seven working groups:

- ✱ WG 1: Glossary.
- ✱ WG 2: Modules, nonconcentrating.
- ✱ WG 3: Systems.
- ✱ WG 5: Quality and certification.
- ✱ WG 6: Balance-of-system components.
- ✱ WG 7: Concentrator modules.

In addition, technical committees JCGTC 82/TC88/TC21/SC21A are responsible for : Decentralized Rural Electrification (DRE).

The members of the IEC working groups are experts acting in an individual capacity; they come from industry, as well as from other technical or governmental organizations.

### 5.2.3.2 Standards Developed for Other Applications Could Be Used for Photovoltaics

IEC standards established for other applications (for example, low-voltage switches, low-voltage connectors, wiring, and the like) could be utilized for PV applications. PV GAP will identify and review these standards to determine their applicability for photovoltaics. If the review shows that these standards are appropriate, PV GAP will list them as an IEC standard to be utilized for PV components or systems, or both.

PV GAP has compiled a list of both the IEC standards for photovoltaics and the IEC standards developed for other applications, which should also be used for photovoltaics. The lists of most of these standards available as of January 2002 are attached as appendices 3 and 4, respectively. A list of IECQ publications can be found in appendix 4.

A list of the open work items and their project leaders is also included in appendix 3.

## 5.2.4 PV GAP Recommended Specifications (PVRs)

Given the urgent need for PV standards, an interim solution was sought to provide internationally accepted PV "guidelines" within a



shorter period than the 2–4 years it takes to develop and establish an IEC standard. The creation of PV GAP facilitated the development of a complementary system to achieve international consensus on new specifications for photovoltaics in no more than six months. These interim specifications are called "PV GAP Recommended Specifications" (PVRs).

The ultimate goal is still to test PV components and systems to international (IEC) standards. Where no IEC standard exists, however, PV GAP will recommend that certain specifications be developed, based on the consensus of experts. In such instances, PVRs are the fastest way to achieve an interim international "benchmark" for a PV product. (See appendix 5 for a list of PVRs.)

PV GAP has established a Technical Specifications Committee to assure that its PVRs are based on a wide consensus within the industry. This committee has a broad and international representation and is open to anyone with proper qualifications.

The PV GAP Technical Specifications Committee, as shown in figure 5.1, may utilize one of the following as the basis of a PVR:

- ✦ A national or regional standard.
- or
- ✦ If the above are not available, a draft submitted by one or more committee members.

#### ***5.2.4.1 National or Regional Standards***

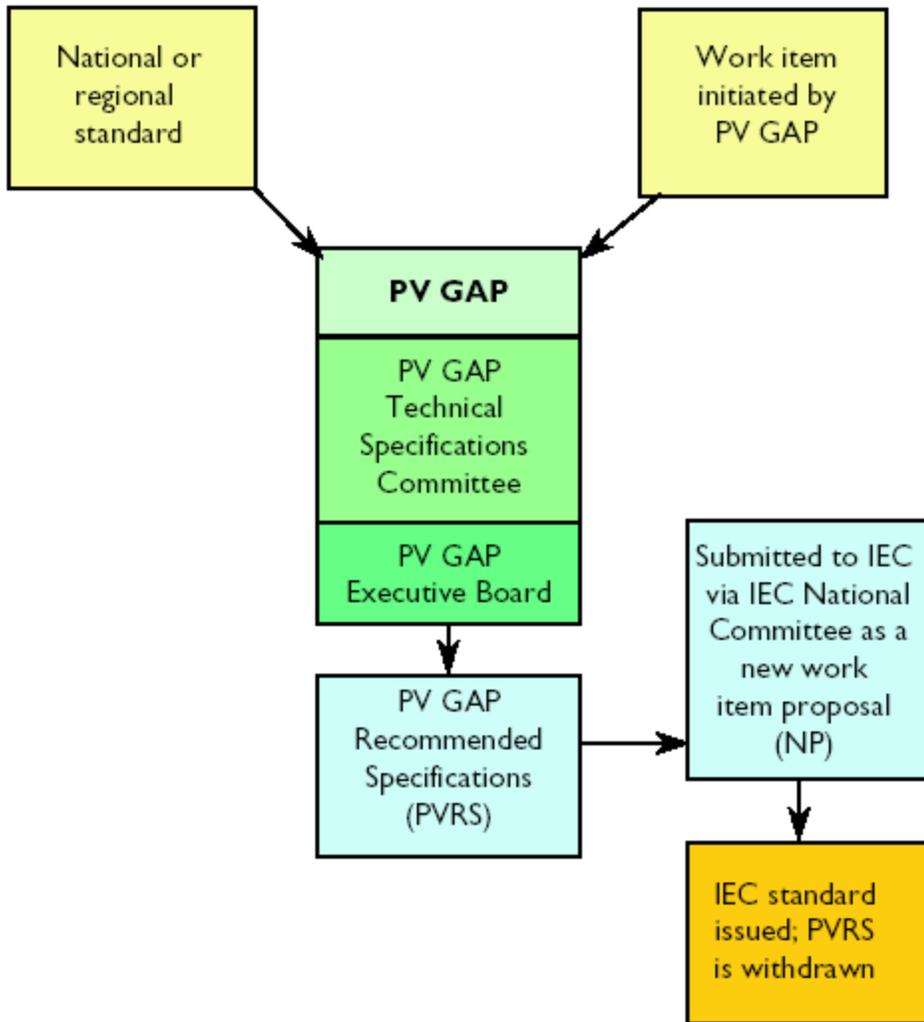
Several national or regional PV standards developed over the years have not been incorporated into the IEC system, or they differ slightly from existing IEC standards. These standards can be very valuable, given the general lack of PV standards. The international industry problem created by multiple national or regional standards has been described above. The advantage of reviewing these national or regional PV standards by PV GAP and establishing a PVR with those found acceptable is that this offers an international specification that eliminates the need for country-by-country retesting.

#### ***5.2.4.2 New Work Item Initiated by PV GAP***

Members of PV GAP may also propose PV standards. For example, the so-called Product Quality Assessment Specification (PQAS) for photovoltaics did not exist until recently. (PQASs will be discussed in section 5.4 below.) PV GAP initiated these specifications. After the draft of the specifications was drawn up, the procedure for issuing the specifications followed the steps described previously. Following the approval of the PV GAP Board, the resulting PVR was submitted to IEC TC 82 as a new work item proposal.



**Figure 5.1 PV GAP Recommended Specifications  
(If no IEC standard exists)**



#### 5.2.4.3 Description of the Process to Establish a PVRS

A draft version of the specification is formulated and circulated among the members of the PV GAP Technical Specifications Committee. It is important to note that the membership of the PV GAP Technical Specification Committee is open to any qualified person in any country. This provides an international consensus for the establishment of a PVRS. Suggested technical modifications are submitted to the chairman of the committee, who reconciles them into a second draft, which is circulated again. The final vote is then either held by correspondence (E-mail) or at a meeting of the Technical Specifications Committee.

The Technical Specifications Committee then sends the PVRS to the PV GAP Board. The PV GAP Board decides whether to accept the PVRS or to ask the Technical Specifications Committee to consider changes. After the PV GAP Board accepts a PVRS, it is published as the interim Recommended Specification to be used until a corresponding IEC standard is completed. If the basis of the original draft PVRS was other than a new IEC work item, the PVRS will be immediately submitted as a new proposal (NP) for a work item to the appropriate IEC technical committee. When the resulting IEC standard becomes available, the PVRS will be withdrawn and no longer used.

At present (as of January 2002), the PV module standards used by PV GAP are the IEC approved module standards. PV GAP has issued Recommended Specifications for other components (charge controllers and inverters), and for total systems.

### Case Study 6

#### DEVELOPMENT OF A CHARGE CONTROLLER FOR NAVIGATIONAL AIDS

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One of the best applications for photovoltaic energy has been in the field of marine navigational aids. However, substantial design efforts were required to overcome the harsh environmental factors associated with this application.

Most navigational aids are deployed in the middle of a body of water, such as a sea or a river. Depending on their location, they may be subject to extremely hot temperatures (as in the Middle East, for example) or extremely cold temperatures (as in Canada). Their support structures are neither firm nor easily oriented toward the sun. Moreover, birds frequently perch or build nests on the modules, fouling all exposed areas.

Various navigation authorities have issued product specifications, because standard products generally cannot meet reliability expectations in marine settings.



The most significant difficulties associated with this application have occurred around system design, battery life, and charge control needs. Two distinct approaches have been utilized: (1) the design of low-voltage modules with a significantly oversized battery and no controller and (2) the use of a standard voltage module with a controller and a smaller battery that satisfies the application requirement.

The latter was utilized for the Suez Canal Authority after an early failure had been experienced. The type of buoy that controls vessels passing through the Suez Canal is an elastic buoy anchored to the bottom of the canal. Its ability to rotate is limited, so module energy production varies more widely than for a fixed installation. Furthermore, the ratio of insolation from summer to winter is four times greater if the module is installed at the winter angle. The original installation was made at an intermediate angle. The combination of the intermediate angle and the small rotational variance in some cases produced too much energy and boiled away the battery electrolyte. In other cases, not enough energy was produced, and the batteries discharged rapidly.

After a thorough analysis of the insolation was performed, new modules with adequate capacity were delivered and installed at a favorable angle for the lowest insolation level. This installation, combined with the use of a charge controller to avoid any overcharging, provided the solution for this vital waterway.

The Canadian Coast Guard utilized this important design decision, with a further requirement for environmental testing and a fail-safe system that ensures operation even if the regulator circuitry fails. In this way, the very real threat to life associated with a navigational light failure was completely avoided. The detrimental impact on the controller of the severe weather conditions in Canadian waters was resolved through the use of an anodized aluminum box with watertight glands for the access of cables.

A temperature-compensating thermistor monitors the battery temperature and allows the voltage output of the controller to increase as the temperature goes down. This feature was needed for locations where very cold temperatures require higher voltages to fully charge the battery. Low-voltage modules would not be able to charge a battery at temperatures below freezing levels.

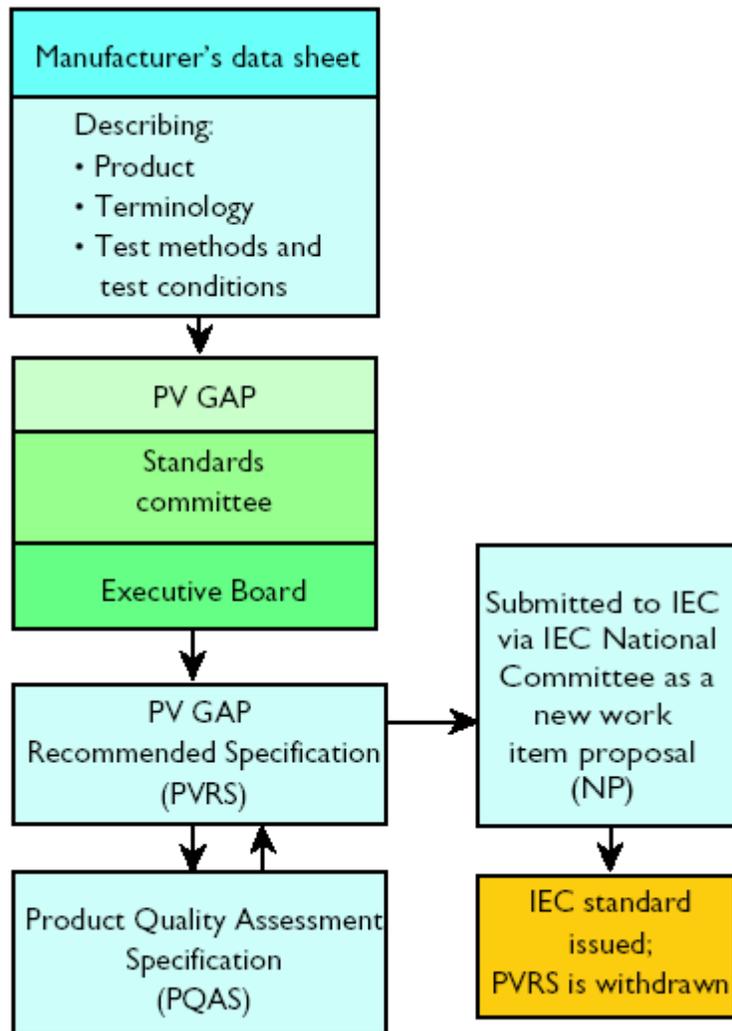
The records of reliability for these controllers have been excellent, with a return rate of less than 0.01%. The manufacturing success is the result of a detailed design effort, environmental tests under extreme conditions, and a thorough quality plan during the fabrication of the units. This plan included incoming component inspection, PC board testing, subassemblies, and final testing and calibration of every completed unit. The customer also performed an on-site sample inspection for every lot delivered.

### 5.3 When There Are No Published Standards

A PV manufacturer may seek product quality approval from PV GAP, even when there is no published IEC standard or PVRS for the component or material. The procedure (see figure 5.2) is as follows:



Figure 5.2 When No Published Standard Is Available



1. The manufacturer must have a data sheet that sufficiently describes the PV component or the material used in the production of a PV component (for example, interconnecting wires). The description must include not only the physical dimensions, but also all the characteristics of the component (for example, temperature coefficient, normal temperature range, electrical parameters, and the like)
2. The manufacturer must expand the data sheet into a component specification that fully describes the following:
  - ❑ Any necessary terminology (for example, temperature coefficient)
  - ❑ The test method (for example, for solderability), including test conditions (for example, time, temperature, and humidity) either referring to an IEC standard test or, in absence of an IEC test, to another test, which must be fully described.
3. The developed material should be submitted to PV GAP for approval.
4. The PV GAP approval process is identical with the approval process described in the development of the PVRs.
5. The PVRs will be issued.
6. A PQAS must also be prepared. PV GAP's central office could help the manufacturer with the first draft.
7. Testing must be performed in an approved testing laboratory (either on the manufacturer's premises or at an independent testing laboratory) that has IECQ accreditation in accordance with ISO/IEC 17025).

## 5.4 Product Quality Assessment Specification

### 5.4.1 Is a Technical Standard Enough?

A manufacturer sends a product to a testing laboratory and receives a test report saying that the product performed successfully. This is good news, but some important questions remain, such as the following:

- ✱ What future changes to the product would require the retesting of the product?
- ✱ What changes require full retesting, and what changes would require repeating only certain tests?
- ✱ If there are no changes, what test(s) must be repeated and how often?
- ✱ If structurally similar products are developed, must all of them be submitted for testing?



The technical standard does not answer these questions. It only provides the test protocol. Instead, one must look to something called the Product Quality Assessment Specification (PQAS) for answers.

### 5.4.2 What Is a Product Quality Assessment Specification?

A Product Quality Assessment Specification (PQAS) is a document that describes when testing will be required for a product (for example, a module) or a group of products with "structural similarity," which is in production for an extended period. The reason for retesting could be one of the following:

- ✦ The product is continuously produced for an extended period (for example, years).
- or
- ✦ The manufacturer has made changes in the materials or components used or in the design of the product.

A PQAS is basically a manufacturer's detailed product specification. For a product to be certifiable, it must be described in a detailed product specification. Standards such as the PV Module Qualification Standard, for example, IEC 61215, specify only the test protocol. They do not describe the manufacturer's product in detail and, therefore, are not certifiable. On the other hand, the UL document, UL 1703, is a certifiable standard to which UL certifies PV modules for safety.

### 5.4.3 What Is in a Product Quality Assessment Specification?

Standards organizations usually do not write detailed specifications for manufacturers' products, because they are all different in one aspect or another. They do, however, write a Blank Product Quality Assessment Specification (B-PQAS). A B-PQAS is a template to be filled out by the manufacturer for a particular product or series of products. When completed, it results in a detailed specification, which is the basis for the product's certification. It describes products that have structural similarity. It also states retesting requirements, based on industry recommendations.

A PQAS comprises the following:

- ✦ Identification of the product.
- ✦ Qualification Approval procedure.
- ✦ Quality conformance inspection.
- ✦ Modifications to the product.
- ✦ Requirement(s) for the marking of the product.
- ✦ Requirement(s) for documentation.



**Identification of the product** (for example, PV module) provides the following information:

- ✦ Specifies construction, for example, glass front, or nonglass; frame material; junction box; and other typical construction details.
- ✦ Provides drawings, including an outline drawing with the main dimensions that are important.
- ✦ Describes electrical characteristics and configuration, for example, maximum power ( $P_{max}$ ), voltage at Maximum power ( $V_{max}$ ), etc., and also the current-voltage characteristics.

**Qualification Approval** includes the following information:

- ✦ Defines the overall approval process.
- ✦ Defines requirements for various levels of manufacturing and subcontracting.
- ✦ Provides minimum testing requirements.

A **quality conformance inspection** includes the following information:

- ✦ Defines requirements for lot by lot acceptance tests
- ✦ Defines requirements for periodic testing. For example: how often you need to repeat different tests from IEC 61215.

See appendix 6, Example of a Blank Product Quality Assessment Specification (B-PQAS), and PVRS-2, and table 3 in appendix 6, Test Schedule for Quality Conformance Inspection.

**Modifications to the product**, which do and do not require retesting, include the following information:

- ✦ Defines which process or product modification requires retesting.
- ✦ Defines the retesting necessary for specific changes to the process for the product.
- ✦ Defines which process or product modifications do not require retesting.

See appendix 6, Example of a Blank Product Quality Assessment Specification (B-PQAS).

**Marking** does the following:

- ✦ Defines what markings shall be on the product.
- ✦ Provides guidance on additional information that the manufacturer may want to put on the label.
- ✦ Provides guidance for information that the manufacturer may want to put on the package.

See appendix 6, Example of a Blank Product Quality Assessment Specification (B-PQAS).

**Documentation** does the following:

- ✦ Defines what documentation shall be included with each delivery of the product.



- \* May require specific product information to be included in this documentation.
- \* Declaration of Conformity declares that the product has been released according to the detailed specification under the supervision of the IECQ procedure.

#### **5.4.4 Time Required to Complete the Blank Product Quality Assessment Specification**

Manufacturers who completed a PQAS (for example, for PV modules) have reported that it took them no more than 15 minutes to complete the B-PQAS.

### **5.5 Structural Similarity and Product Retest**

The concept of structural similarity of a product in defining exactly when a product has to be retested is very important for the manufacturer, as well as for the customer. These cost-saving concepts are benefits derived from utilizing the IECQ system.

As mentioned before, technical standards (for example, the IEC 61215) establish the test protocol. If a product tests successfully, the product quality is expected to be acceptable, but as mentioned before, several questions remain open. For example, if several products are structurally similar, yet some differ in dimensions, the question is Should every size be tested, or is testing of only one size acceptable? The other question concerns whether a product that is in production for an extended period will need to be retested. Also, if the manufacturer has made changes in the product, what change is material and requires retesting and, if retesting is needed, which test should be repeated?

These are important questions for the manufacturer, as well as for the customer. Their answer can do the following:

- \* Save money for the manufacturer.
- \* Eliminate questions as to when or how retesting should be done.

The PQAS addresses these questions. The PQAS reflects the interest of the manufacturer and also the customer, because the terms of the specifications were decided by IEC TC 82 or by PV GAP's technical committee and approved by the Certification Management Committee of the IECQ.

#### **5.5.1 Structural Similarity**

The PQAS identifies a product (for example, a module) or a group of products with "structural similarity." If a product's design, manufacturing method, and materials used are the same, but the dimensions of the product, or for example, the power output or power management capabilities of the product are different, these



products could be considered "structurally similar." In this case, the IECQ system requires the testing of only one type. The supervising inspectorate will select the type from the structurally similar products.

A PQAS represents a big savings for the manufacturer. In its absence, each customer could require testing of the product the customer is considering buying.

### 5.5.2 Retest

After successful initial testing, and when a product is in production for an extended period, when would retesting be required? The reason for retesting could be one of the following:

- ✦ The product is continuously produced for an extended period (for example, years).
- ✦ The manufacturer has made changes in the materials or components used or in the design of the product.

The PQAS addresses all these questions. Again, the time when a product should be retested, or which changes will require retesting, as well as what tests(s) should be redone, have been decided by experts on the basis of the consent of all interested parties. This eliminates questions. It also informs the manufacturer what change in material or production could have an effect on its product's performance.

## 5.6 Testing Laboratories

As mentioned earlier, a product must be tested by an accredited or approved testing laboratory to verify that the product passes all tests required in the standard for that product. The role of the testing laboratory is to test the PV component or system, or both, according to an accepted standard. The criteria for an accepted standard and PQAS have already been discussed.

Tenders (bids) for PV components and systems now require that the PV component or system be tested by a testing laboratory that complies with the ISO/IEC 17025 requirements, and that has been duly accredited by an internationally recognized accreditation organization or approved by IECQ (PV GAP).

The ISO/IEC 17025 is similar in concept to the ISO 9001:2000 requirements. To establish a quality system, the laboratory is required to develop a Quality Manual, which either includes the laboratory's quality system procedures or identifies where they are located. It is further required to establish a quality system, in which is written what each employee does in each step of the testing process, and which makes sure that documentation is kept up-to-date.



### 5.6.1 The Types of Accredited or Approved Testing Laboratories

The PV GAP (IECQ) approval system for testing laboratories covers two types of laboratories:

1. Independent testing laboratories, which are defined as organizations in the business of making testing services available to other organizations, that have the facilities and capability to carry out tests and measurements on PV components or materials in accordance with their specification(s). Independent testing laboratories must be accredited by a duly recognized accreditation organization. The accepted criteria for accreditation of an independent testing laboratory are that the relevant provisions of the ISO/IEC 17025 are met.
2. Laboratories that are part of PV manufacturing companies, which have the proper equipment, personnel, traceability, and so forth to perform the tests prescribed by the standard(s) and specification(s). The manufacturer must have ISO 9001:2000 certification.

Therefore, a PV manufacturer has a choice. The decision will usually be based on cost. The choice gives the manufacturer an opportunity to save money if the independent laboratories are too costly or not conveniently located, and also to program the testing to suit company convenience.

### 5.6.2 The Importance of Reciprocity

Reciprocity ensures that a test report for a product that is tested in a testing laboratory in one country will be accepted in other countries. This saves a large amount of money and time for the PV manufacturer or integrator by avoiding the need to retest a product.

How is international reciprocity of test results achieved? First, the tests should be performed in an accredited testing laboratory having an ISO/IEC 17025 approval from an internationally recognized accreditation body. The accreditation certificate should be acceptable to PV GAP or to a supervising inspectorate of the IECQ or, based on the manufacturer's ISO 9001:2000 certificate, approved by a supervising inspectorate.

The supervising inspectorate's role is the following:

- ✦ To accredit the testing laboratory, or verify that the testing laboratory's accreditation was done by another internationally accepted accreditation body.
- ✦ (If the accreditation was performed by the SI) To periodically audit the testing laboratory to make sure that its accreditation has been properly maintained.

The PV GAP role is the following:



- ✦ To have its Accreditation Review Committee (which has PV experts from several countries) review the accreditation certificate of a PV testing laboratory and, if acceptable, approve the testing laboratory. In this case, the laboratory agrees that it will accept test results from other PV GAP-listed or IECQ-accredited testing laboratories. In this case, PV GAP also notifies IECQ of the approval.

In contrast to accreditation bodies, which are national, supervising inspectorates are connected to each other within the IECQ quality assessment system. Therefore, if one SI accredits a testing laboratory, all the others in every country or region of the world will recognize the tests. This reciprocity of acceptance of test results under the IECQ system is truly invaluable in an international business, such as solar photovoltaics.

A list of supervising inspectorates worldwide is provided in appendix 7. A current list of testing laboratories is presented in appendix 8.

### **5.6.3 Independent Testing Laboratories**

#### ***5.6.3.1 Purpose of Testing Laboratory Quality Systems***

Why is it important for a testing laboratory to develop, institute, and maintain quality processes and procedures? A documented quality system, which in the case of independent testing laboratories is the ISO/IEC 17025, that meets recognized standards does all of the following:

- ✦ Demonstrates the laboratory's commitment to quality.
- ✦ Provides evidence of the laboratory's internal discipline.
- ✦ Indicates consistency and efficiency of work processes.
- ✦ Provides a solid foundation for continuous improvement.
- ✦ Encourages customer confidence.
- ✦ Encourages automatic approval as an unbiased resource.
- ✦ Encourages marketplace recognition.

In addition, such a well-defined quality system provides the testing laboratory with the opportunity to identify system inefficiencies, track and correct deficiencies, and continuously improve testing procedures. All this should significantly improve its success in the competitive market for testing services.

The development of an approved quality system involves a feedback process of continuous assessment, documentation, validation, and revision. The development process generally falls into three broad areas:

- ✦ Reviewing, assessing, and documenting the laboratory's practices and operations.
- ✦ Implementing the quality system.
- ✦ Improving the quality system.



The key to developing a successful quality process program is to involve all employees in its development. These are the people who do the work on a daily basis. They are the people who are most familiar with what works and what doesn't, and they are the people who will be responsible for carrying out any new policies, procedures, and documentation practices.

Unfortunately, the ISO/IEC 17025 is similar to the ISO 9001:2000 standard in that it requires experts to interpret it, and it is not user friendly. In reviewing the ISO/IEC 17025, PV GAP determined that it could easily and inexpensively be simplified and made relevant for small or medium-size testing laboratories. PV GAP subsequently developed the *Photovoltaic Test Laboratory Quality Manual* (see the bibliography). It has been reviewed and approved by many organizations, including testing laboratories, auditing organizations, and PV manufacturers in both industrial and developing countries.

### **5.6.3.2 Accreditation Process**

Accreditation requires recognition as an approved laboratory through a certificate of approval from a duly recognized accreditation organization that itself complies with ISO/IEC Guide 58, *Calibration and Testing Laboratory Accreditation System—General Requirements for Operation and Recognition*, such as the IECQ or accreditation organizations that are signatory to the APLAC Mutual Recognition Agreement, including NATA, HOKLAS, IANZ, SINGLAS, CNLA, A2LA, and NVLAP. An address list can be requested from the PV GAP Secretariat (Geneva, Switzerland).

### **5.6.3.3 Why Must Testing Be Done by an Accredited Testing Laboratory?**

There are two reasons for this requirement:

1. One is that organizations that issue tenders for PV components and systems plan to invest large amounts of money in photovoltaics, so they are understandably cautious. They want assurances that they are buying products that have been tested in a laboratory whose operations comply with existing international standards. This is also advantageous to manufacturers, because it filters out those manufacturers whose products do not meet specifications, and it helps protect the reputation of the PV industry.
2. The other reason is the need for international reciprocity of test results that is only provided by the IECQ system.



### 5.6.4 Manufacturer's Approved Testing Laboratory

Some PV manufacturers may have good in-house testing capabilities. This is needed for controlling product quality, such as classifying modules according to their output power and for the development of new products. For example, solar cell and module manufacturers usually have a solar cell tester to match cells to be assembled in a module and a sun simulator to test the output of the solar modules. For development work, they may have temperature cycling ovens and humidity chambers. Under the IECQ system, in-house testing laboratories that are part of PV manufacturing companies, and that have the proper equipment, personnel, traceability, and so forth that is included in the ISO 9001:2000 certification are suitable to perform the tests prescribed by the standard(s).

This is an interesting and cost-saving aspect of utilizing the IECQ system if the manufacturing company has an ISO 9001:2000 certification, because under the IECQ system, the IECQ's supervising inspectorate will approve the manufacturer's in-house testing facility so that tests could be performed there under the supervision of the IECQ, whereas only those tests that the manufacturer is not equipped for have to be sent out to an independent laboratory.

The PV GAP (IECQ) system is of great advantage because an in-house testing laboratory not only saves cost to the manufacturer, but can also accelerate the introduction of new products and expedite the periodic testing of existing ones, since the manufacturer has control over the scheduling of tests.



# Chapter 6. Summary of the Qualification Process



## 6.1 The Steps to ISO 9001:2000 Qualification

### 6.1.1 General comments

The decision to obtain ISO 9001:2000 qualification should be a strategic decision—not a casual one—because it has a number of important implications, changes, and needs. The decision should take into account the following:

- \* Company management should be committed to the concept of quality management and convinced that this is a profitable move.
- \* Obtaining ISO 9001:2000 qualification should be a total company effort. Because the ISO 9001:2000 is based on a process approach, all departments, their employees, and managers should work in unison to achieve this goal. If you choose to qualify only a sector of your company, all employees within that sector must be fully committed.
- \* The company should be aware of customer needs and requirements for its products and the type of quality system that is required to achieve those goals.
- \* Management should review the costs and benefits of the ISO 9001:2000 qualification and the follow-up benefits from enhanced customer satisfaction and the quality improvement process.
- \* Management should be aware that ISO 9001:2000 qualification is not a one-time effort or project, but a continuous process, which requires managers to play a substantial role in guidance and follow-up with constant periodic reviews and audits from which quality and profit are derived.

### 6.1.2 Preliminary Stage

The preliminary stage of applying for ISO 9001:2000 qualification involves a management review of what is happening in your business, including customer requirements and needs, the quality of your products, your costs, and how nonconforming products in your processes affect your profits. This stage should address such questions as the following:

- \* What do your customers want from you as a supplier?
- \* What type of internal controls do you have to avoid confusion or documentation disasters?
- \* Do you now have a quality system? Is it based on prevention or inspection?

\* What type of business are you in?

- Manufacturing.
- Stocking and distribution.
- Wholesaling or warehousing.
- Installation, repairs, or service.
- Professional consulting.

You must then decide whether all the requirements of the standard are necessary for your activities. These requirements have already been discussed thoroughly. If any requirements are to be excluded, they must be explicitly listed in your Quality Manual with the reasons for their exclusion.

If you decide that the ISO 9001:2000 qualification and certification is important and beneficial for your business, you are ready to start. But remember—you do not need to reinvent the wheel or create an enormous amount of paperwork. **Make the system as simple as you can, and pay attention to those areas where your company will benefit most.** You should first use as much of your present system as possible and then add on the necessary elements to meet ISO 9001:2000 requirements.

### 6.1.3 Setting Up the Quality System

Before you proceed with setting up your quality system, remember that the purpose of a quality system is to create a process within which the business will operate. This process will use all your knowledge and experience in order to ensure that the resultant services or products are known, consistent, and repeatable. The idea is not to limit or inhibit creativity or the development of new methods or devices, but to design and implement a set of procedures that result in high-quality products all the time. A graphical process is presented in figure 6.1.

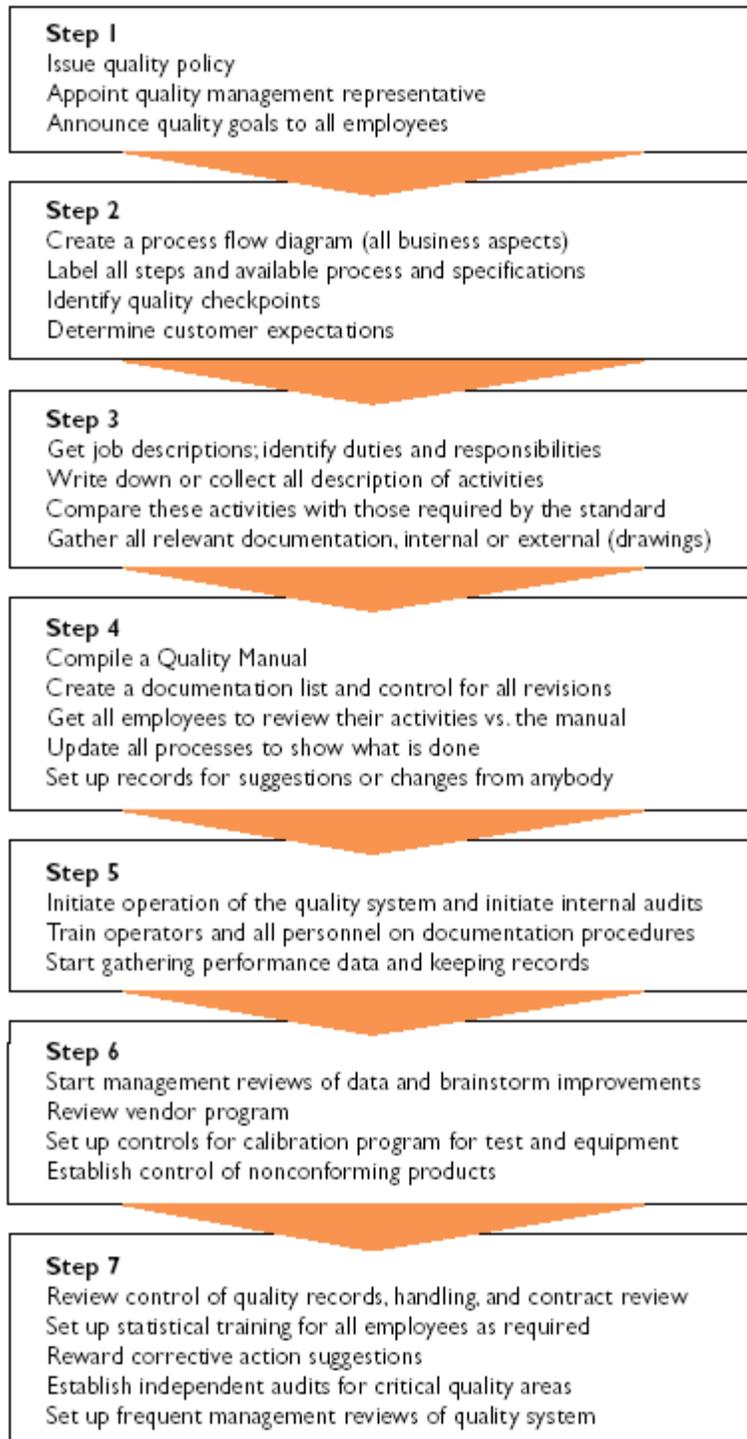
#### *Step 1—Management Commitment*

Your management personnel must be uncompromising in their commitment to the management of the quality process. This starts with their issuing a quality policy statement or document and making sure that their actions are consistent with this policy. At the same time, a management representative should be appointed, because 9001:2000 qualification will take considerable time and effort. The representative should be a high-level leader who is charged with making sure that your company's quality goals are achievable and who has the authority to marshal your company's resources toward attainment of these goals.

Management should also ensure that all employees understand the importance of the quality effort and the benefits that can accrue to the company and to them. The acceptance and commitment of all



**Figure 6.1 The Road to ISO 9001:2000**



**You are now ready for ISO 9000 certification!**

employees is important for system implementation and improved quality.

### ***Step 2—Initial Information Gathering and Analysis***

The management representative should be responsible for getting as many people as possible involved in identifying the steps in these processes. Getting people involved is the only guarantee that the system will work. The outcome of this people-intensive effort should be a set of detailed process flow charts that cover every area or activity in the business. Each step should be labeled and described in detail, and should build on descriptions that are already available. Every quality checkpoint in the system, or approval points (for purchasing or selling), should be noted. You now need to take the time to construct a process flow chart so as to capture the existing information necessary for developing your quality system.. The flow chart should include all the steps in the process, including the process of entering an order, the design process, the purchasing process, the manufacturing process, the shipping process, and even the accounting process.

At the same time, customers' expectations and problems should be identified and tabulated, in order to pinpoint the most important shortcomings of the company and its products or services.

### ***Step 3—Evaluating Your Position***

Once you have reviewed all the above steps, you next need to put together a flow chart and list all the problems or shortcomings that you perceive. In order to evaluate the gaps in your quality process, you should ask all staff what they are doing and have them write a description of what they believe to be their role in the company. This job description should include how they view the impact of their work on the quality of the company's products or services, as well as their responsibilities for a quality service or product.

This information should be compiled and added to the flow chart, and these activities compared to those activities listed in the appropriate ISO standard (see figure 6.2). The next step is to gather information about which functions are documented and designate someone to keep a log of the status of all documentation. **NOTE:** Do not update your documentation now; you only need to identify what documentation already exists.

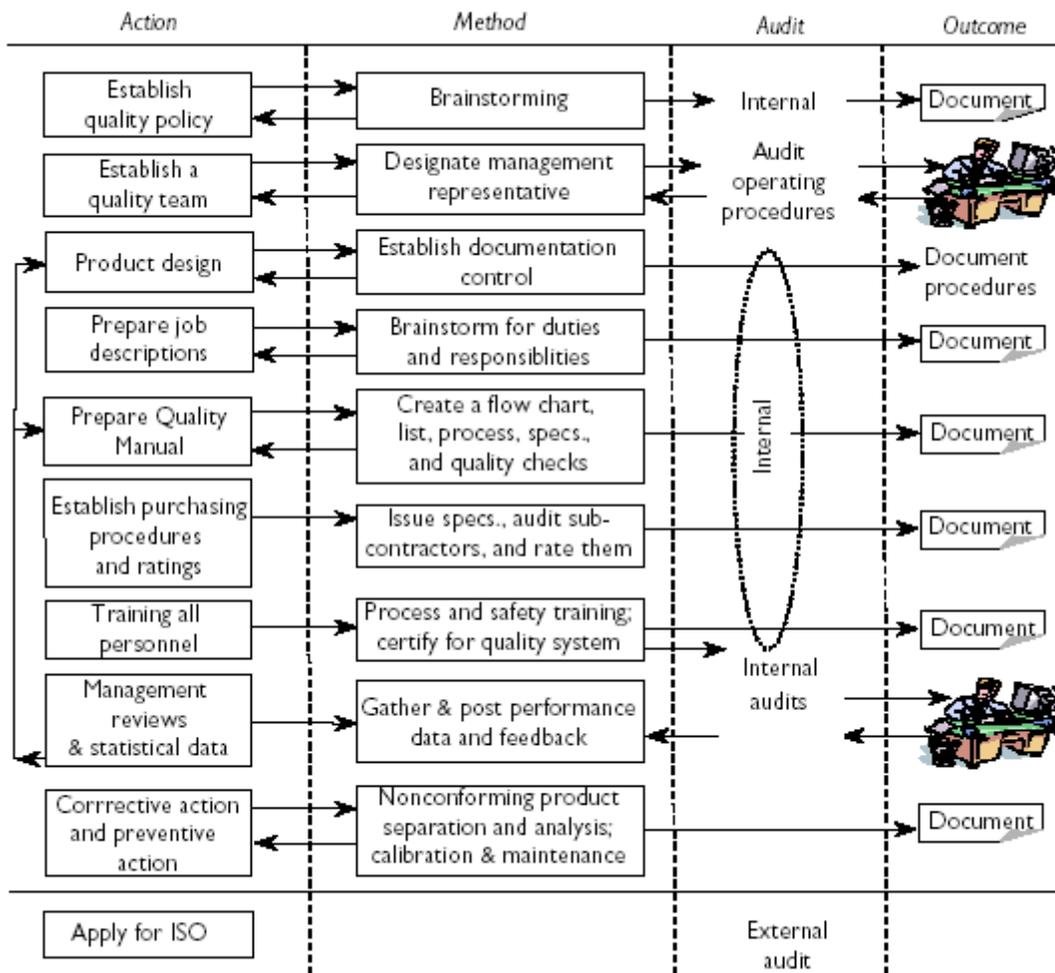
The information generated in this step is very likely to reveal that some functions listed in the standard are missing, whereas others are duplicated. This valuable information lets you know where you are in comparison to where you want to be.

### ***Step 4—Documentation***

Documentation begins with the first draft of your Quality Manual. All the documents included in the manual should be listed



Figure 6.2 ISO Procedures and Processes



and the revision level logged. All drawings should be numbered, identified (for example, as customer drawings, equipment manuals, and the like), and classified as internal or external. The manual should be reviewed and the job descriptions revised in discussion with each employee, in order to validate the activities described in them.

Revision of the documentation about actual processes is an important task. All documents describing processes and procedures should reflect what is actually being done and should be verified by an audit of the operation. If what is being done is different from the specified procedure, the document should be changed to reflect reality.

In the course of conducting internal audits, you may receive comments or suggestions from the employees. These ideas should be captured in writing and given due consideration. Promising ones should be tried later to see if they could produce improvements to the process. Keep good records of where each idea comes from, because it is important to recognize those employees whose suggestions have been implemented.

### ***Step 5—Training, Audits, and Data-Gathering***

At this point, all employees should be trained in the quality system and how they are expected to contribute to it and interact with it. They should know what the system specifies, where to find documentation, how to change it, what responsibilities they have, what approvals they need, and what is expected of them. The training should be job-specific, because each employee will have a role in gathering data. They should also understand how important data collection and data analysis are to your company's quality system in order to obtain quality improvement.

### ***Step 6—Review, Control and Calibration***

The Management Representative plays a key role at this juncture. The system has just started to generate data and employees are reporting conditions in their jobs that may be outside of the documented parameters. The Management Representative ensures that these discrepancies are addressed in a timely manner through Management Reviews, that use brainstorming to seek solutions to problems associated with the processes and to identify new ways of doing things. Management Review meetings are essential to the quality improvement process. The recommended solutions generated in these meetings should be documented and individuals who contributed to these solutions should be recognized.

By now, data should indicate how the production line is performing and how processes affect the conformance or nonconformance of the product. A supplier quality program should be set up, which analyzes the quality and schedule of deliveries and



identifies approved vendors. Purchasing documents shall include detailed specifications for each product or service that is being bought. The controls of the calibration processes should be audited to assure accuracy and proper labeling of equipment. A log should be kept for all equipment that requires calibration. Procedures for the handling of nonconforming products should be established and audited.

The calibration process should be established by either internal or external calibration service. Calibration is a very critical activity. It assures that the customer receives products that meet requirements and that those are verified by accurate test procedures.

### ***Step 7—Statistical Training, Control, and Corrective Action***

Although statistical training is initiated during Step 4 (documentation), at this point it is important for employees to acquire a complete understanding of trends and control. All critical processes should be monitored with visual charts that indicate the operation of the system and the impact of corrective actions and quality improvement steps. The quality charts indicate the savings obtained from the quality system when compared with the data in Step 5.

Management reviews shall monitor the status of quality records, as well as handling and contract review issues. The reviews should include corrective and preventive actions proposed and their results. This is an important difference over the previous standard issue. At this juncture, your system is ready to withstand the scrutiny of customer (external) audits, and you should recognize their value in promoting customer confidence in your quality system.

At this time, if ISO 9000 certification is your goal, you are ready to contact a reputable certification body with the aim of scheduling a preliminary visit. Some IECQ supervising inspectorates (see appendix 7) are also able to provide this service.

#### **6.1.3.1 The Certification Process**

The certification body (or supervising inspectorate) performs the certification process. During the first visit, the auditor conducts a preliminary audit for the purpose of reviewing the status of your quality system. The audits are carried out through personal interviews. The better prepared you are, the better your chances of meeting the audit requirements. After the initial evaluation, the auditor will report the findings and point out any deficiencies or nonconforming details, along with any potential gaps and weaknesses in your Quality Manual or process inconsistencies.



A period will be specified in which you can make corrections. Then, when you are ready, the supervising inspectorate auditor will return. If all areas check out properly, your company will be approved for certification and registration.

**REMEMBER:** The most valuable result of this process is your increased capability to improve quality and the continued savings that such improvements will accrue to your business. To continue to enjoy these benefits and to maintain your certification and registration, you must keep your quality system operating optimally. Regular management reviews are indispensable to maintaining the health and effectiveness of the system. The IECQ recognizes this fact and will schedule periodic visits from the supervising inspectorate.

### **6.1.4 Areas of Relevance to the Various ISO 9001:2000 Requirements**

The following areas are of relevance to the various ISO 9001:2000 requirements:

1. Overall business management
  - \* Management commitment.
  - \* Quality policy.
  - \* Quality planning.
  - \* Responsibility and authority.
  - \* Internal communication.
  - \* Management review of the following:
    - Customer satisfaction and feedback.
    - Document and data control.
    - Control of nonconforming product.
    - Corrective and preventive action review.
    - Review of training and human resources needs.
    - Review of infrastructure and equipment needs.
    - Control of quality records.
    - Internal quality audits.
2. Business activities
  - \* Contract review.
  - \* Design control.
  - \* Purchasing.
  - \* Control of customer-supplied product.
  - \* Process control.
  - \* Inspection and testing.
  - \* Handling, storage, packaging, preservation, and delivery.
  - \* Post delivery activities.
  - \* Servicing.



3. Support to business activities
  - \* Provision of human resources.
  - \* Provision of infrastructure.
  - \* Provision of equipment.
  - \* Product identification and traceability.
  - \* Control of customer-supplied product.
  - \* Control of inspection, measuring, and testing equipment (calibration).
  - \* Inspection and test status.
  - \* Training.
  - \* Statistical techniques.
4. Customer involvement
  - \* Customer satisfaction process reports.
  - \* Contract review.
  - \* Design control.
  - \* Control of customer-supplied product.
  - \* Product identification and traceability.
  - \* Inspection and testing.
  - \* Control of nonconforming product.
  - \* Corrective and preventive action.
  - \* Handling, storage, packaging, preservation, and delivery.

## 6.2 PV GAP/IECQ Approval Process

Section 1.3 in this manual described the need for an international approval program for photovoltaics and how the international PV industry initiated the Global Approval Program for Photovoltaics (PV GAP) to encourage the manufacture of high-quality PV components and systems internationally.

As previously described, PV GAP established a visual PV Quality Mark for components and a PV Quality Seal for systems. The licensing of use of the Mark and Seal is linked to approval by an internationally accepted approval process. PV GAP decided not to set up a new approval system, but to use that of the IEC's Quality Assessment System for Electronic Components (IECQ), because this organization has the only international approval process for photovoltaics at this time. If a new, better, or more cost-effective approval system is established, PV GAP may choose this for the benefit of the industry and for PV users.

The IECQ system of quality approval was selected at this time because of the following:

- \* Already existing internationally accepted PV standards are IEC standards, and the IECQ is a part of the IEC organization.
- \* IECQ is a well-established and internationally accepted approval program.



- \* IECQ system is relatively simple.
- \* IECQ system assures reciprocity, which means that a product manufactured and tested in one country or area need not be retested in another location.
- \* IECQ system is an inexpensive system.

### **6.2.1 How Does the IECQ Approval Process Work?**

As described in section 1.3, PV GAP and the IECQ approval system require the following:

- \* Quality manufacturing based on the ISO 9000:2000 standard.
- \* Products manufactured and tested according to International Standards (IEC or PVRS) by an accredited or approved testing laboratory.
- \* Manufacturer completion of the Product Quality Assessment Specification.
- \* Audit of the manufacturer.

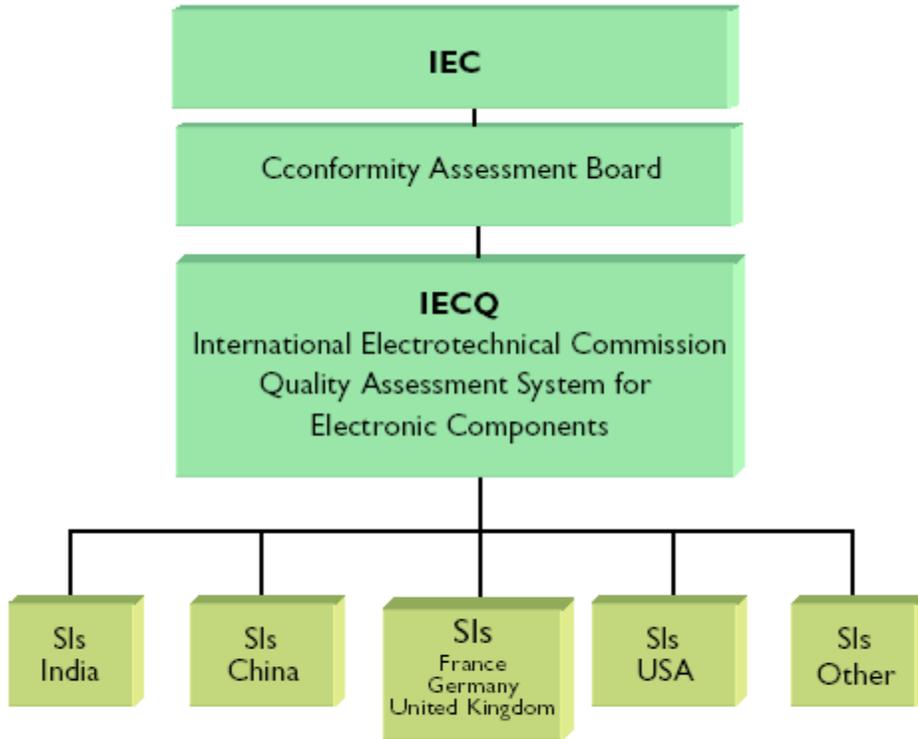
The IECQ system is based on a supervising inspectorate network with many supervising inspectorates located all over the world (see figure 6.3). The supervising inspectorates are the organizations responsible for the surveillance of all procedures for quality assessment necessary for the IECQ system. This includes evaluation for approval and surveillance of manufacturers and independent testing laboratories, the supervision of the certification of conformity, and the audit testing of approved PV components and systems. To satisfy the IECQ, an audit test is carried out on a random basis by a supervising inspectorate, or under its direction, in order to verify the proper application of the specification and the correctness of the manufacturer's test results.

Criteria that an organization must meet in order to become a supervising inspectorate under the IECQ system are as follows:

- \* The prospective supervising inspectorate shall be approved by IECQ's Inspectorate Co-ordination Committee. This assures unified rules and standards and, most importantly, reciprocity within the system.
- \* It shall be free from any influence that could prevent it from acting in an impartial manner.
- \* It shall have the staff, technical competence, and skill to carry out its surveillance and supervisory responsibilities adequately.
- \* It should have, for audit purposes, test facilities or access to test facilities, which are necessary for all normal measurements within its defined technological areas.
- \* It shall ensure that its representatives are under obligation not to disclose any confidential information obtained in the course of their duties.



Figure 6.3 The IECQ System



Note: On the schematic, "SIs" are referred to in the plural because in each country or territory, there may be more than one SI. For example, in the European Union, there are presently five SIs; in the United States, however, there is only one at present.

In order to maintain uniform international criteria for the supervising inspectorates, each supervising inspectorate must have a periodic peer review by two other supervising inspectorates. This provides the mutual respect and familiarity, which is the basis for reciprocity within the system.

A list of the supervising inspectorates can be found in appendix 7. Supervising inspectorates are accredited by IECQ for one or more of the following technological areas:

- \* Passive components.
- \* Active components.
- \* Electromechanical components.
- \* Electromagnetic components.
- \* Electro-optic components.
- \* Film and hybrid film integrated circuits.
- \* Wires and cables.
- \* Printed boards.
- \* Photovoltaics.

The IECQ rules are published in QC 001001 and QC 001002 (see the bibliography).

### **6.2.2 What Steps Must a Manufacturer Take to Get IECQ Approval for Its Products?**

The required number of steps will vary, depending on whether the manufacturer already has a quality system in place and whether an accredited testing laboratory has already tested the products (see figure 6.4).

The following cases illustrate the steps that should be taken in various situations.

- \* **Case 1:** A manufacturer has ISO 9001:2000 approval and its PV product was tested in either an independent testing laboratory that is accredited, based on the ISO/IEC 17025, or in the manufacturer's approved testing laboratory.
- \* **Case 2:** The manufacturer does not have ISO 9001:2000 approval, but its PV product was tested in a testing laboratory that is accredited, based on the ISO/IEC 17025.
- \* **Case 3:** The manufacturer does not have ISO 9001:2000 approval. Its PV product was not tested in a testing laboratory that is accredited, based on the ISO/IEC 17025.

#### **Case 1**

A manufacturer has ISO 9001:2000 approval, and its PV product has been tested in an independent testing laboratory that is accredited, based on the ISO/IEC 17025, or in the manufacturer's approved testing laboratory (described in section 5.6.4).





**Step 1:**

Designate a management representative (DMR), and complete the relevant Blank Product Quality Assessment Specification (B-PQAS).

The DMR appointed for the purpose of the ISO 9001:2000 standard shall be acceptable to the supervising inspectorate as both technically and administratively competent for the purpose of the IECQ system. In addition to being responsible for maintaining liaison with the supervising inspectorate, the DMR shall have the authority to ensure that the organization complies with the requirements of the IECQ system.

**Step 2:**

The DMR should submit the following documents to an IECQ supervising inspectorate:

- ✱ ISO 9001:2000 approval certificate.
- ✱ Certification of the product from a testing laboratory that is accredited, based on the ISO/IEC 17025.
- ✱ Completed PQAS.

**Case 2**

The manufacturer does not have ISO 9001:2000 approval. However, its PV product was tested in a testing laboratory that is accredited, based on the ISO/IEC 17025.

**Step 1:**

Designate a management representative (DMR).

**Step 2:**

Do one of the following, depending on which is the most cost-effective for the company:

- ✱ Establish a manufacturing quality system, based on the material presented in this course. The DMR (see Case 1 for the function of the DMR) should then get in touch with the IECQ's supervising inspectorate and request its approval of the manufacturer's quality system.

or

- ✱ Contact one of the consulting organizations that are in the business of installing the ISO 9001:2000 system in companies, and ask them to implement the system.

**NOTE:** The material presented in this course for implementing a manufacturing quality system is based on the ISO 9001:2000 standard and is intended to facilitate the manufacturer's application process.

**Step 3:**

The implemented ISO 9001:2000 system has to be certified by a certification body, which could be a supervising inspectorate.



**Step 4:**

Complete the relevant Blank Product Quality Assessment Specification (B-PQAS).

**Step 5:**

- ✦ The DMR must provide the completed PQAS to the supervising inspectorate.
- ✦ The DMR shall submit the ISO 9001:2000 certification and the product test certification from an accredited testing laboratory to the supervising inspectorate.

**Case 3**

The manufacturer does not have ISO 9001:2000 approval. Its PV product was not tested in a testing laboratory that is accredited, based on the ISO/IEC 17025.

**Step 1:**

Designate a management representative (DMR).

**Step 2:**

Do one of the following, depending on which is the most cost-effective for the company:

- ✦ Establish a manufacturing quality system, based on the material presented in this course. The DMR (see Case 1 for the function of the DMR) should then get in touch with the IECQ's supervising inspectorate and request its approval of the manufacturer's quality system.  
or
- ✦ Contact one of the consulting organizations that are in the business of installing the ISO 9001:2000 system in companies, and ask them to implement the system.

**NOTE:** The material presented in this course for implementing a manufacturing quality system is based on the ISO 9001:2000 standard and is intended to facilitate the manufacturer's application process.

**Step 3:**

The implemented ISO 9001:2000 system must be certified by a certification body.

**Step 4:**

Complete the relevant Blank Product Quality Assessment Specification (B-PQAS).

**Step 5:**

In agreement with the supervising inspectorate, have the PV product tested at an independent testing laboratory, which has an accreditation based on ISO/IEC 17025, or in the company's approved testing laboratory. The testing laboratory issues a test



report for the product (the supervising inspectorate may witness the testing).

**Step 6:**

- ✦ The DMR must provide the completed PQAS to the supervising inspectorate.
- ✦ The DMR must submit the ISO 9001:2000 approval certification and the product test certification with the testing laboratory test report for the product to the supervising inspectorate.

### **6.2.3 What Does the Supervising Inspectorate Then Do?**

The supervising inspectorate may only review the documents, or it may visit the facility. If everything is found to be in order, an IECQ approval will be issued. IECQ will then notify PV GAP. PV GAP will issue a license to the manufacturer that allows display of the PV Quality Mark and/or the Seal on the approved product(s).

Under IECQ approval, in addition to the required PQAS periodic tests performed by the testing laboratory, the supervising inspectorate may conduct or oversee random audits in order to verify the proper application of the specification and the correctness of the test results of the manufacturer. The opportunity given the supervising inspectorate to make unannounced inspections and randomly select samples is an extremely important feature of the quality assurance program. Random audits separate responsible manufacturers from ones that cut corners and produce poor-quality products.

At the discretion of the supervising inspectorate, the frequency of surveillance (audit) of a manufacturer may be reduced to one visit or less per year if

- ✦ No significant product or process failures have occurred. The manufacturer holds the approval for a minimum of two years.
- ✦ The SI has confidence in the manufacturer, has a good working relation with the DMR, and the company routinely reports tests as a result of changes in the manufacturing of the products, based on the requirements of the B-PQAS.

### **6.2.4 Withdrawal or Suspension of Approval**

IECQ may withdraw its approval for a number of reasons, including loss of ISO 9001:2000 approval, failure of the test of the product, or if the manufacturer intentionally makes misleading or incorrect statements about approved products. The withdrawal could be a temporary suspension in those cases where the reason can be and is remedied within a short time.



## 6.2.5 The PV GAP Approval Process

The IECQ approval process triggers the PV GAP approval process. Once PV GAP is notified by the IECQ that it has approved a manufacturer and its product, PV GAP licenses the use of the PV Quality Mark and/or Seal. The basis for PV GAP licensing the use of the PV Quality Mark and Seal is discussed in detail in section 6.3. PV GAP may revoke this license upon notification that the IECQ has withdrawn its approval of a manufacturer's product.

## 6.2.6 Recognition

Following are two methods of recognizing approved companies:

- ✦ Companies approved by an IECQ SI are published in the IECQ Register of Firms, Products and Services approved under the IECQ system, QC 001005 (see the bibliography).
- ✦ IECQ will convey the name of the approved company and details of its product approval to PV GAP. PV GAP will issue a license to the manufacturer, which authorizes display of the PV GAP PV Quality Mark (for PV components) and/or the PV Quality Seal (for PV systems).

Companies that have PV GAP–licensed products are listed on the PV GAP Web site ([www.pvgap.org](http://www.pvgap.org)). The PV GAP Web site also allows direct connection to the individual Web sites of licensed companies.

## 6.3 PV GAP Mark and Seal

### 6.3.1 How Can People Recognize Quality Products?

In order to specify the quality of PV products, the World Bank and other large organizations have had no choice but to create their own "best practice" specifications for their tender (bid) packages. These specifications may require a manufacturer to provide proof that its facility has an ISO 9001:2000 rating and also require proof from a manufacturer that its product has been tested by a testing laboratory, which has ISO/IEC 17025 accreditation.

If each and every customer had to write its own PV tender specifications, utilizing a variety of standards and testing procedures, the price of photovoltaics would increase. This situation would place an enormous burden on customers who need to produce and issue tender packages. In addition, PV manufacturers and system assemblers would have to devote considerable time and resources to comply with the various specifications and testing procedures of different tenders.

Abbreviations, such as ISO, IEC, JRC Ispra, UL, NREL, IEEE, IECQ, ASTM, JQAO, CENELEC, and others, along with the various

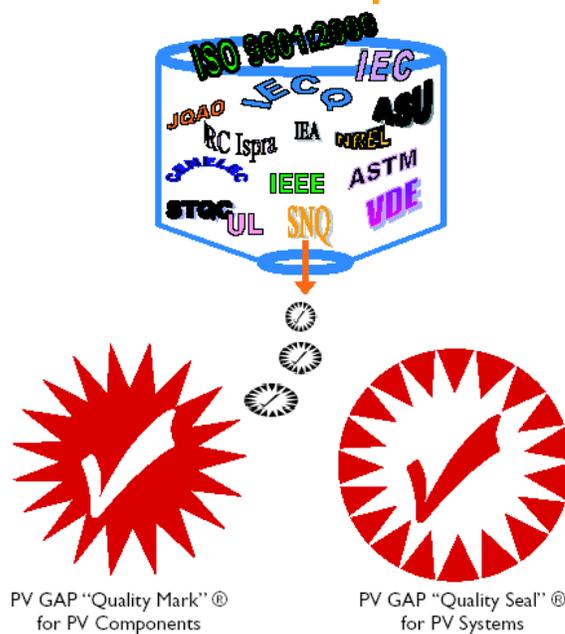


standards and certification schemes, are known to experts in the field of photovoltaics. The vast majority of customers buying PV products, however, or banks providing loans for PV product purchase are not familiar with these organizations and cannot tell which PV systems or components conform to international standards.

Quality recognition is not a problem unique to the PV Industry. Years ago, other industries found a simple solution. They created a quality mark or seal to display on products. This system is used by many industries in many countries to help customers identify products of approved quality. For example, the "WoolMark" label distinguishes woolen products of an approved quality from those whose quality is poor or unknown, and the UL seal distinguishes products that have been tested for safety from untested products or those that have not passed its safety tests.

The PV industry has become large enough and important enough on an international scale to establish its own Quality Mark and Seal in order to identify properly designed and manufactured PV components and systems, as well as to safeguard its integrity. This required a simple and inexpensive international mechanism by which customers could easily distinguish between a PV product with proven and known quality, and a PV product with unknown quality—a mechanism that would eliminate the need for manufacturers to supply certificates to each and every customer. (When somebody buys a woolen coat with the "WoolMark" label on it, the manufacturer does not need to provide certification concerning standards and test reports, or other proof that the coat is wool.) Figure 6.5 illustrates the simplicity of a Quality Mark.

**Figure 6.5 Quality Mark and Quality Seal**



Based on well-established precedents in other industries, PV GAP established an internationally accepted PV Quality Mark and Seal for the PV industry. It determined that, as with other industries, both a Mark and a Seal were needed. The reason is that, if there were only one Mark used on components, customers might mistakenly assume that the Mark signified approval of the entire system. As an example, a table lamp has a quality mark because it uses an approved wire. The customer could easily assume that not just the wiring, but also the entire table lamp was tested and approved. Therefore, PV GAP decided to use a Mark to identify an approved component and a different Seal to identify an approved system. In the table lamp example, the wire, plug, or the metal construction would be labeled by a mark, but the entire lamp, after being tested and approved, would get a different seal.

### **6.3.2 What Is the Benefit of a “PV Quality Mark/ Seal”?**

The purpose of displaying the PV Quality Mark/Seal is to

- ✦ Distinguish PV products with proven quality from other PV products whose quality is unknown.
- ✦ Provide a uniform symbol for worldwide recognition.
- ✦ Build consumer confidence in PV products.
- ✦ Serve as a marketing tool.
- ✦ Provide the basis for specifying the quality of PV products in tenders (bids).

#### **6.3.2.1 Benefits to Customers and Manufacturers**

Some customers choosing PV systems or PV components may rely on manufacturer data sheets. In most cases, customers buy a particular product because it is a recognized name, or because it is cheapest. In any case, manufacturers gain advantages when their product is distinguished with a quality mark. Before long, after bad experiences with unmarked products and good ones with marked products, word will spread that products carrying the quality mark are preferable, even if more costly, because they are superior in quality and reliability. The PV Quality Mark or Seal also builds name recognition for the manufacturer's product.

#### **6.3.2.2 Tenders**

Organizations issuing tenders will soon learn that they can rely on products with the “PV Quality Mark” or “Seal” and will require them. This will reduce the burden of preparation and control on these organizations and on manufacturers and suppliers, thus lowering the cost to consumers.

This is illustrated by the action taken by the World Bank (see box 1.2) who has advised its clients, “Visual recognition simplifies for



customers the selection of quality products. It also eliminates the need for country-by-country recertification, as PV GAP establishes the credentials of the PV manufacturer and the product. This simplifies administrative procedures, is less costly to suppliers, gives the buyer a greater confidence in the quality of the products, and can encourage intercountry trade.”

### **6.3.2.3 Opening the International Market**

An international PV Quality Mark and Seal will make it possible for quality PV products manufactured in one part of the world to be recognized and accepted in any other part of the world. Therefore, it will help open up the international PV market to participating manufacturers.

### **6.3.3 Who Can Display the “PV Quality Mark and Seal”?**

The purpose of the PV Quality Mark and Seal is to identify PV products approved under the IECQ/PV GAP approval process. PV manufacturers having approved product(s) will be licensed to display the Mark or the Seal, or both, on these products.

Licenses are issued when all the following conditions are met:

- ✦ The PV manufacturer's production has an ISO 9001:2000 certificate that was issued or verified by the IECQ (supervising inspectorate).
- ✦ The PV manufacturer's product (component and/or system) was tested and found compliant by an independent testing laboratory having an ISO/IEC Guide 17025 accreditation or by an approved testing laboratory of the manufacturer. The accreditation or the approval was verified or issued by IECQ (supervising inspectorate).
- ✦ The PV manufacturer signs the PV GAP license agreement.

A license can be revoked if the PV manufacturer loses ISO 9000 approval or product approval.

### **6.3.4 PV Manufacturer's Identification Number**

Each licensed PV manufacturer will receive an exclusive identification number (see the examples in figure 6.6), which must be printed under the Mark or Seal. This system is used in other industries to protect manufacturers from fraud.

### **6.3.5 The Cost of PV GAP Licensing**

This extremely important issue was discussed in section 1.3.9. A detailed and factual discussion of the subject appears in appendix 8. The following deals only with the costs related to the licensing fee.

PV GAP was created with the explicit instruction that it lighten and not add to cost burdens on the PV industry. PV GAP elected to



use the services of IECQ for the approval process. IECQ does not charge PV GAP for the services it provides. PV GAP operates with very low administrative costs. PV industry members determine the PV GAP license fee. At present, small PV manufacturers pay \$250 per year for the PV GAP license, whereas manufacturers with annual sales of \$100 million or more will pay \$3,000 per year.

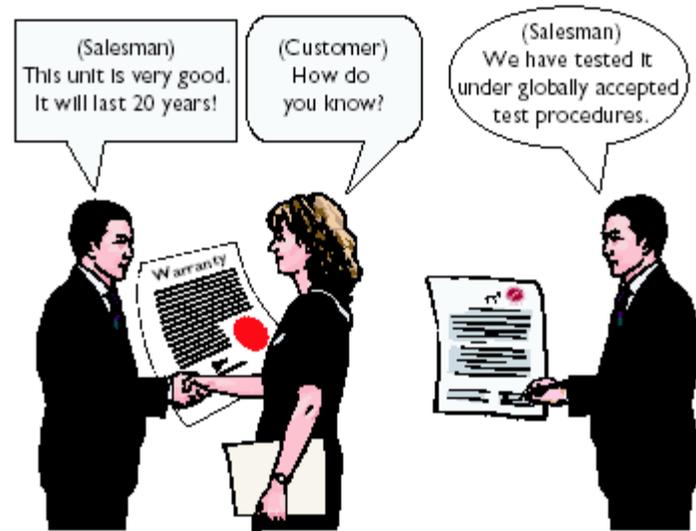
## 6.4 The Costs and Benefits of Quality

The question of cost is inevitably on the mind of every business manager. Managers relate costs to profits. Higher costs mean lower profits. Therefore, efforts are usually made to find ways to reduce costs. Unfortunately, this sometimes occurs at the expense of quality. Managers may try to reduce costs by using cheaper materials, thereby settling for lower precision components, accepting cheaper but nonconforming materials from subcontractors, or changing to new processes without proper verification and validation.

These approaches to cost reduction are the opposite of what should be done. Products made with low-quality materials usually perform poorly. Low-quality processes also increase the number of nonconforming products, which elevate customer rejection rates. In other words, these approaches shift quality screening to the end of the process line. Whatever is missed by inspection ends up in the customers' hands. This cost reduction strategy has been discarded by industry, because it results in the expensive loss of both credibility and customers.

In contrast, the ISO 9001:2000 processes work to create the level of quality necessary to meet all requirements for the performance of the product. Reducing scrap or nonconforming products reduces the cost of maximizing the plant's output. It is cheaper to make 99 good products out of every 100 than to make 80 cheaper ones out of 100. Not only is good quality always cheaper, but the capacity of the plant is also increased, when only 101 units have to be produced instead of 125, in order to fill an order of 100 acceptable units.

**Figure 6.6 The Importance of Quality Marks and Quality Seals**



### 6.4.1 The Voice of the Customer

Table 6.1 provides a few testimonials from customers around the world.

**Table 6.1 The Voice of the Customer**

*ISO 9000 is a proactive standard of quality management, i.e. a standard that tries to foresee problems and solutions as opposed to conventional quality control based on inspection, where one reacts to the findings of inspection.*

M. L. Gupta  
Joint Director  
Export Inspection Council  
India

*It is difficult to see how you could run your business without addressing the management aspects covered by the ISO 9000 requirements. In other words, if ISO 9000 was done away with overnight, then you would have to develop something which would end up looking very much like it.*

John D. Simmonds  
Mobil, USA

*Each dollar invested generates at least a four-fold return, if the standard is implemented well.*

Robert Doré  
Municipality of St. Agustin  
de Demaures, Canada

*At IBM, by embarking on the ISO 9000 journey, it is reasonable to expect lower costs, improved customer satisfaction, greater brand loyalty and stronger market performance.*

Dr. Jack E. Small  
IBM, USA



## 6.4.2 Who Benefits from ISO 9001:2000 Implementation?

Customers and users benefit for the following reasons:

- ✦ They receive only conforming materials.
- ✦ Your company is dependable and reliable.
- ✦ Products are available when needed.

People working for the supplier benefit for the following reasons:

- ✦ They have better working conditions.
- ✦ They have more job satisfaction.
- ✦ Workplace health and safety are improved.
- ✦ Workplace morale is improved.
- ✦ Employment is more stable.

Owners and investors benefit for the following reasons:

- ✦ They receive increased returns on their investments.
- ✦ They see improved operational results.
- ✦ Market share grows.

Subcontractors and partners benefit from the following:

- ✦ Relationships with the supplier are more stable.
- ✦ Business opportunities grow.
- ✦ Partnerships are better, and mutual understanding increases.

Society in general benefits for the following reasons:

- ✦ Legal and regulatory requirements are met.
- ✦ Industrial health and safety are improved.

## 6.4.3 Results That Speak for Themselves

Data compiled by the U.S. General Accounting Office from the 20 companies that scored highest on the Malcom-Baldrige applications quantify the benefits of implementing ISO 9001:

<b>Improvement in reliability</b>	11.3%
<b>Improvement in on-time delivery</b>	4.7%
<b>Reduction in processing time</b>	12.0%
<b>Reduction in errors</b>	10.3%
<b>Cost reduction</b>	9.0%
<b>Increase in market share</b>	13.7%

## 6.4.4 Comparison of Quality Systems

Table 6.2 shows a comparison of the organizational cultures typified by the old inspection methodology and the new prevention methodology.



**Table 6.2 Comparison of Quality Systems**

	<b>Inspection</b>	<b>Prevention</b>
<b>Values</b>	Production Cost Schedule	Customer Quality Waste elimination
<b>Organization Behavior</b>	Autocratic/bureaucratic Top-down Pyramidal decisions	Participatory Bottom-up problem-solving Shared decisions
<b>Employee</b>	Commodity Adversary Cog in system	Capable/trained member Growth potential Part of team
<b>Results</b>	Little pride or loyalty Competitive decline Resource failure	Continuous improvement Competitive advantage

Professor Deming explains the difference between the two systems by saying, “What happens in the inspection system is that management does not know what to do, and embarks on a random walk trying various ideas. In the end, they dissipate energy but fail to reach a goal.”

With an ISO 9001:2000 quality system, operators see their efforts rewarded with better products. They feel proud of being able to participate in the solution of problems and of receiving recognition for what they are doing. When people are doing a good job, they feel encouraged to do more and become more efficient and productive.

The effectiveness of quality improvement programs should always be measured in financial terms. A well-implemented quality system should reduce losses caused by errors in manufacturing or defective materials and should improve customer satisfaction significantly. The key measurements are prevention, appraisal, and failures. Prevention and appraisal are investments, and failures are costs. The cost of failures could be internal or external. Internal costs are associated with a defective product that has to be thrown out or reworked, whereas external costs are associated with the shipping and return of a defective product from the customer; with consequent loss of money and perhaps also of the customer.

The conventional axiom in the old school of quality inspection is that higher levels of quality require higher costs and that the optimal cost of higher quality will reach a balance between added cost for in-house inspection and rejection compared with field replacements. This is based on the principle of 100% inspection of the finished product. Prevention is a better approach. Costs are reduced because the number of defects is reduced. The total cost



will increase only if process variation goes out of control; and that is precisely what the ISO 9001:2000 process is set up to prevent.

### **6.4.5 Conclusion**

The cost of implementing the PV GAP system has been demonstrated to be very low as compared to the cost of the product. This was shown in section 1.3, which indicated a cost of less than 2% of standard manufacturing costs. In addition, the cost reduction savings from the quality process has been experienced to be usually better than 10% of costs.

This indicates that a large savings potential can be achieved by establishing and operating a quality system in a service or manufacturing company.

For a PV company, the greatest benefit, nonetheless, is the achievement of customer satisfaction and the world recognition that can be obtained when a PV GAP Mark or Seal is on its products. The enhancement of the quality and service of PV technology and the testimony of satisfied customers will expand the use of the technology worldwide. This is a benefit for the industry and for potential consumers everywhere.



# Appendixes

1. How Expensive Is It for a PV Manufacturer to Set Up and Operate a Quality Management System?
2. Example of a Standard Quality Plan
3. Publications Issued by IEC TC 82
4. IEC Standards of Possible Use for PV
5. PV GAP Recommended Specifications
6. Example of a Blank Product Quality Assessment Specification (B-PQAS)
7. Supervising Inspectorates
8. Provisional List of Testing Laboratories



# Appendix 1.

## How Expensive Is It for a PV Manufacturer to Set Up and Operate a Quality Management System?



The Global Approval Program for Photovoltaics (PV GAP) was initiated by the worldwide PV Industry, and supported by financial institutions and government agency funding programs to establish an easy recognition system for quality PV products. PV GAP created a PV Quality Mark for PV components and a PV Quality Seal for PV Systems. Manufacturers will be licensed to display the Mark and/or Seal on their products if they fulfill the approval requirements. To minimize expenses, PV GAP is at present relying on IEC's Quality Assessment System for Electronic Components (IECQ).

The manufacturer that is able to display the PV GAP PV Quality Mark or Seal on a product derives obvious benefits:

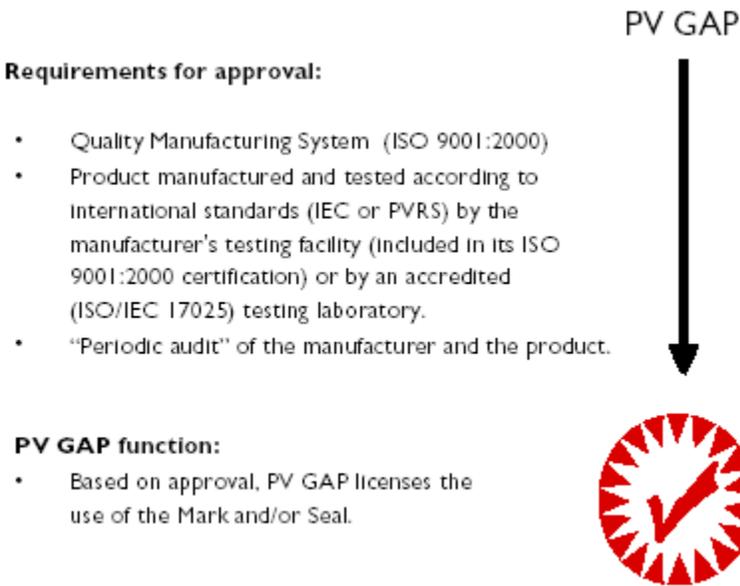
- ✦ The manufacturer's quality product is distinguished from products of unknown quality that do not have the PV Quality Mark or Seal.
- ✦ Besides the marketing advantage of raising the customer's confidence in the products, products displaying the PV Quality Mark or Seal have another important advantage. They are accepted in every country, whereas products not qualified to display the Mark or Seal must present credentials in every country. This is illustrated by the World Bank decision (<http://www.worldbank.org/html/fpd/energy/photovoltaics.htm>) to advise its clients to accept products displaying the PV GAP Mark and Seal. Those that do not have the Mark or Seal must be recertified country by country according to each country's requirements.

Figure A1.1 shows what is required for IECQ approval and PV GAP licensing of the PV GAP Quality Mark and or Seal.

The obvious question is how expensive is it for a manufacturer to obtain PV GAP approval to display the PV Quality Mark and/or Seal on its products? Can a small or medium-size company afford it?

Apart from the expenses of testing, the costs to establish the needed requirements for a manufacturer depend on the size of the company. For a smaller company, it will be less and for larger ones more.

**Figure A1.1 PV GAP Approval System**



## The Case of a Small or Medium-Size PV Manufacturing Company

### Assumptions

- ✦ As an example, let's consider a small or medium-size PV cell and module manufacturing company that produces 1 MWp per year and has 50 employees. Some manufacturers obtain test certificates for their products from an accredited (ISO/IEC 17025) testing laboratory (in the case of modules according to IEC 61215 for crystalline and IEC 61646 for thin film standards), but let's assume that the manufacturer starts from scratch, has no approved manufacturing quality system, has to set up the quality manufacturing system (ISO 9001:2000) in its manufacturing operation, and must have its modules tested at an accredited testing laboratory.
- ✦ Another assumption is that the sales price of the module is \$3.00 per Wp.

### First Year Expenses

1. ISO 9001:2000: Setting up the quality manufacturing system.  
The PV GAP training manual, *Quality Management in Photovoltaics: Quality Control Manual for Manufacturers*, provides the necessary information to help a manufacturer set up the ISO 9001:2000 system in their operation. An estimated 2 man months are

approximately needed in order to install the system, including the 5-day training course. The expense for this would vary from country to country. Taking Germany as an example, it is estimated that this would cost Euro 16,500 (about \$15,000).

A comparison (based on the experience of consultants who helped to set up the ISO 9001:2000 system in a company of that size) indicates that a consulting organization would charge the manufacturer about \$25,000 to perform this service.

2. The manufacturers ISO 9001:2000 certification.

Based on information received from the VDE Testing and Certification Institute of Germany, this would convert into U.S. dollars according to table A1.2.<sup>1</sup>The European<sup>2</sup>Co-operation for Accreditation (EA) has published a guideline of the suggested auditor days based on the number of employees, which is shown in table A1.1. As can be seen, the number of "auditor days" depends on the size of the company (number of employees).



**Table A1.1 Suggested Number of Auditor Days, Initial Assessment**

<i>Certificated entity (number of employees)</i>	<i>Initial assessment (auditor days)</i>	
	<i>Total</i>	<i>On-site minimum</i>
Less than 5	2.0	1.0
5-9	2.5	1.5
10-19	3.0	2.0
20-29	4.0	2.5
30-59	6.0	4.5
60-100	7.0	5.0
100-250	8.0	6.0
250-500	10.0	7.0
500-1,000	12.0	9.0

**Table A1.2 Estimated Cost of Employees to a Certified Company**

<i>Certificated entity (number of employees)</i>	<i>Cost (\$)</i>
Up to 20	3,800
21-50	5,000
51-100	7,000
101-250	8,000
251-500	11,000

The ISO 9001:2000 certification will cost the manufacturing company with 50 employees about \$5,000.

3. Module testing in an accredited testing laboratory.

A guideline, based on the information published in December 2001 on the Web site of the Arizona State University's testing laboratory ([www.asu.edu/east/ptl](http://www.asu.edu/east/ptl)) is that complete type testing of a PV module will cost about \$25,000.

The IECQ approval process utilizes a Product Quality Assessment Specification (PQAS) (described in detail in section 5.4). PQAS also includes the concept of structural similarity. In the case of modules, this means, for example, that only one size has to be tested, which is an important savings for the manufacturer.

4. License fee to be paid to PV GAP: \$750.

**Total expense for the first year (considering a 1 MWp per year production)**

If an outside consultant is used: \$55,750 or a total of **\$0.056 per watt**.

If the ISO 9001:2000 system is set up in-house: \$45,750 or a total of **\$0.046 per watt**.

**2nd Year Expenses**

1. ISO 9001:2000: The quality manufacturing system is in place. No expense.
2. ISO 9001:2000 annual surveillance.

The European Co-operation for Accreditation (EA) published a guideline of the suggested auditor days based on the number of employees,<sup>1</sup> which is shown in table A1.3.

**Table A1.3 Suggested Number of Auditor Days, Second Year**

<i>Certified entity (number of employees)</i>	<i>Annual surveillance (auditor days)</i>	
	<i>Total</i>	<i>On-site minimum</i>
Less than 5	1.0	0.5
5-9	1.0	0.5
10-19	1.0	1.0
20-29	1.5	1.0
30-59	2.0	1.0
60-100	2.0	1.5
100-250	2.5	2.0
250-500	3.0	2.0
500-1,000	4.0	3.0



In Germany the annual surveillance for a company with 50 employees would cost \$1,700.

3. Module testing in an accredited testing laboratory.

According to the PVR5 2, if the manufacturer makes no changes in the module, no retesting is required.

License fee to be paid to PV GAP: \$750.

4. Total expense for year 2: \$2,450.

### **Total expense for the second year (considering a 1 MWp per year production):**

Will add a negligible \$0.0025 per watt.

### **Benefits**

On the other side of the coin are the benefits the manufacturer will get by installing and operating the IECQ approval system and the PV GAP licensing of the PV Quality Mark or Seal (see table A1.4).

The potential cost savings from a well-established quality management system are a minimum of 9% of the total cost of the product (see section 6.4.3 of the manual). Therefore, if the cost is \$2.00 per watt, the cost savings should be \$0.18 per watt for a net savings of \$0.12 per watt after the approval is achieved and the system installed.



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1. *EA Guidelines on the Application of EN 45012* (European Co-operation for Accreditation; <http://www.european-accreditation.org>), September 2000-rev.00.

**Table A1.4 The Rewards of Quality**

Leveling the playing field	Customers can differentiate between quality products and products of poor or unknown quality.  The same quality standard is used globally.
Reliability and durability of PV products	The reputation of PV products is important.  Financing of PV products will become easier.
Customer satisfaction	Market expansion will be a natural result.
Participation in tenders	Tenders require quality products. Globally uniform quality standards make it possible for tenders to specify the same testing.
Opening export markets	Reciprocity of testing will open export markets.
Customer recognition of quality products by the "PV Quality Mark and Seal"	The "PV Quality Mark and Seal" will help all companies, large or small, differentiate their products from products of inferior quality.
Cost reduction by manufacturing improvements	The in-line rejects and finished product nonconformity have been reduced by 9% in most companies where the system is established.
Cost reduction for system companies buying PV GAP marked products	Purchasing components from a company that is approved to use the Mark and Seal means not having to retest these products, because they are identified as good quality and meeting all specified requirements. Significant savings and confidence in the products purchased gives a significant advantage.



# Appendix 2: Example of a Standard Quality Plan

TITLE  
**MANUFACTURING COMPANY  
OF PHOTOVOLTAICS PRODUCTS**

NUMBER

PAGE 1 OF 3

## **Standard Quality Plan for Photovoltaic Cells, Modules, and Photovoltaic Systems**

### **I. OBJECTIVE**

To describe the quality control plan to ensure the quality of photovoltaic cells, modules, and systems at all stages of manufacture. Testing, storage, and packaging, including that of input materials and components fabricated in-house and or bought out, are covered

### **II. SCOPE**

This Quality Plan is a standard quality plan for photovoltaic cells, modules, and photovoltaic systems.

It shall be applicable to the following areas:

1. Control of all incoming materials and components—direct or indirect.
2. Control of critical manufacturing processes.
3. Control of bought-out items.
4. Control of assembly and final testing if finished products test includes routine and type test.
5. Control of handling, storage, and packaging.
6. Control of final inspection.
7. Control of inspection, measurement, and test equipment.
8. Any special requirements of the customer that require changes in electrical/mechanical characteristics and/or test specifications as additional instructions given against specific purchase order (PO) or contract.

### **III. CONTENTS**

This Standard Quality Plan describes the inspection carried out for all materials, components, semifinished products at key stages of manufacturing, including final inspection and testing, storage, preservation, and packaging at works and at site, and calibration of gauges, measuring, and test equipments.

The various documents referred to in this Standard Quality Plan are internal documents, the details of which are available for perusal at this Division.

REVISIONS 01. Renamed Company

APPROVED: Boss on 3/2/2003

PREPARED:  
Helper

ISSUED:  
Person in Charge

DATE:  
3/2/2003

**IV. IMPLEMENTATION**

The implementation of the Standard Quality Plan is mandatory for all standard or catalogued products as per plan indicated.

**Standard Quality Plan for Photovoltaic Cells,  
 Modules, and Photovoltaic Systems**

Sl. No.	Material or component tested/inspected	Characteristics tested/inspected	Quantity tested/inspected	Reference document/ acceptance norm	Format or record	Implementing department
<b>A. Photovoltaic cells &amp; modules</b>						
<b>A.1 Incoming materials and Components</b>						
a.1.1	Silicon wafers, screens, silver paste, PV module components (glass, EVA, Tedlar, aluminum frame, gasket, scrim, terminal box, soft solder, interconnects, bus bars, silicone adhesive)	Appearance, physical parameters, dimensional	Sample	BOM No. 1111	Q In	QC & Stock
a.1.2	Gases, chemicals, consumable materials	Appearance, physical parameters, dimensional	Sample	BOM No 1112	Q In	QC & Stock
<b>A.2 Critical processes &amp; semi-finished products</b>						
a.2.1	Etching, diffusion, coin-stack edging	Manufacturing process control	100 %	SPC- 5001 to SPC- 5010	P.M.I.	Prodn. QC
a.2.2	Screen printing, firing Semi-finished products diffused silicon wafer	Manufacturing process and test control	100 %	SPC- 5011 and STC- 5015	P.M.I.	Prodn. QC
<b>A.3 Assembly and Final Testing of Finished Products</b>						
a.3.1	Final testing of photovoltaic cells and modules	Testing instructions	100 %	STC- 5016 to STC- 5020	P.M.I.	Prodn.QC
a.3.2	Routine acceptance and special tests Final Inspection of finished products	Per quality management Work instructions	100 %	QMS-FPT101 to FPT104	Q.M.I.	QC SPC

TITLE  
**MANUFACTURING COMPANY  
 OF PHOTOVOLTAICS PRODUCTS**

NUMBER

PAGE 3 OF 3

SI. No.	Material or component tested/inspected	Characteristics tested/inspected	Quantity tested/inspected	Reference document/ acceptance norm	Format or record	Implementing department
<b>A.4 Handling and packaging</b>						
a.4.1	Handling, storage and packaging instructions	As per handling and packaging instructions: FPS 5021 to FPS 5027			P.M.I.	Prodn. & QC Final QC
<b>A.5 Inspection, measurement and test equipment</b>						
a.5.1	Calibration	Per procedures of operating and test equipment. Work instructions			P.M.I.	Prodn.& QC
<b>B. Photovoltaic systems</b>						
<b>b.1 Bought-out materials and components</b>						
b.1.1	Mechanical items: Module mounting structures, junction boxes, hardware, cubicle and painting	Dimensional, visual, electrical parameters	Sample	BOM No: HS-1-500 to 520 PS No: Pur. HS 1-500 to 520	Test plan: HS1-500	QC-Sys HS
b.1.2	Electrical items: Charge controller, inverter, battery charger, luminaries with electrics, batteries, switch gear, cables, cooling or exhaust fans.	Dimensional, electrical parameters	Sample	BOM No: HS-1-500 to 520 PS No: Pur. HS 1-520 to 530	Test plan: HS1-510	QC-Sys HS
b.1.3	Electronic items: Diodes, transistors, power devices, LEDs, populated PCBs	Dimensional, visual, electrical parameters and solderability	Sample	BOM No: HS-1-500 to 520 PS No: Pur. HS 1-520 to 530	Test plan: HS1-510	QC-Sys HS
b.1.4	Inspection of packing for mechanical, electrical and electronic items, spares, etc.	Dimensional and visual	Sample	BOM No: HS-1-500 to 520 PS No: Pur. HS 1-540	Test plan: HS1-540	QC-Sys HS

APPROVED: Boss on 3/2/2003

PREPARED:  
Helper

ISSUED:  
Person in Charge

DATE:  
3/2/2003

# Appendix 3:

## Publications Issued by IEC TC 82

### **IEC 60891 Ed. 1.0**

Procedures for temperature and irradiance corrections to measured I-V Characteristics of crystalline silicon photovoltaic devices.

### **IEC 60891 Amd. 1 Ed. 1.0**

Amendment no. 1.

### **IEC 60904-1 Ed. 1.0**

Photovoltaic devices. Part 1: Measurement of photovoltaic current-voltage characteristics.

### **IEC 60904-2 Ed. 1.0**

Photovoltaic devices. Part 2: Requirements for reference solar cells.

### **IEC 60904-2 Amd.1 Ed. 1.0**

Amendment no. 1.

### **IEC 60904-3 Ed. 1.0**

Photovoltaic devices. Part 3: Measurement principles for terrestrial photovoltaic (PV) solar devices with reference spectral irradiance data.

### **IEC 60904-5 Ed. 1.0**

Photovoltaic devices. Part 5: Determination of the equivalent cell temperature (ECT) of photovoltaic (PV) devices by the open-circuit voltage method.

### **IEC 60904-6 Ed. 1.0**

Photovoltaic devices. Part 6: Requirements for reference solar modules.

### **IEC 60904-6 Amd. 1 Ed. 1.0**

Amendment no 1.

### **IEC 60904-7 Ed. 2.0**

Photovoltaic devices. Part 7: Computation of spectral mismatch error introduced in the testing of a photovoltaic device.

### **IEC 60904-8 Ed. 2.0**

Photovoltaic devices. Part 8: Measurement of spectral response of a photovoltaic (PV) device.

### **IEC 60904-9 Ed. 1.0**

Photovoltaic devices. Part 9: Solar simulator performance requirements.

### **IEC 60904-10 Ed. 1.0**

Photovoltaic devices. Part 10: Methods of linearity measurement.

**IEC 61173 Ed. 1.0 (1992-09)**

Overvoltage protection for photovoltaic (PV) power generating systems. Guide.

**IEC 61194 Ed. 1.0 (1992-12)**

Characteristic parameters of stand-alone photovoltaic (PV) systems.

**IEC 61215 Ed. 1.0 (1993-04)**

Crystalline silicon terrestrial photovoltaic (PV) modules. Design qualification and type approval.

**IEC 61277 Ed. 1.0 (1995-03)**

Terrestrial photovoltaic (PV) power generating systems. General and guide.

**IEC 61345 Ed. 1.0 (1998-02)**

UV test for photovoltaic (PV) modules.

**IEC 61646 Ed. 1.0 (1996-11)**

Thin-film terrestrial photovoltaic (PV) modules. Design qualification and type approval.

**IEC 61683 Ed. 1.0**

Photovoltaic systems. Power conditioners. Procedure for measuring efficiency.

**IEC 61701 Ed. 1.0 (1995-03)**

Salt mist corrosion testing of photovoltaic (PV) modules.

**IEC 61702 Ed. 1.0 (1995-03)**

Rating of direct coupled photovoltaic (PV) pumping systems.

**IEC 61721 Ed. 1.0 (1995-03)**

Susceptibility of a photovoltaic (PV) module to accidental impact damage (resistance to impact test).

**IEC 61724 Ed. 1.0 (1998-04)**

Photovoltaic system performance monitoring. Guidelines for measurement, data exchange, and analysis.

**IEC 61725 Ed. 1.0 (1997-05)**

Analytical expression for daily solar profiles.

**IEC 61727 Ed. 1.0 (1995-06)**

Photovoltaic (PV) systems. Characteristics of the utility interface.

**IEC 61829 Ed. 1.0 (1995-03)**

Crystalline silicon photovoltaic (PV) array. On-site measurement of I-V characteristics.

**IEC 61836TR2 Ed. 1.0 (1997-10)**

Solar photovoltaic energy systems. Terms and symbols.

**IEC/PAS 62111 Ed. 1.0**

Specifications for the use of renewable energies in rural decentralized electrification.

## IEC TC 82 Work in Progress

**IEC 61215 Ed. 2.0      Project Leader: J. H. Wohlgemuth**

Crystalline silicon terrestrial photovoltaic (PV) modules-design qualification and type approval.

**IEC 61727 Ed. 2.0      Project Leader: S. Chalmers**

Photovoltaic (PV) systems-characteristics of the utility interface.

**IEC 61730-1 Ed. 1.0    Project Leader: S. Jochums**

Photovoltaic module safety qualification-Part 1: Requirements for construction.

**IEC 61730-2 Ed. 1.0    Project Leader: W. Wiesner**

Photovoltaic module safety qualification-Part 2: Requirements for testing.

**IEC 61836 TR Ed. 2.0   Project Leader: G. Howell**

Solar photovoltaic energy systems-terms and symbols.

**IEC 61853 Ed. 1.0      Project Leader: J. Wohlgemuth**

Performance testing and energy rating of terrestrial photovoltaic (PV) modules.

**IEC 62078 Ed. 1.0      Project Leader: W. Wiesner**

Certification and accreditation program for photovoltaic (PV) components and systems-guidelines for a total quality system.

**IEC 62093 Ed. 1.0      Project Leader: F. Wouters**

Balance-of-system components for photovoltaic systems-design qualification and type approval.

**IEC 62108 Ed. 1.0      Project Leader: R. McConnell**

Concentrator photovoltaic (PV) receivers and modules-design qualification and type approval.

**IEC 62109 Ed. 1.0      Project Leader: T. Zgonena**

Electrical safety of static inverters and charge controllers for use in photovoltaic (PV) power systems.

**IEC 62116 Ed. 1.0      Project Leader: I. Tsuda**

Testing procedure-islanding prevention measures for power conditioners used in grid connected photovoltaic (PV) power generation systems.

**IEC 62124 Ed. 1.0      Project Leader: Frank Wouters**

Photovoltaic (PV) stand-alone systems-design qualification and type approval.

**IEC 62145 Ed. 1.0      Project Leader: J. Wohlgemuth**

Crystalline silicon PV modules-blank detail specification.

**IEC 62234 Ed. 1.0      Project Leader: G. Howell**

Safety guidelines for grid connected photovoltaic (PV) systems mounted on buildings.

**IEC 62253 Ed. 1.0      Project Leader: P. Kremer**

Direct coupled photovoltaic pumping systems-design qualification and type approval.

**IEC 62257 Ed. 1.0      Project Leader: A. Schmitt**

Specifications for the use of renewable energies in rural decentralized electrification.

**IEC 62257-1 Ed. 1.0      Project Leader: A. Schmitt**

Recommendations for small renewable energy and hybrid systems for rural electrification-Part 1: General introduction to rural electrification.

**IEC 62257-2 Ed. 1.0      Project Leader: A. Schmitt**

Recommendations for small renewable energy and hybrid systems for rural electrification-Part 2: From requirements to a range of electrification systems.

**PNW 82-263 Ed. 1.0      Project Leader: D.G. Infield**

Maximum power point tracking.

**PWI 82-1 Ed. 1.0**

Photovoltaic electricity storage systems.

*Source:* Information generated from IEC Web site on January 4, 2002: [www.iec.ch](http://www.iec.ch).

# Appendix 4: IEC Standards Possibly Useful for PV

**Taken from the *PV GAP Reference Manual, Version 1.1, ©1998.*  
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## **Batteries**

IEC 61044 Ed. 1.0	Opportunity-charging of lead-acid traction batteries.
IEC 61056-1 Ed. 1.0	Portable lead-acid cells and batteries (valve-regulated types).
IEC 61056-2 Ed. 1.0	Part 1: General requirements, functional characteristics. Methods of test. Portable lead-acid cells and batteries (valve-regulated types).
IEC 61056-3 Ed. 1.0	Part 2: Dimensions, terminals and marking. Portable lead-acid cells and batteries (valve-regulated types).
IEC 60254-1 Ed. 3.0	Part 3: Safety recommendations for use in electric appliances. Lead-acid traction batteries.
IEC 60254-2 Ed. 3.0	Part 1: General requirements and methods of test. Lead-acid traction batteries.
IEC 60896-1 (1987-01)	Part 2: Dimensions of cells and terminals and marking of polarity on cells. Stationary lead-acid batteries. General requirements and methods of test.
IEC 60896-1 Amd.1 Ed. 1.0	Part 1: Vented types. Amendment no. 1.
IEC 60896-1 Amd.2 Ed. 1.0	Amendment no. 2.
IEC 60896-1 Ed. 1.0	Stationary lead-acid batteries. General requirements and methods of test.
IEC 60896-1-am1 (1988-01)	Part 1: Vented types. Amendment no. 1.
IEC 60896-1-am2 (1990-12)	Amendment no. 2.
IEC 60896-2 (1995-11)	Stationary lead-acid batteries. General requirements and test methods.
IEC 60896-2 Ed. 1.0	Part 2: Valve-regulated types. Stationary lead-acid batteries. General requirements and test methods.
IEC 60095-1 Ed. 5.0	Part 2: Valve-regulated types. Lead-acid starter batteries.
IEC 60095-2 Amd.1 Ed. 3.0	Part 1: General requirements and methods of test. Amendment no. 1.
IEC 60095-2 Amd.2 Ed. 3.0	Amendment no. 2.
IEC 60095-2 Ed. 3.0	Lead-acid starter batteries.
IEC 60095-4 Amd.1 Ed. 1.0	Part 2: Dimensions of batteries and dimensions and marking of terminals. Amendment no. 1.
IEC 60095-4 Ed. 1.0	Lead-acid starter batteries. Part 4: Dimensions of batteries for heavy trucks.
IEC 60952-1 (1988-07)	Aircraft batteries.
IEC 60952-1 Ed. 1.0	Part 1: General test requirements and performance levels. Aircraft batteries.
IEC 60952-2 (1991-03)	Part 1: General test requirements and performance levels. Aircraft batteries.
	Part 2: Design and construction requirements.

IEC 60952-2 Ed. 1.0	Aircraft batteries. Part 2: Design and construction requirements.
IEC 60952-3 (1993-07)	Aircraft batteries. Part 3: External electrical connectors.
IEC 60952-3 Ed. 1.0	Aircraft batteries. Part 3: External electrical connectors.
<b>Cabling/wiring</b>	
IEC 60610 (1978-01)	Principal aspects of functional evaluation of electrical insulation systems: Aging mechanisms and diagnostic procedures.
IEC 60611 (1978-01)	Guide for the preparation of test procedures for evaluating the thermal endurance of electrical insulation systems.
IEC 60614-1 (1994-03)	Conduits for electrical installations. Specification. Part 1: General requirements.
IEC 60614-1-am1 (1995-09)	Amendment no. 1.
IEC 60614-2-1 (1982-01)	Specification for conduits for electrical installations. Part 2: Particular specifications for conduits. Section 1: Metal conduits.
IEC 60614-2-1-am1 (1993-10)	Amendment no. 1.
IEC 60614-2-5 (1992-11)	Specifications for conduits for electrical installations. Part 2: Particular specifications for conduits. Section 5: Flexible conduits.
IEC 60811-1-1 (1993-10)	Common test methods for insulating and sheathing materials of electric cables. Part 1: Methods for general application. Section 1: Measurement of thickness and overall dimensions. Tests for determining the mechanical properties.
IEC 60811-1-2 (1985-07)	Common test methods for insulating and sheathing materials of electric cables. Part 1: Methods for general application. Section 2: Thermal aging methods.
IEC 60811-1-2-am1 (1989-11)	Amendment no. 1.
IEC 60811-1-4 (1985-07)	Common test methods for insulating and sheathing materials of electric cables. Part 1: Methods for general application. Section 4: Test at low temperature.
IEC 60811-1-4-am1 (1993-08)	Amendment no. 1.
IEC 60811-4-1 (1985-10)	Common test methods for insulating and sheathing materials of electric cables. Part 4: Methods specific to polyethylene and polypropylene compounds. Section 1. Resistance to environmental stress cracking. Wrapping test after thermal aging in air—M.
IEC 60811-4-1-am2 (1993-08)	Amendment no. 2.
IEC 60812 (1985-07)	Analysis techniques for system reliability—procedure for failure mode and effects analysis (FMEA).
IEC 60998-1 (1990-05)	Connecting devices for low voltage circuits for household and similar purposes. Part 1: General requirements.

IEC 60998-2-1 (1990-05)	Connecting devices for low voltage circuits for household and similar purposes. Part 2-1: Particular requirements for connecting devices as separate entities with screw-type clamping units.
IEC 60998-2-2 (1991-11)	Connecting devices for low-voltage circuits for household and similar purposes. Part 2-2: Particular requirements for connecting devices as separate entities with screwless-type clamping units.
IEC 60998-2-3 (1991-11)	Connecting devices for low-voltage circuits for household and similar purposes. Part 2-3: Particular requirements for connecting devices as separate entities with insulation piercing clamping units.
IEC 60998-2-4 (1993-05)	Connecting devices for low-voltage circuits for household and similar purposes. Part 2-4: Particular requirements for twist-on connecting devices.
IEC 60998-2-5 (1996-01)	Connecting devices for low-voltage circuits for household and similar purposes. Part 2-5: Particular requirements for connecting boxes (junction and/or tapping) for terminals or connecting devices.

#### **Charge controller**

IEC 60439-1 (1992-12)	Low-voltage switchgear and control-gear assemblies. Part 1: Type-tested and partially type-tested assemblies.
IEC 60439-1-am1 (1995-11)	Amendment no. 1.
IEC 60439-1-am2 (1996-12)	Amendment no. 2.
IEC 60439-2 (1987-11)	Low-voltage switchgear and control-gear assemblies. Part 2: Particular requirements for bus-bar trunking systems (busways).
IEC 60439-2-am1 (1991-09)	Amendment no. 1.
IEC 60439-3 (1990-12)	Low-voltage switchgear and control-gear assemblies. Part 3: Particular requirements for low-voltage switchgear and control-gear assemblies intended to be installed in places where unskilled persons have access for their use. Distribution boards.
IEC 60439-3-am1 (1993-10)	Amendment no. 1.
IEC 60439-4 (1990-12)	Low-voltage switchgear and control-gear assemblies. Part 4: Particular requirements for assemblies for construction sites (ACS).
IEC 60439-4-am1 (1995-12)	Amendment no. 1.
IEC 60439-5 (1996-03)	Low-voltage switchgear and control-gear assemblies. Part 5: Particular requirements for assemblies intended to be installed outdoors in public places. Cable distribution cabinets (CDCs) for power distribution in networks.
IEC 60529 (1989-11)	Degrees of protection provided by enclosures (IP Code). Applies to the classification of degrees of protection provided by enclosures for electrical equipment with a rated voltage not exceeding 72,5 kV. Has the status of a basic safety publication.

#### **DC safety**

IEC 61204 (1993-02)	Low-voltage power supply devices, DC output. Performance characteristics and safety requirements.
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## Inverter

- IEC 60146-1-1 (1991-04) General requirements and line commutated converters.  
Part 1-1: Specifications of basic requirements.
- IEC 60146-1-1-am1 (1996-07) Amendment no. 1 to IEC 146-1-1.
- IEC 60146-1-2 (1991-04) General requirements and line commutated converters.  
Part 1-2: Application guide.
- IEC 60146-1-3 (1991-04) General requirements and line commutated converters.  
Part 1-3: Transformers and reactors.

## Lamps

- IEC 60400 (1996-06) Lampholders for tubular fluorescent lamps and starter holders.
- IEC 60400-am1 (1997-04) Amendment no. 1.
- IEC 60598-1 (1996-12) Luminaires.  
Part 1: General requirements and tests.
- IEC 60598-2-1 (1979-01) Luminaires.  
Part 2: Particular requirements. Section 1: Fixed general purpose luminaires.
- IEC 60598-2-1-am1 (1987-01) Amendment no. 1.
- IEC 60598-2-23 (1996-04) Luminaires.  
Part 2: Particular requirements. Section 23: Extra low voltage lighting systems for filament lamps.
- IEC 60598-2-3 (1993-04) Luminaires.  
Part 2: Particular requirements. Section 3: Luminaires for road and street lighting.
- IEC 60598-2-3-am1 (1997-04) Amendment no. 1.
- IEC 60598-2-4 (1997-04) Luminaires.  
Part 2: Particular requirements. Section 4: Portable general purpose luminaires.
- IEC 60598-2-5 (1979-01) Luminaires.  
Part 2: Particular requirements. Section 5: Floodlights.
- IEC 60598-2-5-am1 (1987-01) Amendment no. 1.
- IEC 60598-2-5-am2 (1993-04) Amendment no. 2.
- IEC 60598-2-7 (1982-01) Luminaires.  
Part 2: Particular requirements. Section 7: Portable luminaires for garden use.
- IEC 60598-2-7-am1 (1987-01) Amendment no. 1.
- IEC 60598-2-7-am2 (1994-08) Amendment no. 2.
- IEC 60598-2-8 (1996-07) Luminaires.  
Part 2: Particular requirements. Section 8: Handlamps.
- IEC 60081 (1984-01) Tubular fluorescent lamps for general lighting service.
- IEC 60081-am1 (1987-01) Amendment no. 1.
- IEC 60081-am2 (1988-01) Amendment no. 2.
- IEC 60081-am3 (1992-07) Amendment no. 3.
- IEC 60081-am4 (1993-09) Amendment no. 4.
- IEC 60081-am5 (1994-12) Amendment no. 5.
- IEC 60810 (1993-10) Lamps for road vehicles. Performance requirements.
- IEC 60810-am1 (1994-07) Amendment no. 1.
- IEC 60924 (1990-07) DC supplied electronic ballasts for tubular fluorescent lamps. General and safety requirements.
- IEC 60924-am1 (1993-03) Amendment no. 1.

IEC 60925 (1989-06)	DC supplied electronic ballasts for tubular fluorescent lamps. Performance requirements.
IEC 60925-am1 (1996-05)	Amendment no. 1.
IEC 60095-1 Amd.1 Ed. 5.0	Amendment no. 1.
IEC 60095-1 Amd.2 Ed. 5.0	Amendment no. 2.
IEC 61162-1 (1995-11)	Maritime navigation and radio communication equipment and systems. Digital interfaces. Part 1: Single talker and multiple listeners. Contains the requirements for data communication between maritime electronic instruments, navigation, and radio communication.

# Appendix 5: PV GAP Recommended Specifications

## PV GAP Recommended Specifications as of October 2001.

<b>Reference</b>	<b>Title</b>	<b>Remarks</b>	<b>Availability</b>
PVRS 1	<i>Photovoltaic Stand-Alone Systems—Design Qualification and Type Approval</i> ; first edition 1997-10; 44 pages	Covers components (except lamps) and indoor testing of systems. Based on JRC-ISPRA testing experience.	Available: US\$20, including mailing
PVRS 2	<i>Crystalline Silicon Terrestrial Photovoltaic (PV) Modules; Blank Detail Specification</i> ; first edition 1998-12; 14 pages	Makes IEC 61215 certifiable.	Available: US\$20, including mailing
PVRS 3	<i>Thin-Film Terrestrial Photovoltaic (PV) Modules; Blank Detail Specification</i> ; first edition 1999-05; 15 pages	Makes IEC 61646 certifiable.	Available: US\$20, including mailing
PVRS 4	<i>Photovoltaic (PV) Stand-Alone Systems, with a System Voltage below 50 V; Blank Detail Specification</i> ; third draft 2000-10; 11 pages	Draft that is intended to make IEC 82/243/CD, August 2000 (with any further amendments, and as published by the IEC in due course), certifiable. One of the documents on which IEC 82/243/CD is based is NREL/TP-520-27031 (see PVRS 9).	Available as draft, free of charge
PVRS 5	(reserved for future use)	Reserved for a future specification for SHS batteries/accumulators.	Not available at present
PVRS 6	<i>Charge Controllers for Photovoltaic (PV) Stand-Alone Systems with a Nominal System Voltage below 50 V; Blank Detail Specification</i> ; first edition 2000-06; 12 pages	Makes GEF/WB China Renewable Energy Development (RED) Project Specification certifiable (see PVRS 6A).	Available: US\$20, including mailing
PVRS 6A	<i>Annex—Specification and Testing Procedure</i> ; first edition 2000-06; 17 pages	Reproduced with the kind permission of the Project Management Office (PMO), World Bank/GEF Assisted China Renewable Energy Development Project; State Economic and Trade Commission, Beijing; People's Republic of China; May 1999, Beijing	Available, free of charge
PVRS 7	(reserved for future use)	Reserved for a future specification for SHS lighting systems.	Not available at present
PVRS 8	<i>Inverters for Photovoltaic (PV) Stand-Alone Systems; Blank Detail Specification</i> ; first edition 2000-06; 13 pages	Makes WB/GEF China Renewable Energy Development Project specification certifiable (see PVRS 8A).	Available: US\$20, including mailing

<b>Reference</b>	<b>Title</b>	<b>Remarks</b>	<b>Availability</b>
PVRS 8A	<i>Annex—Specification and Testing Procedure</i> ; first edition 2000–06; 17 pages	Reproduced with the kind permission of the Project Management Office (PMO), World Bank/GEF Assisted China Renewable Energy Development Project; State Economic and Trade Commission, Beijing; People's Republic of China; May 1999, Beijing	Available, free of charge
PVRS 9	<i>Procedures for Determining the Performance of Stand-Alone Photovoltaic Systems</i> ; 2000–01; 34 pages	<p>This is document NREL/TP-520–27031, September 1999, which was prepared by authors from NREL, Sandia National Laboratories, Florida Solar Energy Center, Southwest Technology Development Institute, and Photovoltaics for Utility Scale Applications.</p> <p>The procedures cover complete outdoor system testing and provide a common approach for evaluating whether a given PV system is suitable to perform the function for which it was designed and manufactured to accomplish, and whether it will provide adequate power to run the load.</p> <p>This is one of the documents on which the IEC TC 82 Committee Draft referred to under PVRS 4 (see above) is based.</p>	Available, free of charge

Source: Printed with permission from the PV GAP Web site: [www.pvgap.org](http://www.pvgap.org).

# Appendix 6. Example of a Blank Product Quality Assessment Specification (B-PQAS)



## Crystalline Silicon Terrestrial Photovoltaic (PV) Modules

### Qualification Approval under the IEC Quality Assessment System for Electronic Components (IECQ)

#### 1. General

##### 1.1 Scope

This PV GAP Recommended Specification is a blank detail specification applicable to crystalline silicon terrestrial photovoltaic (PV) modules of assessed quality. PV modules according to this specification are provided for operation in solar home system applications. However, as PV modules, they are also suitable for other applications, as described in the manufacturer's data sheets.

This specification references IEC 61215 requirements and methods of testing to be used in detail specifications derived from this specification, and lists the technical criteria that are necessary and sufficient to assess the quality of the PV modules in accordance with the IECQ Qualification Approval procedure described in QC 001002-3, clause 3.

##### 1.2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this PV GAP Recommended Specification.

IEC 61215: 1993, *Crystalline silicon terrestrial photovoltaic (PV) modules – Design qualification and type approval*.

IEC 61345: 1998, *UV test for photovoltaic (PV) modules*.

QC 001002-2: 1998, *Rules of Procedure of the IEC Quality Assessment System for Electronic Components (IECQ) – Part 2, Documentation*.

QC 001002-3: 1998, *Rules of Procedure of the IEC Quality Assessment System for Electronic Components (IECQ) – Part 3, Approval procedures*.

QC 001005, *Register of Firms, Products and Services approved under the IECQ System, including ISO 9000*.

### 1.3 Front page of detail specification

The layout of the front page of detail specification shall be as shown in table 1 (see the key below the form).



**Table 1. Front Page of Detail Specification**

(1)	(2) PQCxxxAAxxxx Edition: 199x/200x Page 1 of x
Electronic components of assessed quality in accordance with:  IEC 61215: 1993	(3) (4)
Detail specification for crystalline silicon terrestrial PV modules of assessed quality  Type: (5)  Construction: (6)	
Outline drawing (7)  Dimensions in millimeters:	Applications: (8)
Electrical characteristics (see 2.1 and 2.2) (9)	
Mechanical characteristics (see 2.3) (10)	
Note: Information about manufacturers who have components approved according to this detail specification is available in the current QC 001005.	

### *Key to front page*

The numbers between brackets on the front page correspond to the following indications, which should be given.

### *Identification of the detail specification*

1. The name of the National Standards Organization under whose authority the detail specification is published and, if applicable, the organization from whom the detail specification is available.
2. The IECQ logo and the number allotted to the completed detail specification by the National Standards Organization or the IECQ National Authorized Institution. (PQCxxx is the IECQ provisional specification reference allocated earlier by the IECQ Secretariat to the blank detail specification. AA is the country identifier, e.g., FR for France, DE for Germany, IN for India, US for United States of America.)
3. The number and the year of availability of the IEC standard concerning test and measurement procedures for the PV modules and/or sectional specification; also national reference, if different.
4. If different from the IECQ number, the national number of the detail specification, date of issue, and any further information required by the national system, together with any amendment numbers.

### *Identification of the PV module*

5. Type: for example, glass front, or nonglass.
6. Construction: frame material, junction box, glass type, sealing, and other typical construction details.
7. An outline drawing with the main dimensions, which are of importance for interchangeability. Alternatively, this drawing may be given in an annex to the detail specification, but (7) should always contain an illustration of the general outer appearance of the PV module.
8. Typical field of applications.
9. Electrical characteristics.
10. Mechanical characteristics.

## **2 Characteristic values of the PV module**

### **2.1 Electrical characteristics**

Examples of the electrical characteristics for a PV module that are to be reported are shown in table 2.



**Table 2. Example of Electrical Characteristics for a PV Module**

<i>Electrical parameters</i>		<i>Limits 5%</i>
Maximum power ( $P_{max}$ )	W	
Maximum power voltage ( $V_{pmax}$ )	V	
Maximum power current ( $I_{pmax}$ )	A	
Short-circuit current ( $I_{sc}$ )	A	
Open-circuit voltage ( $V_{oc}$ )	V	
Current-temperature coefficient	A/°C	
Voltage-temperature coefficient	V/°C	
Power-temperature coefficient	%/°C	
Nominal operating cell temperature (NOCT)	°C	
Maximum system operating voltage ( $V_{smx}$ ) (see 10.3 of IEC 61215)	V	

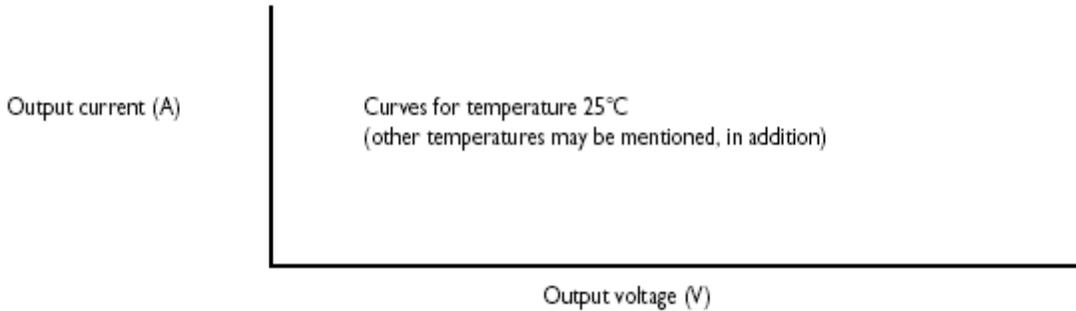
NOTE: These data represent the performance of typical modules, as measured at their output terminals, and do not include the effect of such additional equipment as diodes and cabling. The data are based on measurements made at standard test conditions (STC), which are as follows:

- Illumination of 1 kW/m<sup>2</sup> at air mass solar reference spectrum of AM 1,5 (except for the temperature coefficient characteristics, where IEC 60904-1, referenced in 10.4 of IEC 61215, states that irradiance shall be at least 800W/m<sup>2</sup>).
- Cell temperature of 25°C or as otherwise specified (on curves).

## 2.2 Current-voltage characteristics

Sample current-voltage curves for a PV module may be presented as shown in figure 1.

**Figure 1: Current-Voltage Characteristics**



## 2.3 Mechanical characteristics

Output cable, connector, or terminals.  
Mass (kg).

## 2.4 Additional information (not for inspection purposes)

For example

- \* Optional protective backplate.
- \* Mounting hardware kits.

## 3 Qualification Approval Procedure

### 3.1 General

The Qualification Approval procedure shall be in accordance with QC 001002-3, clause 3, with fixed sampling (3.1.4 a) of QC 001002-3).

**NOTE 1:** Qualification Approval is preceded by ISO approval of the manufacturer (QC 001002-3, clause 2). ISO 9001:2000 approval covers all the quality system requirements, the quality system being described in a Quality Manual and complying with ISO 9001:2000. Therefore, details, such as the address of the place of manufacture, do not belong to the detail specification, which is a publicly available specification for anyone to use.

**NOTE 2:** Other types of IECQ product or process approval, namely Capability Approval, Technology Approval (including Manufacturing Line Approval), and Specialist Subcontractor Approval, are more concerned with the process aspects. Therefore,

in this blank detail specification for Qualification Approval, such aspects are not covered.

### **3.2 Primary stage of manufacture**

Formation of the contact metallization on the solar cell. The manufacturer of the solar cells, on whom the overall quality and reliability of the PV module are strongly dependent, shall have a quality system that meets the requirements of ISO 9002 or ISO 9001 or hold IECQ manufacturer's approval (see QC 001002-3, clause 2) for the manufacturing site.

### **3.3 Subcontracting**

Subcontracting of the primary and subsequent stages of manufacture is permitted, under the conditions laid down in QC 001002-3, clauses 2 and 3.

### **3.4 Technical requirements**

Sampling, testing, pass criteria, and classification of major visual defects shall be in accordance with IEC 61215.

**NOTE:** This blank detail specification cannot add requirements that do not exist in IEC 61215. This is because IEC 61215 was prepared by an IEC technical committee (IEC TC 82) in which all IEC National Committees may participate.

Reporting, as well as issuing of the Qualification Approval certificate, shall be in accordance with QC 001002-3 clause 3.

### **3.5 Increased severity**

Detail specifications derived from this blank detail specification may make the severities of test, the end-of-test requirements, or the sampling levels more severe. These severities, or requirements, can never be made less stringent.

### **3.6 Preparation of detail specifications**

An individual manufacturer may prepare a detail specification from this blank detail specification and submit it to the responsible national organization for verification of compliance to the IECQ rules and the allocation of a number. After allocation of the number, the manufacturer may commence Qualification Approval testing under the surveillance of the IECQ Supervising Inspectorate (SI). After completion of the testing, the manufacturer or the responsible organization shall publish the detail specification.

A group of manufacturers may act together to produce a common detail specification with one of them accepting the responsibility for the submission for verification and the allocation of a number, the procedure being the same as above.



The above actions may be in cooperation with one or more customers.

Detail specifications may also be prepared by a responsible organization or by an IEC technical committee.

### 3.7 Product identification and traceability

The minimum period referred to in 2.3.2 of QC 001002-3, italic subclause heading 4.8, for maintenance of records, shall be five years.

## 4 Quality conformance inspection

Quality conformance inspection comprises the tests stated in table 3:

- \* Group A: Lot-by-lot (100% inspection) tests.
- \* Group C: Periodic tests.

All tests in table 1 are mandatory. Where a subgroup contains cumulative tests, the order of the tests is mandatory. Specimens subjected to tests denoted as destructive (D) shall not be released for delivery.

## 5 Modifications likely to affect Qualification Approval

For the modifications listed below, the Qualification Approval tests in IEC 61215 shall be repeated as indicated:

(a) Modification to cell technology.

For modifications such as

- \* metallization materials and/or process,
- \* anti-reflective coating,
- \* diffusion process,
- \* order of cell process, and
- \* change of manufacturing site of the solar cells,

Repeat

- \* thermal cycling, 200 cycles (10.11),
- \* humidity freeze (10.12),
- \* damp heat (10.13),
- \* outdoor exposure (10.8), and
- \* hot spot endurance (10.9).

(b) Modification to encapsulation system

For modifications such as

- \* different materials,
- \* different additives,
- \* different primer or method of priming, and
- \* modification of encapsulation process (that is, different time, temperature, pressure, and so forth),



**Table 3 Test Schedule for Quality Conformance Inspection**

Subclause number and test of IEC 61215	Destructive (D) or nondestructive (ND)	Conditions of test	Sample size and acceptance criterion			Performance requirements
			p	n	c	
<b>Group A inspection (100%)</b>						
<b>Subgroup A1</b>						
Visual inspection	ND					As in 10.1 of IEC 61215.
4 Marking		Check that marking is present				Clear and indelible. See the outline drawing in item (7) of the cover page of this specification and any related tables.
— Dimensions (gauging)						
<b>Subgroup A2</b>						
10.2 Performance at STC	ND					See 2.1 and the manufacturer's data sheet with the calibration reference.
10.3 Insulation test						As in 10.3 of IEC 61215.
<b>Group B inspection covering additional important characteristics</b>						
None						
<b>Group C inspection (periodic)</b>						
<b>Subgroup C1</b>						
			24	1	0	When changes in product. See 2.1
10.4 Measurement of temperature coefficients	ND					See 2.1.
10.5 Measurement of NOCT	ND					See 2.1.
10.6 Performance at NOCT	ND					See 2.1, first five items.
10.7 Performance at low irradiance	ND					See manufacturer's data sheet.

(continued to following page)

**Table 3 Test Schedule for Quality Conformance Inspection, Continued**

Subclause number and test of IEC 61215	Destructive (D) or nondestructive (ND)	Conditions of test	Sample size and acceptance criterion	Performance requirements
<b>Group A inspection (100%)</b>				
<b>Subgroup A1</b>				
Visual inspection	ND			As in 10.1 of IEC 61215.
4 Marking		Check that marking is present		Clear and indelible.
— Dimensions (gauging)				See the outline drawing in item (7) of the cover page of this specification and any related tables.
<b>Subgroup A2</b>				
10.2 Performance at STC	ND			See 2.1 and the manufacturer's data sheet with the calibration reference.
10.3 Insulation test				As in 10.3 of IEC 61215.
<b>Group B inspection covering additional important characteristics</b>				
None				
<b>Group C inspection (periodic)</b>				
<b>Subgroup C1</b>				
			24 1 0	When changes in product. See 2.1
10.4 Measurement of temperature coefficients	ND			See 2.1.
10.5 Measurement of NOCT	ND			See 2.1.
10.6 Performance at NOCT	ND			See 2.1, first five items.
10.7 Performance at low irradiance	ND			See manufacturer's data sheet.

(continued to following page)

**Table 3 Test Schedule for Quality Conformance Inspection, Continued**

Subclause number and test of IEC 61215	Destructive (D) or nondestructive (ND)	Conditions of test	Sample size and acceptance criterion			Performance requirements
			p	n	c	
<b>Subgroup C1 (continued)</b>						
10.8 Outdoor exposure test	D	After, repeat tests 10.1, 10.2, 10.3 of IEC 61215				
10.9 Hot spot endurance	D					
<b>Subgroup C2</b>						
10.10 UV test	D	IEC 61345	12	2	0	See clause 7 of IEC 61345.
10.11 Thermal cycling		50 cycles After, repeat tests 10.1, 10.2, 10.3 of IEC 61215				See 10.1, 10.2, 10.3 of IEC 61215.
10.12 Humidity freeze						See 10.1, 10.2, 10.3 of IEC 61215.
10.14 Robustness of terminations				1	0	See 10.14.5 of IEC 61215.
10.15 Twist				1	0	See 10.15.4 of IEC 61215.
<b>Subgroup C3</b>						
10.11 Thermal cycling	D	200 cycles	12	2	0	See 10.11.5 of IEC 61215.
<b>Subgroup C4</b>						
10.13 Damp heat	D	1 000h	12	2	0	See 10.13.4.
10.16 Mechanical load				1	0	See 10.16.4.
10.17 Hail				1	0	See 10.17.5.

Key:  
 p = periodicity (in months)  
 n = sample size  
 c = acceptance criterion (permitted number of nonconforming items)

Repeat

- \* thermal cycling, 200 cycles (10.11),
- \* UV (10.10, IEC 61345)/thermal cycling, 50 cycles (10.11)/humidity freeze (10.12) sequence,
- \* insulation test (10.3), and
- \* outdoor exposure (10.8).

(c) Modification to superstrate

For modifications such as

- \* different material,
- \* different thickness,
- \* different additives, and
- \* different preparation process,

Repeat

- \* UV (10.10, IEC 61345)/thermal cycling, 50 cycles (10.11)/humidity freeze (10.12) sequence,
- \* twist test (10.15),
- \* mechanical load test (10.16),
- \* insulation test (10.3),
- \* hail test (10.17), and
- \* damp heat (10.13) (if nonglass)

(d) Modification to backsheet/substrate

For modifications such as

- \* different thickness,
- \* different additives, and
- \* different preparation process,

Repeat

- \* UV (10.10, IEC 61345)/thermal cycling, 50 cycles (10.11)/humidity freeze (10.12) sequence,
- \* robustness of terminations (10.14), and
- \* damp heat (10.13) (if non-glass).

If there is a change from superstrate to substrate design or from substrate to superstrate design, the entire qualification test sequence in IEC 61215 shall be conducted.

(e) Modification to frame and/or mounting structure

For modifications such as

- \* cross-section of frame
- \* different framing material, and
- \* elimination of frame altogether,

Repeat

- \* mechanical load test (10.16),
- \* outdoor exposure (10.18),
- \* UV (10.10, IEC 61345)/thermal cycling, 50 cycles (10.11)/humidity freeze (10.12) sequence, if plastic material is used, and



- \* hail test (10.17), unless tempered glass is used as superstrate.

(f) Modification to junction box/electrical termination

For modifications such as

- \* different material,
- \* different design, and
- \* different method of attachment,

Repeat

- \* robustness of terminations (10.14),
- \* thermal cycling, 200 cycles (10.11), and
- \* insulation test (10.3).

(g) Lower- or higher-efficiency cells in identical package and identical cell process

Repeat

- \* hot-spot endurance (10.9),
- \* thermal cycle, 200 cycles (10.11), and
- \* damp heat (10.13).

## 6 Modifications that do not require retesting

Provided that all structural components, materials used, and processes (including cell process) remain the same, the following modifications shall not require retesting:

- \* fewer cells in module, and
- \* smaller cells in module, as long as each cell has the same number of interconnects and equivalent numbers of solder bonds per unit area.

## 7 Marking

Marking of the PV module shall be in accordance with clause 4 of IEC 61215. The detail specification may also require that, in addition, the following be marked:

- \* maximum power (W),
- \* maximum power current (A),
- \* open-circuit voltage (V),
- \* short-circuit current (A), and
- \* NOCT (°C).

Marking of the package may also be required, for example

- \* manufacturer's name, logo, or trademark,
- \* model/type number, and
- \* serial number.



## 8 Documentation

For each delivery, a manufacturer's or distributor's Declaration of Conformity according to QC 010002-2 shall be included. The name and the site of the manufacturer of the solar cells shall be stated on the Declaration of Conformity.

## 9 Annexes

Annexes may be included, if necessary, to show more details on PV module dimensions, mounting, terminal dimensions, and so forth.



# Appendix 7: Supervising Inspectorates

BSI  
CEPREI  
Gosstandart of Russia

IMQ  
KTL  
LCIE/SNQ  
RCJ

SEV  
STQC  
UL  
VDE

BSI	BSI Product Services Mr. L. A. Pillinger Mayland Avenue GB Hemel Hempstead HP2 4SQ United Kingdom	Tel.: + 44-1442-278-676 Fax: + 44-1442-278-621 E-mail: len.pillinger@bsi-global.com
CEPREI	China Electronic Product Reliability and Environmental Testing Research Institute (CEPREI) Mr. Zhang Jian Box 1501-33 Guangzhou 510 610 China	Tel.: + 86-20-872-36606 Fax: + 86-20-872-36230 E-mail: info@ceprei.org
Gos- standart of Russia	Gosstandart of Russia Mr. A. A. Biktchentaev 9 Leninsky Prospect 117049 Moscow Russian Federation	Tel.: + 7-095-2364044 Fax: + 7-095-2376032 E-mail: Eltech@gost.ru
IMQ	Istituto Italiano del Marchio di Qualità (IMQ) Mr. F. Pezzoli Via Quintiliano 43 I-20138 Milano Italy	Tel.: + 39-02-5073-395 Fax: + 39-02-5099-1524 E-mail: fabio.pezzoli@imq.it
KTL	Korea Testing Laboratory (KTL) Korea Institute of Industrial Technology Mr. J. K. Ham 222-13 Kuro-dong Kuro-gu Seoul 152-053 Korea (Republic of)	Tel.: + 82-2-86014-75 Fax: + 82-2-86014-56 E-mail: jkham@ctl.re.kr
LCIE/ SNQ	LCIE/SNQ Mr. P. Guillon 33 avenue du Général Leclerc BP 8 F-92266 Fontenay-aux-Roses Cedex France	Tel.: + 33-1-40955541 Fax: + 33-1-40955530 E-mail: philippe.guillon@lcie.fr

RCJ	Reliability Center for Electronic Components of Japan (RCJ) Mr. N. Shiono Shin-Daiichi Building 6F 3-4-13 Nihonbashi, Chuo-ku Tokyo 103-0027 Japan	Tel.: + 81-3-32726420 Fax: + 81-3-32722926 E-mail: shiono@rcj.dp.u-netsurf.ne.jp URL: www.rcj.or.jp
SEV	Swiss Electrotechnical Association (SEV) Mr. H. Berger Luppenstrasse 1 CH-8320 Fehraltorf Switzerland	Tel.: + 41-1-9561314 Fax: + 41-1-9561321 E-mail: heinz.berger@sev.ch
STQC	STQC Directorate Mr. K. C. Chhabra Ministry of Information Technology Electronics Niketan 6 CGO Complex New Delhi 110 003 India	Tel.: + 91-11-4362381 Fax: + 91-11-4363083 E-mail: stqc_cert@hotmail.com URL: www.iecee.org/cbscheme/NCB/IN-STQC.htm
UL	Underwriters Laboratories, Inc. (UL) Mr. J. A. Chiamonte 1285 Walt Whitman Road Melville, NY 11747-3081 USA	Tel.: + 1-631-271-6200 Fax: + 1-631-439-6024 E-mail: joseph.a.chiamonte@us.ul.com URL: www.ul.com
VDE	VDE Testing and Certification Institute Mr. G. Dreger Merianstrasse 28 D-63069 Offenbach Germany	Tel.: + 49-69-8306535 Fax: + 49-69-8306636 E-mail: pi.dreger@vde.com

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Source: IECQ Web site: [www.iecq.org/html/sis.htm](http://www.iecq.org/html/sis.htm).

# Appendix 8. Provisional List of Testing Laboratories

Laboratory	Type of accreditation	Products that are tested	Capability
<b>A. Laboratories accredited by IECQ and listed by PV GAP</b>			
Arizona State University Photovoltaic Testing Laboratory Arizona State University East 7349 East Unity Avenue Mesa, AZ 85212 USA Tel.: (480) 727-1220 Fax: (480) 727-1223 E-mail: l.ji@asu.edu www.asu.edu/east/ptl	Accredited to ISO/IEC 17025	Modules of all types	All types of tests for IEC 61215 and IEC 61646

## **B. Other accredited laboratories in the process of being listed by PV GAP**

Joint Research Centre of the European Commission (JRC) European Solar Test Installation (ESTI) TP 263 Via Fermi I-21020 Ispra (VA) ITALY Tel.:+39 332 785 885 Fax: +39 332 785 561 Fax: +39 332 789 268 E-mail: jennifer.rundle@jrc.it <a href="http://www.jrc.it/">http://www.jrc.it/</a> <a href="http://iamest.jrc.it/">http://iamest.jrc.it/</a> European Solar Test Installation Tel: +39 332 789 196 Fax: +39 332 789 268	Accredited to ISO/ IEC 17025	Modules of all types	All types of tests indoors and outdoors reliability test
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------	----------------------	-------------------------------------------------------------------

<p>Florida Solar Energy Center (FSEC)  1679 Clearlake Road  Cocoa, FL 32922-5703 USA  Tel.: (407) 638-1470  Fax: (407) 638-1010  E-mail: <a href="mailto:ventre@fsec.ucf.edu">ventre@fsec.ucf.edu</a>  <a href="http://www.fsec.ucf.edu">http://www.fsec.ucf.edu</a>  Tel.: (321) 638-1500  Fax: (321) 638-1010</p>	<p>Accredited to ISO/  IEC 17025</p>	<p>Small home systems</p>	<p>All types of tests  outdoors for Stand  Alone PV Systems.</p>
<p>BPPT/LSDE Indonesia  PUSPIPTEK, Serpong  Tangerang 15314  Indonesia  Tel.: +62 21 756-0550  Fax: +62 21 756-0904  E-mail: <a href="mailto:lsde@lsde.puspiptek.net">lsde@lsde.puspiptek.net</a>  <a href="http://www.lsde.net/">http://www.lsde.net/</a></p>	<p>Accredited to ISO/  IEC 17025</p>	<p>Modules of all types</p>	<p>Testing modules,  components,  systems and  applications</p>
<p>ETDC Bangalore, India  Electronics Test &amp; Development  Centre  Ring Road  Peenya Industrial Estate  Bangalore 560 058  India  Tel.: +91 80 839 4252  Fax: +91 80 839 1804</p>	<p>Accredited to ISO/  IEC 17025</p>	<p>Modules of all types</p>	<p>Testing modules</p>
<p>CEPREI, Guangzhou, China  110 Dongguan Zhuang Road,  Box 1501-33  Guangzhou 510 610  China  Tel.: (86) 20 872 36606  Fax: (86) 20 872 36230  E-mail: <a href="mailto:info@ceprei.org">info@ceprei.org</a>  <a href="http://www.ceprei.org/english/">http://www.ceprei.org/english/</a></p>	<p>Accredited to ISO/  IEC 17025</p>	<p>Modules</p>	<p>Testing modules.</p>

Intertek Testing Services,  
ETL SEMKO  
70 Codman Hill Rd.  
Boxborough, MA 01719  
USA  
Tel.: (978) 263-2662  
Fax: (978) 263-7086  
3933 US Route 11  
Industrial Park  
Cortland, NY 13045  
Tel.: (607) 753-6711  
(800) 967-5352  
Fax: (607) 756-9891  
E-mail: [icenter@etlsemko.com](mailto:icenter@etlsemko.com)  
[www.etlsemko.com](http://www.etlsemko.com)

Accredited to ISO/  
IEC 17025

Some components

Testing some  
systems  
components.

TÜV Rhineland, Cologne,  
Germany  
Am Grauen Stein  
D-51105 Cologne  
Germany  
Tel.: +49 221 806 2711  
Fax: +49 221 806 1350  
E-mail: [tie@umwelt-tuv.de](mailto:tie@umwelt-tuv.de)  
<http://www.de.tuv.com/>

Accredited to ISO/  
IEC 17025

Modules and  
system components

Testing modules,  
components,  
systems and  
applications

### C. Laboratories approved for ISO 9001, not accredited under ISO/IEC17025

GENEC, France  
CEA Cadarache  
13108 St. Paul lez Durance  
FRANCE  
Tel.: +33 442 25 66 02  
Fax: +33 442 25 73 65  
E-mail :  
[malbranche@macadam.cea.fr](mailto:malbranche@macadam.cea.fr)  
<http://www.cea.fr/>

ISO 9001 approved

Modules and  
system testing.  
Outdoor facilities  
and BOS testing

JET, Japan  
Japan Electrical Safety and  
Environment Technology  
Laboratories (JET)  
5-14-12, Yoyogi, Shibuya-ku  
Tokyo, 151-8545 Japan  
Tel.: +81 3 3466 5162  
Fax: +81 3 3466 5106  
E-mail: [shirai\\_k@jet.or.jp](mailto:shirai_k@jet.or.jp)  
[www.jet.or.jp](http://www.jet.or.jp) or [http://](http://www.iecee.org/cbscheme/NCB/JP-JET.htm)  
[www.iecee.org/cbscheme/NCB/JP-](http://www.iecee.org/cbscheme/NCB/JP-JET.htm)  
JET.htm

ISO 9001 approved

Modules and  
system testing.  
Appliances and  
inverter testing.

Fraunhofer-Institut, Germany  
Fraunhofer-Institut für  
Grenzflächen- und  
Bioverfahrenstechnik IGB  
(Fraunhofer Institute for Interfacial  
Engineering and Biotechnology)  
Nobelstrasse 12  
70569 Stuttgart  
Germany  
Tel.: +49 7 11/9 70-40 01  
Fax: +49 7 11/9 70-42 00  
E-mail: [info@igb.fraunhofer.de](mailto:info@igb.fraunhofer.de)  
<http://www.igb.fhg.de/>

ISO 9001 approved

Modules and  
system testing.

ECN, Netherlands  
The Netherlands Energy Research  
Foundation (ECN)  
P.O. Box 1  
1755 ZG Petten  
The Netherlands  
Tel.: +31 224 564949  
Fax: +31 224 564480  
E-mail: [info@ecn.nl](mailto:info@ecn.nl)  
<http://www.ecn.nl>

ISO 9001 approved

Modules and  
system testing.

CANMET, Canada  
CANMET Energy Technology  
Centre—Varenes  
Natural Resources Canada  
1615 Lionel-Boulet Boulevard  
P.O. Box 4800  
Varenes, Quebec  
Canada J3X 1S6  
E-mail:  
webmaster@cedrl.mets.nrcan.gc.ca  
<http://cedrl.mets.nrcan.gc.ca/>

ISO 9001 approved

Modules and  
system testing.

NREL, Colorado, USA  
National Renewable Energy  
Laboratory (NREL)  
1617 Cole Blvd.  
Golden, CO 80401 USA  
Tel.: (303) 275-3000  
<http://www.nrel.gov>

ISO 9001 approved

Module and Cell  
testing

Sandia National Laboratories, USA  
Business type: PV Testing  
Product types: Equipment testing  
Sandia National Laboratories  
PO Box 5800  
Albuquerque, NM 87185 USA  
Tel.: (505) 844-2154  
E-mail: [eesbt@sandia.gov](mailto:eesbt@sandia.gov)  
[http://www.sandia.gov/  
Renewable\\_Energy/renewable.html](http://www.sandia.gov/Renewable_Energy/renewable.html)

BOS testing

#### **D. Laboratories with appropriate equipment but not yet accredited**

IT Power, UK  
The Manor House  
Chineham Court  
Lutyens Close  
Chineham, Hampshire RG24 8AG  
United Kingdom  
Tel.: +44 1256 392700  
Fax: : +44 1256 392701  
E-mail:  
[Bernard.mcnelis@itpower.co.uk](mailto:Bernard.mcnelis@itpower.co.uk)  
<http://www.itpower.co.uk>

PV test and training  
Center

CIEMAT, Spain  
Avda. Complutense, 22  
28040 Madrid  
Spain  
Tel.: +91 346 60 00 (ext. 68 30)  
E-mail: [sisifo@ciemat.es](mailto:sisifo@ciemat.es)  
<http://www.ciemat.es/>

Expects approval for  
ISO 9001 in 2002

Modules and system  
testing.

CIEFES, Senegal

Starting development

CDER, Morocco  
Rue Machaar El Haram, Quartier  
Issil, Marrakech  
Morocco  
Tel.: +212 4 309807  
Fax: +212 4 309807  
E-mail [psemaroc@mtds.net.ma](mailto:psemaroc@mtds.net.ma)

Installing equipment  
for systems and  
battery testing.

*Note:* Information was obtained from the Web site <http://www.pvpower.com/pvstst.html> and from the Web sites of individual laboratories. List reflects updates as of August 2002.

# Glossary of Terms



**Acceptance tests:** Tests performed on an ongoing piece-by-piece or statistical sampling basis of the as-manufactured and/or installed product or system for the purpose of verifying the acceptability of the current manufacturing and/or installation processes and materials.

**Accreditation:** The procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

**Approval:** Permission for a product, process, or service to be marketed or used for stated purposes or under stated conditions.

**(As) needed/(as) appropriate/(as) necessary:** These indicate requirements that may or may not apply to your business.

**Audit:** A systematic and independent examination to determine whether or not quality activities and related results comply with planned arrangement, and whether or not these arrangements are implemented effectively and are suitable to achieve objectives.

**Auditor:** An individual who is tasked with performing audits.

**Bid:** See Tender.

**Certification:** The procedure by which a third party gives written assurance that a product, process, or service conforms to specified requirements.

**Certify:** Third party gives written assurance that a product, process, or service conforms to specified requirements.

**Component:** A constituent part of a product.

**Conformity evaluation:** The systematic examination of the extent to which a product, process, or service fulfills specified requirements.

**Continual improvement:** Recurring activity to increase the ability to fulfill requirements.

**Contract:** Agreed-upon requirements between a supplier and customer transmitted by any means.

**Corrective action:** An action taken to eliminate the causes of an existing situation of nonconformity, defect, or other undesirable condition in order to prevent recurrence.

**Customer:** An individual or organization that purchases and receives a commodity, product, or service provided by the supplier.

**Deficiency:** Substandard or noncomplying, relative to objective standards.

**Document:** Information and its supporting medium, for example, record, specification, procedure document, drawing, report, or standard. The medium could be paper or a magnetic, electronic, or optical computer disc, photograph, or the like.

**Documentation:** Furnishing or authenticating with documents; evidence of a process; conformity to historical or objective facts or standards.

**IEC:** International Electrotechnical Commission.

**IECQ:** IEC Quality Assessment System for Electronic Components.

**Inspection:** Conformity evaluation by observation and judgment accompanied, as appropriate, by measurement, testing, or gauging.

**ISO 9000:** A group of standards, under the International Organization for Standardization (ISO), which specify requirements for quality systems and which provide guidance to aid in the interpretation and implementation of the quality system.

**Management representative:** The organization's representative who shall have defined authority for ensuring that a quality system is established, implemented, and maintained in accordance with the standard, and for reporting on the performance of the quality system to management for review and as a basis for improvement of the quality system.

**Manager:** The person who exercises authority, takes responsibilities, makes decisions, and fulfills similar managerial functions on behalf of the business.

**Nonconformity:** Any instance of failure to meet a specified requirement.

**Objective evidence:** Information that can be proven true, based on facts obtained through observation, measurement, test, or other means.

**Organization:** A company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.

**Photovoltaic:** Solid-state, semiconductor-based solar electric technology that directly converts light energy into electricity.

**Preventive action:** An action taken to eliminate the causes of a potential nonconformity, defect, or other undesirable situation, in order to prevent occurrence.

**Procedure:** A specified way to perform an activity; a description that details by whom, with what, when, where, and how processes are carried out.

**Process:** A series of actions or activities directed to a planned or specific result or product that transform inputs into outputs.

**Product:** The result of activities or processes.

**Project:** A unique process consisting of a set of coordinated and controlled activities with a start and finish dates, undertaken to achieve an objective conforming to specific requirements, including the constraints of time, cost, and resources.



**PV GAP:** Global Approval Program for Photovoltaics: a worldwide organization for promoting satisfactory photovoltaic products and systems.

**Qualification test:** A test performed on a randomly selected set of components or a calibration performance of unknowns usually by means of interlaboratory comparisons.

**Quality:** The totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.

**Quality assurance:** All the planned and systematic activities implemented within the quality system and demonstrated, as needed, to provide adequate confidence that an entity will fulfill requirements for quality.

**Quality control:** Operational techniques and activities that are used to fulfill requirements for quality.

**Quality improvement:** Actions taken throughout the organization to increase the effectiveness and efficiency of activities and processes, in order to provide added benefits to both the organization and its customers.

**Quality management system:** A management system to direct and control an organization with regard to quality.

**Quality manager:** A management representative with responsibility for the quality system, its implementation, and its maintenance.

**Quality Manual:** The document in which is compiled the organization's procedures and documentation for quality and quality improvement programs.

**Quality plan:** The document setting out the specific quality practices, resources, and sequence of activities relevant to a particular product, project, or contract.

**Quality policy:** The overall intentions and direction of an organization with regard to quality as formally expressed by top management.

**Quality system:** The organizational structure and procedures by which an organization's processes are carried out, and through which are written down how things are done and the results are recorded to show how things were done.

**Quality team:** An organization's team of management and staff responsible for developing and reviewing the organization's quality systems.

**Registrar:** An independent, third-party body that audits organizations for accreditation or certification and registers those qualified organizations.

**Review:** The broad overview of the activities relevant to the situation under study; here, used in three situations: management review, contract review, and design review.



**Service:** The result generated by activities at the interface between the supplier and the customer and by supplier internal activities to meet the customer needs. Also the nontangible result of a process or effort (for example, testing, maintenance, repair, or consulting).

**Shall:** This means a requirement has to be followed whenever it occurs in the manual.

**Should (may/can):** These items are normally used to suggest or recommend a course of action. They are never used to indicate a requirement that must be followed.

**Specified requirements:** Product requirements prescribed by the customer and agreed to by the supplier. Also, requirements prescribed by the supplier that are perceived as satisfying a market need.

**Subcontractor:** Any organization from which you purchase products or services, or both. You normally refer to them as your vendors.

**Supplier:** Organization or person that provides a product.

**Supply chain:** A set of interrelated resources and activities that accepts inputs from suppliers, adds value to those inputs, and produces outputs for customers.

**Tender:** An offer made by a supplier in response to an invitation to satisfy a contract award to provide a product or service.

**Training:** Processes to introduce, expand, and/or improve the knowledge and skills of individuals and teams in a systematic way.

**Vendor:** An outside provider of a product or service.

**Verification:** Confirmation, through the provision of objective evidence that specified requirements have been fulfilled.

**Validation:** Confirmation by the examination and recording of physical evidence that the requirements for a specific intended use or application have been fulfilled.

Photovoltaic Terms:

**Balance of system:** The parts of a system other than the array of photovoltaic modules, including switches, controls, meters, power conditioning equipment, support structure for the array, batteries, and energy storage, if any. Symbol: BOS.

**Distributed generating system:** The facility and equipment comprising an electricity generation system that is connected and operated in parallel with a utility distribution system. Owner system may or may not be connected to the electricity transmission system.

**Grid-connected operation:** The operating mode in which a photovoltaic system generates electricity in parallel with a utility supply authority.



**Photovoltaic effect:** The generation of direct current voltage by the absorption of light.

**Photovoltaic system:** An installed assembly of modules and other system components that generate and supply electricity suitable for connection to an electrical load. The component list and system configuration varies as a function of the application.

**Stand-alone operation:** The operating mode in which a system's load is electrified solely by the system and not in parallel with supply authority or other electricity generator.



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