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Unit Resource Manual

Manufacturing Skills Australia Courses

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Aims of the Competency Unit:

A Quality Management System (QMS) is a collection of business processes focused on achieving quality policy and quality objectives to meet customer requirements. It is expressed as the organizational structure, policies, procedures, processes and resources needed to implement quality management. This unit covers working within a quality improvement system, either individually or in a team situation.

This unit is applicable for any work within a quality improvement system in a manufacturing, engineering or related environment. The definition of customer is wide and applies to the next person or organisation receiving the product or service. Application may include quality inspection of own or other employee's work up to the level of the employee's technical competence.

Unit Hours:

18 Hours

Prerequisites:

None.

Elements and Performance Criteria

1.	Work within a quality system.	1.1	Instructions and procedures are followed and duties are performed in accordance with requirements of quality improvement system.
		1.2	Conformance to specifications is ensured.
		1.3	Defects are detected and reported according to standard operating procedures.
		1.4	Performance of operation or quality of product or service is monitored to ensure customer satisfaction.
2.	Engage in quality improvement.	2.1	Current performance is assessed.
		2.2	Established performance measures are identified.
		2.3	Specifications and standard operating procedures are identified.
		2.4	Defects are detected and reported according to standard operating procedures.
		2.5	Process improvement procedures are participated in.
		2.6	The improvement of internal/external customer/supplier relationships is participated in.
		2.7	Performance of operation or quality of product or service is monitored to ensure customer satisfaction.

Required Skills and Knowledge

Required skills include:

- reading, interpreting and following information on written job sheets, instructions, standard operating procedures and drawings
- checking and clarifying task-related information
- entering information onto workplace documents
- checking for conformance to specifications
- identifying duties of the individual within the quality improvement system
- identifying customers' requirements with respect to the operation or quality of the product or service
- reporting where appropriate, defects detected
- carrying out work in accordance with the process improvement procedures
- performing numerical operations, geometry and calculations/formulae within the scope of this unit

Required knowledge includes:

- quality system terminology and concepts, e.g.
    - quality assurance - planning to meet customers' requirements
    - quality control - checks and procedures to ensure customer requirements are met
    - quality inspection - inspecting and testing products and services
    - total quality control - a company-wide approach that combines both quality assurance and quality control so that the customer is always satisfied
- commonly accepted meaning/s of the terms quality and quality system
- the reasons for following the requirements of the quality improvement system
- strategies and approaches for working within a quality system
- procedures to be followed in undertaking the work
- specifications to which the individual's work is to comply
- reasons for ensuring work conforms to specification
- benefits of good quality:
    - quality products
    - reduced costs
    - customer confidence, satisfaction and loyalty
    - good reputation
    - job satisfaction
    - solving problems
    - increased competitiveness
    - keeping up with technology
- costs and consequences of poor quality e.g.
    - lost customers
    - accidents
    - wastage
    - lost time
    - low morale
    - conflict
- procedures for reporting defects
- examples of common defects
- quality improvement procedures
- four steps of the quality cycle: plan, do, check, act
- reasons for following process improvement procedures
- examples of ways in which customer/supplier relationships can be improved
- benefits of good customer/supplier relationship
- hazards and control measures associated with applying quality procedures, including housekeeping
- safe work practices and procedures

Assessment:

A student can be assessed as competent for this unit if they can demonstrate an understanding of applying quality systems through completing the Skill Practice Exercises to the satisfaction of the teacher or assessor.

Lesson Program:

Unit hour unit and is divided into the following program.

Topic	Skill Practice Exercise
Topic 1 – Quality Management:	MEM15002-SP-0101
Topic 2 – Quality Inspection:	MEM15002-SP-0201
Topic 3 – Quality Improvement:	MEM15002-SP-0301
Topic 4 – Defect Detection:	MEM15002-SP-0401
Topic 5 – Risk Assessment:	MEM15002-SP-0501

Contents:

Contents:

Topic 1 – Quality Management:

1.1 Quality Assurance or Quality Control:

Quality Assurance (QA) and Quality Control (QC) both form an integral part of the organisation's quality management plan, and the effectiveness of delivery teams relies on the differences being well understood by all stakeholders, including management.

Effective quality systems can contribute enormously to the success of projects, but the counterpoint is that, when poorly understood, the quality systems are likely to be weak and ineffective in ensuring that the delivered system is delivered on time, built by the team within their allocated budget, and satisfies the customer's requirements.

Quality Assurance or is it Quality Control? Many people say "QA" while they actually mean is "QC". The ambiguity consistently creates problems and is a sure way of undermining a project. Projects are negatively affected as it tends to lead to strained conversations and makes reaching consensus difficult.

Although QA and QC are closely related concepts, and are both aspects of quality management, they are fundamentally different in their focus:

- Quality Assurance is the process of managing for quality.
- Quality Control is used to verify the quality of the output

Achieving success in a project requires both QA and QC. If only QA is applied, then a set of processes results that can be applied to ensure great quality in the delivered solution, but the delivered solution itself is never actually quality-checked.

Likewise, if the focus is only on QC, results in simply conducting tests without any clear vision for making the tests repeatable, for understanding and eliminating problems in testing, and for generally driving improvement into the means that are used to deliver the solutions.

In either case, the delivered solution is unlikely to meet the customer expectation or satisfy the business needs that gave rise to the project in the first place.

1.1.1 Understanding the Difference Between QA and QC:

The difference between QA & QC is covered in AS/NZS 9000:2008 standards. These standards relate to quality management systems and are designed to help organisations meet the needs of customers and other stakeholders. In terms of the standard, a quality management system is comprised of quality planning and quality improvement activities, the establishment of a set of quality policies and objectives that will act as guidelines within an organisation, and QA and QC.

In AS/NZS 9000 (ISO 9000), Quality Assurance is defined as:

> "A part of quality management focused on providing confidence that quality requirements will be fulfilled"

Quality Control is defined as:

> "A part of quality management focused on fulfilling quality requirements"

The definitions lay a good foundation, but they are too broad and vague to be useful although, alternate definitions could be expanded to state:

Quality Assurance:

> "The function of software quality that assures that the standards, processes, and procedures are appropriate for the project and are correctly implemented"

Quality Control as:

> "The function of software quality that checks that the project follows its standards, processes, and procedures, and that the project produces the required internal and external (deliverable) products"

Simply put, Quality Assurance focuses on the process of quality, while Quality Control focuses on the quality of output.

1.1.2 Quality Assurance – Prevention:

QA is focused on planning, documenting and agreeing on a set of guidelines that are necessary to assure quality. QA planning is undertaken at the beginning of a project, and draws on both specifications and industry and/or company standards. The typical outcomes of the QA planning activities are quality plans, inspection and test plans, the selection of defect tracking tools and the training of people in the selected methods and processes.

The purpose of QA is to prevent defects from entering into the solution in the first place. In other words, QA is a pro-active management practice that is used to assure a stated level of quality for an initiative.

Undertaking QA at the beginning of a project is a key tool to mitigate the risks that have been identified during the specification phases. Communication plays a pivotal role in managing project risk, and is crucial for realising effective QA. Part of any risk mitigation strategy is the clear communication of both the risks, and their associated remedies to the team or teams involved in the project.

1.1.3 Quality Control – Detection

Quality Control, on the other hand, includes all activities that are designed to determine the level of quality of the delivered solutions. QC is a reactive means by which quality is gauged and monitored, and QC includes all operational techniques and activities used to fulfil requirements for quality; these techniques and activities are agreed with customers and/or stakeholders before project work is commenced.

QC involves verification of output conformance to desired quality levels which means that the solution is checked against customer requirements, with various checks being conducted at planned points in the development lifecycle. Teams will use, amongst other techniques, structured walkthroughs, testing and code inspections to ensure that the solution meets the agreed set of requirements.

1.1.4 Benefits of Quality Management

The benefits of a structured approach to quality management cannot be ignored.

Quality Control is used, in conjunction with the quality improvement activity, to isolate and provide feedback on the causes of quality problems. By consistently using this approach across projects, the feedback mechanism works towards identifying root-cause problems, and then developing strategies to eliminating these problems. Using this holistic approach ensures that teams achieve ever higher levels of quality.

As a consequence of formulating and executing a quality management plan the company can expect:

- Greater levels of customer satisfaction, which will very likely result in both repeat business, as well as referral business
- A motivated team that not only understand the policy objectives of the quality management plan, but who also actively participate in executing the plan
- Elimination of waste by eliminating rework arising from either the need to address bugs, or to address gaps in the solution's ability to meet customer requirements
- Higher levels of confidence in planning, since the tasks arising from unplanned rework will fall away
- Financial rewards for the company, which are a consequence of new projects from existing and referral clients, as well as through the reduction of monies spent on rework tasks.

As the company's quality management plan matures, the confidence of all stakeholders will grow. The company will be seen to be more effective and efficient in delivering an agreed solution to clients.

1.2 Quality Assurance:

Quality assurance (QA) is a process-centred approach to ensuring that a company or organization is providing the best possible products or services. It is related to quality control, which focuses on the end result, such as testing a sample of items from a batch after production. Although these terms are sometimes used interchangeably, quality assurance focuses on enhancing and improving the process that is used to create the end result, rather than focusing on the result itself. Among the parts of the process that are considered in QA are planning, design, development, production and service.

Advantages of Quality Assurance Include:

- Costs are reduced because there is less wastage and re-working of faulty products as the product is checked at every stage
- It can help improve worker motivation as workers have more ownership and recognition for their work (see Herzberg)
- It can help break down 'us and them' barriers between workers and managers as it eliminates the feeling of being checked up on
- With all staff responsible for quality, this can help the firm gain marketing advantages arising from its consistent level of quality

1.2.1 The Shewhart Cycle:

There are many QA tools that organizations can use and that will help guide them through the steps that are needed to ensure that their processes are as efficient and productive as possible. One of the most popular tools is called the Shewhart cycle, which was developed by Dr. W. Edwards Deming, a 20th-century American management consultant who named the tool after his associate, Walter A. Shewhart; this cycle for quality assurance consists of four steps: Plan, Do, Check and Act (PDCA). At the end of Shewhart cycle, which also is called the Deming cycle or PDCA cycle, the steps are repeated to ensure that the process is being evaluated and improved on a constant basis.

1.2.2 Four Steps:

During the first step of the PDCA cycle, Plan, the organization should establish its objectives and determine the processes or changes in the processes that are required to deliver the desired results. The second step, Do, is when the processes or changes are developed and tested. In the third step, Check, the processes or changes are monitored and evaluated to determine whether the results are meeting the predetermined objectives. The final step, Act, is when actions that are necessary to achieve the desired improvements are fully implemented into the process. The cycle can then be repeated, beginning with new objectives being planned.

1.2.3 Excellence in Every Component:

The Shewhart cycle can be an effective method for achieving quality assurance because it analyses the existing conditions and methods that are used to provide the product or service to customers. The goal is to ensure that excellence is inherent in every component of the process. Quality assurance also helps determine whether the steps that are used to provide the product or service are appropriate for the time and conditions. In addition, if the cycle is repeated throughout the lifetime of the product or service, it helps improve the company's efficiency by ensuring that the process is always being refined and improved.

1.2.4 Attention to Detail:

Quality assurance demands a degree of detail in order to be fully implemented at every step. Planning, for example, could include determining specific levels of quality or measurable results that the organization wants to achieve. Checking could involve testing and other objective measurements to determine whether the goals were met, rather than mere subjective evaluation of quality. Acting could mean a total revision in the manufacturing process to correct a technical or cosmetic flaw or very small changes to improve efficiency or accuracy.

Competition to provide specialized products and services often results in breakthroughs as well as long-term growth and change. Quality assurance verifies that any customer

offering, regardless whether it is new or evolved is produced and offered with the best possible materials, in the most comprehensive way and with the highest standards. The goal to exceed customer expectations in a measurable and accountable process is provided by quality assurance.

1.3 Quality Control:

Quality control is a process that is used to ensure a certain level of quality in a product or service. It might include whatever actions a business deems necessary to provide for the control and verification of certain characteristics of a product or service. Most often, it involves thoroughly examining and testing the quality of products or the results of services. The basic goal of this process is to ensure that the products or services that are provided meet specific requirements and characteristics, such as being dependable, satisfactory, safe and fiscally sound.

Companies that engage in quality control typically have a team of workers who focus on testing a certain number of products or observing services being done. The products or services that are examined usually are chosen at random. The goal of the quality control team is to identify products or services that do not meet a company's specified standards of quality. If a problem is identified, the job of a quality control team or professional might involve stopping production or service until the problem has been corrected. Depending on the particular service or product as well as the type of problem identified, production or services might not cease entirely.

Usually, it is not the job of the quality control team or professional to correct quality issues. Typically, other individuals are involved in the process of discovering the cause of quality issues and fixing them. After the problems are overcome and the proper quality has been achieved, the product or service continues production or implementation as usual.

Many types of businesses perform these types of quality checks. Manufacturers of food products, for example, often have employees who test the finished products for taste and other qualities. Clothing manufacturers have workers inspect garments to ensure that they are properly sewn. Service-oriented companies often have representatives who observe the services being performed or who do follow-up checks to ensure that everything was done properly.

Quality control also might involve evaluating people. If a company has employees who don't have adequate skills or training, have trouble understanding directions or are misinformed, the quality of the company's products or services might be diminished; this is especially important for service-oriented companies, because the employees are the product that they provide to customers.

Often, quality control is confused with quality assurance though the two are similar, but there are some basic differences. Quality control is concerned with examining the product or service, the end result; quality assurance is concerned with examining the process that leads to the end result. A company would use quality assurance to ensure that a product is manufactured in the right way, thereby reducing or eliminating potential problems with the quality of the final product.

Advantages of Quality Control:

- With quality control, inspection is intended to prevent faulty products reaching the customer. The approach means having specially trained inspectors, rather than every individual being responsible for their own work. Furthermore, it is thought that inspectors may be better placed to find widespread problems across an organisation.

Disadvantages of Quality Control:

- A major problem is that individuals are not necessarily encouraged to take responsibility for the quality of their own work.

- Rejected product is expensive for a firm as it has incurred the full costs of production but cannot be sold as the manufacturer does not want its name associated with substandard product. Some rejected product can be re-worked, but in many industries it has to be scrapped – either way rejects incur more costs,
- A quality control approach can be highly effective at preventing defective products from reaching the customer. However, if defect levels are very high, the company's profitability will suffer unless steps are taken to tackle the root causes of the failures.

1.3.1 Quality Control in Manufacturing:

In the rush to get products out the door quickly while minimizing cost and maximizing profit, many manufacturers neglect the quality control testing of their products. The failure of some companies to use a quality control system are well documented, as seen in product recalls from many large international motor vehicle manufacturers. Even the great Titanic may have suffered from quality control issues; many believe she sank so quickly in part because of faulty rivets weakening the part of the hull that collided with the iceberg.

In manufacturing, quality control is a process used to ensure products meet a company's quality requirements before they are sold into the external market. Quality control in manufacturing emphasizes the importance of thoroughly examining and testing the quality of products to find defects. Companies that use quality control in manufacturing processes typically have a team of workers who focus on testing a certain number of products at random to determine whether they meet the company's standards.

1.3.2 Benefits of Using Quality Control in Manufacturing:

The most obvious beneficiary of quality control is the customer, who receives a high-quality product; this in turn benefits the company by ensuring customer satisfaction, which leads to repeat business, customer loyalty, and spreading the word about the quality of the company's product. Therefore, quality control in manufacturing pays off for a company in both reputation and revenue.

Companies with quality control procedures in place are far less likely to face product recalls or safety hazards from poorly constructed products. The cost associated with these recalls can be steep: In 2009, one vehicle manufacturer had to recall 12.4 million cars worldwide for sticky gas pedals and floor mats that could jam accelerators, at a cost of approximately $2 billion; this could have been avoided had quality control been properly implemented.

1.3.3 Incorrect Implementation of Quality Control in Manufacturing :

Quality control in manufacturing is usually performed at the end of the production process, before products go out to other companies or consumers. This approach has limited effectiveness, because defects are uncovered only after the product is ready to be packaged or shipped. Therefore, time and resources are wasted creating defective products.

QC introduced at every stage of the manufacturing process would reduce time and wastage, and improve productivity leading to greater profits.

1.3.4 Using Quality Assurance with Quality Control in Manufacturing:

The aim of quality assurance is to streamline a production process such that finished products are more likely to meet the company's quality criteria. The difference between quality control and quality assurance is that quality control evaluates the finished product, while quality assurance ensures the manufacturing process will produce high quality products. Quality assurance can be combined with quality control to avoid the limitations of using only quality control in manufacturing.

1.3.5 Quality Control, Quality Assurance and Lean Manufacturing:

Companies that use quality assurance to prevent problems during production and quality control as a final check before distribution will benefit by wasting less resources, which is a component of lean manufacturing, which aims to get rid of any part of the production

process that is unnecessary, resulting in a more efficient production process. By using both quality assurance and quality control, a company can guarantee they are sending out the highest quality products possible while saving time and money because of gains in efficiency.

1.3.6 Implementing Quality Control in Manufacturing:

Quality assurance along the manufacturing process should adequately prevent defective products. However, a quality control process should still be in place as a final check for product quality. To implement an effective quality control program, a company should first decide which quality standards the product is required to meet. Management must then select what percent of each batch of products will be tested for quality. Next, designated employees will test the products and report the results to management. Product quality testing methods will vary greatly depending on the type of products the company manufactures.

If defective products are found, management must decide whether to repair or reject those products. If a large percentage of products have defects, management will bring production to a halt until whatever is causing the problem is corrected. The quality assurance process should then be reviewed to determine why the problem was not prevented. Management must ensure the quality assurance and quality control in manufacturing processes are ongoing to ensure all defects have been fixed and to detect new product defects as they come.

1.4 Corrective and Preventive Action:

Corrective and preventive action (CAPA, can also be called corrective action/preventive action, or simply corrective action) are improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations. CAPA is a concept within good manufacturing practice (GMP), and numerous ISO business standards; it focuses on the systematic investigation of the root causes of identified problems or identified risks in an attempt to prevent their recurrence (for corrective action) or to prevent occurrence (for preventive action).

Corrective actions are implemented in response to customer complaints, unacceptable levels of product non-conformance, issues identified during an internal audit, or adverse or unstable trends in product and process monitoring such as would be identified by statistical process control (SPC). Preventive actions are implemented in response to the identification of potential sources of non-conformity.

To ensure that corrective and preventive actions are effective, the systematic investigation of the root causes of failure is pivotal. CAPA is part of the overall quality management system (QMS).

The concepts are:

- Clearly identified sources of data which identify problems that will be investigated.
- Root cause analysis to identify the cause of a discrepancy or deviation and suggest corrective actions of a problem which is identified.

A common misconception is that the purpose of preventive action is to avert the occurrence of a similar potential problem. The process is all part of corrective action, because it is a process of determining such similarities that should take place in the event of a discrepancy.

Preventive action is any proactive methodology used to determine potential discrepancies before they occur and to ensure that they do not happen (thereby including, for example, preventive maintenance, management review or other common forms of risk avoidance). Corrective and preventive actions both include investigation, action, review, and further action if so required. It can be seen that both fit into the PDCA (plan-do-check-act) philosophy as determined by the Deming-Shewhart cycle.

Investigations to root cause may conclude that no corrective or preventive actions are required, and additionally may suggest simple corrections to a problem with no identified

systemic root cause. When multiple investigations end in no corrective action, a new problem statement with expanded scope may be generated, and a more thorough investigation to root cause performed.

Implementation of corrective and preventive actions is the path towards improvement and effectiveness of Quality Management Systems. Corrective actions are nothing but the action/s based on the problem identification. The problem or a non-conformance can be identified internally through staff suggestions, management reviews, document reviews or internal audits. Customer complaints/suggestions, customer rejections, non-conformities raised in customer/third party audits and recommendations by the auditors are the external sources which lead to find the root cause of the problem.

Corrective action is a reaction to any of the cause/non-conformance mentioned above and can be divided in two phases of action:

1. Identification of root cause: Total Quality Management tools such as fish-bone or cause and effects analysis can be practiced. CAPA is appropriate and effective if and only if the root cause of problem(s) has been identified.
2. Taking necessary actions: The effectiveness of the corrective action taken has to be verified periodically through a systematic approach of PDCA (Plan-Do-Check-Act) cycle.

Preventive action is prediction of problem and trying to avoid the occurrence (fail safe) through self-initiated actions and analysis related with processes/products which can be initiated with the help of active participation of staff members/workers through improvement teams, improvement meetings, opportunities for improvement during internal audits, management review, customer feedback and deciding own goals quantized in terms of business growth, reducing rejections, utilizing the equipment effectively, etc.

Examples of corrective actions include:

- Error Proofing
- Process Redesign
- Product Redesign
- Training or enhancement/ modification of existing training programmes
- Improvements to maintenance schedules
- Improvements to material handling or storage

In some cases a combination of such actions may be necessary to fully correct the problem.

1.4.1 The PDCA Cycle:

The management team have created a creditable concept of where a company needs to be in the future but something is wrong and needs to be modified. Two questions can be asked:

1. Is everyone 100% correct?
2. Is everyone absolutely certain the solution will work in every way?

Where the consequences of getting things wrong are significant, it often makes sense to run a well-crafted pilot project so if the pilot doesn't deliver the expected results, there is a chance to fix and improve things before being fully committing reputations and resources. So how can it be ensured sure that it is right, not just this time but every time? The solution is to have a process that everyone can follow when there is a need to make a change or solve a problem; a process that will ensure everyone plans, tests and incorporates feedback before committing to implementation.

A popular tool is the Plan-Do-Check-Act Cycle and is often referred to as the Deming Cycle or the Deming Wheel after its proponent, W Edwards Deming. It is also sometimes called the Shewhart Cycle.

Deming is best known as a pioneer of the quality management approach and for introducing statistical process control techniques for manufacturing to the Japanese, who

used them with great success. He believed that a key source of production quality lay in having clearly defined, repeatable processes. The PDCA Cycle as an approach to change and problem solving is very much at the heart of Deming's quality-driven philosophy.

The four phases in the Plan-Do-Check-Act Cycle involve:

- Plan: Identifying and analysing the problem.
- Do: Developing and testing a potential solution.
- Check: Measuring how effective the test solution was, and analysing whether it could be improved in any way.
- Act: Implementing the improved solution fully.

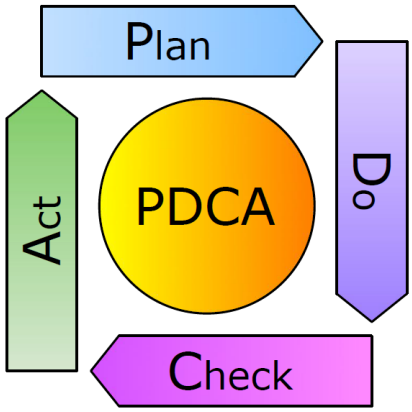

Figure 1.1 – The PDCA Cycle

There can be any number of iterations of the "Do" and a "Check" phase, as the solution is refined, retested, re-refined and retested again. The PDCA Cycle encourages a methodical in the approach to problem solving and implementing solutions to ensure the highest quality solution possible is achieved.

Step 1 – Plan:

First, identify exactly what the problem is. It may be useful to use tools like Drill Down, Cause and Effect Diagrams, and the 5-Why to help get to the root of it. Once this has been done, it may be appropriate to map the process that is at the root of the problem. Next, draw together any other information needed that will help to start sketching out solutions.

Step 2 – Do:

This phase involves several activities:

- Generate possible solutions.
- Select the best of these solutions, perhaps using techniques like Impact Analysisthem. to scrutinize
- Implement a pilot project on a small scale basis, with a small group, or in a limited geographical area, or using some other trial design appropriate to the nature of your problem, product or initiative.

Note: The phrase "Plan Do Check Act" or PDCA is easy to remember, but it's important everyone is quite clear exactly what "Do" means. ""Do" means "Try" or "Test"; it does not mean "Implement fully." Full implementation happens in the "Act" phase.

Step 3 – Check:

In this phase, the effectiveness of the pilot solution has been is measured, and any learnings from it that could make it even better gathered together. Depending on the success of the pilot, the number of areas for improvement that have been identified, and the scope of the whole initiative, it may be decided to repeat the "Do" and "Check" phases, incorporating the additional improvements. Once the costs would outweigh the benefits of repeating the Do-Check sub-cycle any more have been satisfied, the final phase can be implemented.

Step 4 – Act:

The solution can be fully implemented. However, the use of the PDCA Cycle doesn't necessarily stop there. If the PDCA or Deming Wheel is being used as part of a continuous improvement initiative, the Plan Phase (Step 1) needs to be reapplied, and other areas pursued for improvement.

Skill Practice Exercises:

Skill Practice Exercise MEM15002-SP-0101.

Write a short essay of approximately 200 words on an improvement to Quality Management with emphasis on Quality Control within your current, or a former workplace.