III. LITERATURE REVIEW

3.1 Quality Management System

Quality management system is an integrated strategic management system that involves all staff using qualitative and quantitative methods to continuously improve the process within the organization to meet the needs, desires, and expectations of customers. Conceptually, quality management can be applied to both goods and services, because the thing that is emphasized in the application of quality management is the improvement of quality systems. Some things to consider for this improvement consist of: planning, quality control, and improvement of the new system.

Basically, the industrial process should be viewed as a continuous improvement (continuous industrial process improvement), consisting of a series of cycles that start from the existence of product idea, all the way through product development, production, and distribution to consumers. Later on, based on the feedback from the customers, creative ideas can be developed to continually improve old items and their production process. Five things that are paramount to consider in the development of Quality Management Systems are: customer focus, total involvement, benchmarks, systematic support, and continuous improvement (Potocki KA and Brocato RC 1995).

3.1.1 Quality Control

Quality control defines as a system of technical activities undertaken on a continuous basis. Quality control is a system of technical activities that are carried on continuously to measure and control quality while doing development. Quality control consists of three factors that must be tested of physical, chemical, and microbiological.

Quality control in industry terms can be defined as a process to delegate responsibility and authority for management activities by using methods that can guarantee satisfactory results. Quality control measures can be classified into four types, namely the new design control, incoming material control, product control and the study of specific processes (Feigenbaum 1989).

According to the Indonesian Quality Management Association (1986), the techniques commonly used in quality control program includes seven tools, namely:

1. Check Sheet
2. Stratification
3. Pareto Diagram
4. Histogram
5. Scatter Diagram
6. Fishbone Diagram
7. Control Charts
3.1.2 Quality Assurance

Quality Assurance can be interpreted as a real earnest and continued efforts to give satisfaction and trust in the public users of the product (consumers) for the quality of products produced. In this sense, satisfaction and consumer confidence are the goals and benchmarks of success as well as quality assurance. Consumers can be satisfied with the quality of a product, but not necessarily believe in the continuity of the quality of the product in the future. To that end, companies need to provide a quality guarantee for the quality of the product to the consumer (Soekarto 1990).

Quality Assurance in the food industry includes a wide variety of activities that must be done continuously. The main task of the Quality Assurance is to provide information about the efforts to follow the various quality parameters previously set at each stage of the production process. Provision of this information in the production is necessary and must be done as soon as possible because it can be used to correct the phases of the production process if it is less precise in progress that can result in losses for producers.

3.1.3 Quality Management

Quality management is an activity that brings a company at a certain quality level. Quality management has four main components of quality planning, quality control, quality assurance and quality improvement. Quality management is not only focus on product/service quality, but also means to accept it. Quality management uses quality assurance and control processes as well as products to obtain a more consistent quality management.

Nestlé has applied quality management system based on standards and regulations in order to make compliance status for excellence. These are both national and international standards/regulations such as The International Organization for Standardization, The Codex Alimentarius, The European Food Safety Authority, The National Agency of Drug and Food Control, and Indonesian Council of Ulema. These compliance requirements are described in the following subsequent sections:

3.2 The International Organization For Standardization (ISO)

The International Organization for Standardization or is known as ISO, is a worldwide federation of national standards bodies from some 100 countries. ISO is a non-governmental organization established in 1947 (ISO 2012). The ISO has the mission which is to promote the development of standardization and related activities in the world with a view to facilitating the international exchange of goods and services, and to developing cooperation in the spheres of intellectual, scientific, technological and economic activity (Trace Center 2012).

According to Trace Center (2012), ISO standards are developed according to the following principles:
• Consensus
  The views of all interests are taken into account: manufacturers, vendors and users, consumer groups, testing laboratories, governments, engineering professions and research organizations.

• Industry-wide
  Global solutions to satisfy industries and customers worldwide.

• Voluntary
  International standardization is market-driven and therefore based on voluntary involvement of all interests in the market-place.

There are three main phases in the ISO standards development process (Trace Center 2012). The need for a standard is usually expressed by an industry sector that communicates this need to a national member body. The latter proposes the new work item to ISO as a whole. The first phase involves definition of the technical scope of the future standard once the need for an International Standard has been recognized and formally agreed. This phase is usually carried out in working groups which comprise technical experts from countries interested in the subject matter. A second phase is entered during which countries negotiate the detailed specifications within the standard. This is happen once agreement has been reached on which technical aspects are to be covered in the standard. This phase is the consensus-building phase. The final phase comprises the formal approval of the resulting draft International Standard. The acceptance criteria stipulate approval by two-thirds of the ISO members that have participated actively in the standards development process, and approval by 75% of all members that vote), following which the agreed text is published as an ISO International Standard.

Most standards require periodic revision. Several factors combine to render a standard out of date: technological evolution, new methods and materials, new quality and safety requirements. ISO has established the general rule that all ISO standards should be reviewed at intervals of not more than five years in order to take account of these factors. It is necessary to revise a standard earlier in occasion.

According to ISO (2012), participating members of ISO are called “P” members, as opposed to observing members, who are called “O” members. ISO has 162 national members out of the 205 total countries in the world and has three membership categories:

• Member bodies are national bodies considered the most representative standards body in each country. These are the only members of ISO that have voting rights.

• Correspondent members are countries that do not have their own standards organization. These members are informed about ISO’s work, but do not participate in standards promulgation.

• Subscriber members are countries with small economies. They pay reduced membership fees, but can follow the development of standards.

3.2.1 ISO 22000: 2005

ISO 22000 is a standard developed by the International Organization for Standardization dealing with food safety. ISO 22000 is a Food Safety Management System which can be applied to any organization in the food chain, from farm to fork. This is a general derivative of ISO 9000.
The ISO 22000 does not have specific requirements for prerequisite program (PRPs), but requires that the organizations identifies and implements the appropriate programs. Food processors and manufactures can use the ISO Technical specification ISO/TS 22002-1 to develop their PRP programs. It outlines the requirements for PRP programs that are applicable to the organizations.

In order to build an appropriate Food Safety Management System, ISO 22000 requires effective prerequisite programs in place to ensure a clean sanitary environment, a Hazard Analysis and Critical Control Plan developed to identify, prevent, and eliminate food safety hazards, and established documented food safety management system processes to manage food safety throughout the organizations. This food safety management processes includes from management and business planning aspects to day to day communication and operations affecting food safety.

Based on ISO 22000, this standard contains the specific requirements to be addressed by the Food Safety Management System. The standard requires food safety management system processes including:

- Having an overall Food Safety Policy for organization, develop by top management
- Setting objectives that will drive company efforts to comply with this policy
- Planning and designed a management system and documenting the system
- Maintaining records of the performance of the system
- Establishing a group of qualified individuals to make up Food Safety Team
- Defining communication procedures to ensure effective communication with important contacts outside the company (regulatory, customers, suppliers and others) and for effective internal communication
- Having an emergency plan
- Holding management review meetings to evaluate the performance of the Food Safety Management System
- Providing adequate for the effective operation of the Food Safety Management System including appropriately trained and qualified personnel, sufficient infrastructure and appropriate work environment to ensure food safety
- Implementing Prerequisite Programs
- Following HACCP Principles
- Establishing a traceability system for identification of product
- Establishing a corrective action system and control of nonconforming product
- Maintaining a documented procedure for handling withdrawal of product
- Controlling monitoring and measuring devices
- Establishing and maintaining and internal audit program
- Continually updating and improving the Food Safety Management System

3.2.2 ISO 9001: 2008

ISO 9001 is International Standard for Quality Management System – requirements. ISO 9001 is used to establish and update organization’s quality management system. It can be applied to all types of organizations. More than one million organizations around the worlds are independently certified ISO
11 management systems. This is one of the most commonly used as a management tool most widely used in today's world.

Quality management system ISO 9001: 2000 based on eight quality management principles. These principles can be used by senior management as a framework to guide the organization towards improved performance. The eight quality management principles aimed at improving the performance of the system to process that takes place in accordance with the main focus is effectiveness continual improvement. The eight management principles are:

1. Customer Focus

All the planning and implementation of the system are solely to satisfy the customer. Survival of the company or organization is largely determined how the views of customers to the organization. Customer focus is only possible if the customer expectations known. It is necessary to first identify the market segments in order to know the expectations of customers. Focus on customer satisfaction is a special characteristic that distinguishes between organizations or companies with traditional or modern organizations. In the traditional organization, top management is the focus of the organization and who became the most satisfied, in other words, the customer is somewhat marginalized. Modern organizations reverse this paradigm by making the customer as the main focus or become party to be satisfied with the service organization.

2. Leadership

Top management serves as a leader in guarding the implementation of the system that all movement is always controlled organizations in a single command with the same commitment and synergy of movement on each element of the organization. A leader has a great share in determining the direction and objectives. A leader shall also have the ability to create a vision into reality at the same time make it happen. Applying leadership principles will result benefit for organization. The people will understand and be motivated towards goals and objectives, activities will be evaluated, adapted and applied in a single manner, minimizing communication errors between the levels in the organization, raises desire to participate and contribute to continuous improvement.

3. Involvement of Everyone

All the elements in the organization involved and concerned in the implementation of quality management system according to the function of each work, even to the office boy should always do their best and prove worthy of their performance and quality, to function as an office boy. Involvement is a fundamental and essential personnel in quality management principles. Personnel at all levels are the primary capital firm, where the full involvement of its ability to greatly benefit the company. With the involvement of personnel as s whole, it will generate a sense of belonging and responsibility in solving the problem.

4. Process Approach

In the context of ISO 9001: 2000, the organization requires a process approach to the identification, implementation, management and conduct of ongoing (continual improvement) process requires for quality management system, and managing the interactions of each process that aims to achieve organizational goals. These processes are covered by the three things which are monitoring and measuring process: core processes, process support and management processes.

5. Approach Against Management System
Implementation of the system on how to approach emphasizes the identification, understanding, managing interrelated processes for achieving corporate objectives and increase the effective and efficient not only eliminates problems that occur. Therefore Kaizen Concept, continual improvement is emphasized. The pattern of management aims to improve the way in eliminating the root cause problems and make improvement to eliminate potential problems. Some of the profits earned by the systems approach include the integration and alignment process will achieve the best results from the desired ability to focus its efforts in key processes, give confidence to interested parties, such as consistency, effectiveness, and efficiency of the organization.

6. **Continual Improvement**

   Improvement is the spirit of the implementation of ISO 9001: 2008 is an activity which is done repeatedly to increase the ability to meet quality requirements. Continual improvement should be fixed target company. In continual improvement process occurs constantly approach and be done with it immediately after completion. This will be the standard and the challenge to make improvements again.

7. **Making Decisions Based on Fact**

   Every decision in the implementation of the system is always based on facts and data. There is no data (evidence of implementation) is not equal to the implementation of ISO 9001: 2008 system of effective decision-making that is based on analysis of data and information that can be accounted for. For that there are some things that need to be prepared by an organization to implement quality management, among others, should establish adequate information systems for each process such as the supply of data from suppliers, raw materials, process conditions, and others; the use of statistical techniques or methods relevant for data analysis, do record control (records, files, etc.) well; develop techniques check sheet for the various processes and activities to facilitate the daily data collection.

8. **Mutually Beneficial Relationships with Suppliers**

   Suppliers are not helper, but business partners. Business partners because it must occur in a pattern of mutually beneficial relationships in order to improve both the ability to deliver value. According Muhandri T and Kadarisman D (2005) there are two kinds of policy directions for the relationship with suppliers, which is the opposite, and are called friends (corporation or partnership).

3.2.3 **ISO/IEC 17025: 2005**

ISO/IEC 17025: 2005 is the main standard used by testing and calibration laboratories. ISO/IEC 17025: 2005 was first issued in 1999 by the International Organization for Standardization and the International Electro-technical Commission (IEC) (Clarity Connect 2013). It is originally known as ISO/IEC Guide 25, ISO/IEC 17025: 2005 was initially issued by the International Organization for Standardization in 1999. ISO/IEC 17025 is applied directly to those organizations that produce testing and calibration results. In 2005, a second release of the standard was made after it was agreed that it needed to be more closely aligned with the 2000 version of ISO 9001 in term of its quality system words which include greater emphasis on the responsibilities of senior management. The second release
explicitly describes requirements for continual improvement of the management system itself, and particularly, communication with the customer.

There are two main clauses in ISO/IEC 17025 – Management Requirements and Technical Requirements (Anonim 2011). Management requirements are related to the operation and effectiveness of the quality management system within the laboratory. This clause has similar requirements to ISO 9001. The second one, technical requirements, includes factors which determines the correctness and reliability of the tests and calibrations performed in laboratory namely competence of staff; environment control; testing methodology; equipment and measurement traceability; and reporting of test and calibration results.

Laboratories that can demonstrate compliance with ISO/IEC 17025 at assessment have demonstrated they operate using sound management practices. These laboratories are technically competent to perform specific tests, calibrations and/or measurements as well as at the same time are able to generate technically valid results for which they hold accreditation. Laboratories are reevaluated periodically by the accreditation body to ensure their continued compliance with requirements and to check that their standard of operation is being maintained. The laboratory may also be required to participate in relevant proficiency testing programs between reassessments, as a further demonstration of technical competence (Standards.org 2011).

3.3 Codex Alimentarius

The Codex Alimentarius is a collection of internationally adopted food standards and related texts presented in a uniform manner. Its name is derived from the Codex Alimentarius Austriacus (2012). Its texts are developed and maintained by the Codex Alimentarius Commission, a body that was established in early November 1961 by the Food and Agriculture Organization of the United Nations (FAO), was joined by the World Health Organization (WHO) in June 1962, and held the first session in Rome in October 1963 (Codex Alimentarius Commission 2012). The Commission’s major aims are to protect the health of consumers and ensure fair practices in the international food trade. The Codex Alimentarius is recognized by the World Trade Organization as an international reference point for the resolution of disputes concerning food safety and consumer protection (Codex Alimentarius Commission 2006).

Based on Codex Alimentarius Commission 2010, the publication of the Codex Alimentarius is intended in order to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization. In addition it is intended in order to facilitate international trade. The Codex Alimentarius includes standards for all the principle foods, whether processed, semi-processed or raw, for distribution to the consumer. In order to the extent necessary to achieve the purposes of the Codex Alimentarius as defined, materials for further processing into foods should be included. In addition to standards for specific foods, the Codex Alimentarius contains general standards covering matters such as food hygiene, food additives, residues of pesticides and veterinary drugs, contaminants, labeling and presentation, methods of analysis and sampling, and import and export inspection and certification. It also contains guidelines for the management of official, such as governmental import and export inspection and certification systems for foods.
Codex standards and related texts are not a substitute for national legislation or alternative to it. Every country’s laws and administrative procedures contain provisions with which it is essential to comply. Codex standards and related texts contain requirements for ensuring consumer a safe, wholesome food product free from adulteration, correctly labelled and presented. A Codex standard for any food or foods should be drawn up in accordance with the Format for Codex Commodity Standards and contain.

In order to ensure that Codex Alimentarius Commission are consistent with and reflect current scientific knowledge and other relevant information, they and their subsidiary bodies are committed to revision as necessary of Codex standards and related texts. A standard or related text shall be revised or removed in accordance with the Procedures for the Elaboration of Codex Standards and Related Texts when required. Each member of the Codex Alimentarius Commission is responsible for identifying and presenting to the appropriate committee, any new scientific and other relevant information that may warrant revision of any existing Codex standards or related texts (Codex Alimentarius Commission 2010).

3.4 The European Union Food Regulation

The European Food Safety Authority (EFSA) is the keystone of European Union (EU) risk assessment regarding food and feed safety (European Food Safety Authority 2002). EFSA’s remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health. In all these fields, EFSA’s most critical commitment is to provide objective and independent science-based advice and clear communication grounded in the most up-to-date scientific information and knowledge. EFSA also provides independent scientific advice and communication on existing and emerging risks associated with the food chain in close collaboration with national authorities and in open consultation with its stakeholders.

The European Food Safety Authority (EFSA) was set up in January 2002, following a series of food crises in the late 1990s, as an independent source of scientific advice and communication on risks associated with the food chain. EFSA was created as part of a comprehensive programme for improving EU food safety, ensuring a high level of consumer protection and restoring and maintaining confidence in the EU food supply. It monitors and analyses information and data on biological hazards, chemical contaminants, food consumption and emerging risks. These areas of work are carried out by EFSA’s scientific units supported by working groups and networks. The Authority also supports the development of risk assessment approaches (European Food Safety Authority 2002).

EFSA has role to assess and communicate on all risks associated with the food chain. A large part of EFSA’s work is undertaken in response to specific requests for scientific advice because EFSA’s advice serves to inform the policies and decisions of risk managers. Requests for scientific assessments are received from the European Commission, the European Parliament and EU Member States. EFSA also undertakes scientific work on its own initiative.

According to European Food Safety Authority, 2002, EFSA’s advice frequently supports the risk management and policy-making processes. These may involve the process of adopting or revising European legislation on food or feed safety. In addition, it also includes deciding whether to approve regulated substances such as pesticides and food additives, or, developing new regulatory frameworks and
policies for instance in the field of nutrition. EFSA is not involved in these management processes, but its independent advice gives them a solid scientific foundation.

EFSA aims to provide appropriate, consistent, accurate and timely communications on food safety issues to all stakeholders and the public at large, based on the Authority’s risk assessments and scientific expertise. EFSA follows a workflow in developing its scientific opinions. EFSA has developed a comprehensive body of good risk assessment practices to guide its Scientific Panel and Committee experts to help ensure EFSA opinions respect the highest scientific standards. EFSA implements a quality assurance system to continually review and strengthen the quality of its scientific work.

Since its creation, EFSA has established key operating principles and rules which have been adopted by its Management Board which include a commitment to openness and transparency in all of the Authority’s work (European Food Safety Authority 2002). In addition the Authority is bound by European Union legislation on issues such as public access to documents. EFSA is legally obliged to publish on its website outcomes of its scientific work as well as main management documentation such as budgets, accounts and contracts in accordance with its Founding Regulation. All of EFSA’s activities are guided by a set of core values, such as excellence in science, Independence, Openness and transparency, and responsiveness.

3.5 The National Agency Of Drug And Food Control (NA-DFC)

The NA-DFC (Badan Pengawas Obat dan Makanan or BPOM) is an institution in Indonesia which is responsible to supervise and control the pharmaceutical, food, cosmetics and medical device industries (Anonim 2012). In addition it has a function to assess and evaluate national policy in food and drug. Furthermore, NA-DFC also has a function to provide guidance and service to the public in general planning field, administration, organization and governance, administration, finance, archives, coding, equipment and household. The NA-DFC is a non departmental government institution based on Presidential Decree No. 166, 2000. The agency is responsible directly to the President for its operation and builds policy coordination with the Minister of Health and Social Welfare (The National Agency of Drug and Food Control Indonesia 2001).

The NADFC is established with a national and international networking, authority to conduct law enforcement with highly credible professionalism. The organization in NA-DFC consist of Permanent Secretariat; Deputy of Therapeutic Products and Narcotics, Psychotropics, and Addictive Substance Control; Deputy of Traditional Medicines, Cosmetics and Complementary Product Control; Deputy of Food Safety and Hazardous Substance Control; National Laboratory of Drug and Food Control; Center of Drug and Food Investigation; Center of Drug and Food Research; and Center of Drug and Food Information (The National Agency of Drug and Food Control Indonesia 2001). The corporate cultures brought by the NA-DFC were professionals, credible, quick response, teamwork, and innovative (The National Agency of Drug and Food Control Indonesia 2001).

The NA-DFC has a vision for becoming an innovative, credible and internationally recognized drug and food regulatory authority for public protection. It also has mission to conduct pre-market evaluation and post-market control based on international standard; to implement quality management system consistently; to optimize partnership with stakeholders in various lines; to empower public in
protecting themselves from the risk and harmful drug and food to health; and to build the learning organization (The National Agency of Drug and Food Control Indonesia 2001). Some basic principles of the Drug and Food Control System (DFCS) were safeguarding with speedy, accurate and professional actions; management of conduct based on level of risk and scientific evidence; total quality assurance covering the whole production and distribution cycle; national scale and inter provinces with international networking; national authority supporting law enforcement; strong and cohesive national network of quality control laboratory with access to global network; and information system network on product safety and quality (The National Agency of Drug and Food Control Indonesia 2001).

3.6 Indonesian National Standards

Indonesian National Standards (Standard Nasional Indonesia or SNI) is the only authorised standard applied nationally in Indonesia. Indonesian National Standards was formulated by the Technical Committee and defined by National Standardization Institution (Badan Standardisasi Nasional or BSN) (National Standardization Agency of Indonesia 2011). National Standardization Agency of Indonesia is the authority who co-ordinates the standardisation system in Indonesia. Indonesian National Standards consist of standard for commodity, tool and machine, system as well as method. This standard is aimed to protect the people against treats relating to safety, health and fraud, and to promote production and trade of both domestic and international. Indonesian National Standards is generally applied voluntarily. Once it relates to human safety and health aspects or environment conservation, its application become mandatory under a technical regulation issued by relevant institution (Iwantoro, S 2002).

In order to have a wide acknowledgement from different stakeholders, SNI is formulated in accordance with the following WTO Code of good practice (National Standardization Agency of Indonesia 2011):

- Openness: so that all related stakeholders will be able to participate in SNI development;
- Transparency: Transparent so that all relevant stakeholders can follow SNI development from programming, formulation up to the establishment stages and can easily obtain all information related to SNI development;
- Consensus and impartiality: so that all relevant stakeholders can take advantage of the existence for their own purpose and be fairly treated;
- Effectiveness and relevance: in order to be able to facilitate trade due to its awareness of market demand and not opposing to the existing regulations;
- Coherence: Coherent with the international standard development so that the our market will not be isolated from the global market development and will certainly improve the international trade; and
- Development dimension: in order to be able to focus on public and national interests in enhancing national economic competitiveness.
3.7 Indonesian Council of Ulema

Indonesian Council of Ulema (Majelis Ulama Indonesia or MUI) is a non-governmental organization that facilitate the platform or forum for theologians, zu'uma and intellectual of Islam in Indonesia. The forum was held on the date of 7 Rajab 1395 Hijra, 26 July 1975 in Jakarta, Indonesia (Anonim 22011). The MUI was founded by the Indonesian New Order under the Suharto administration as a body to produce fatwa and to advise the Muslim community on contemporary issues. Indonesian Council of Ulema acts as an interface between the Indonesian government, which is secular, and the Islamic community. The government stated three goals for the Indonesian Council of Ulema. The first is strengthening religion in the way the Pancasila describes to ensure national resilience; the second is as participation of the Ulama in national development, and the third is to maintain the harmony between the different religions in Indonesia (Wessel 1996).

Indonesian Council of Ulema has vision for becoming trusted halal certification body in Indonesia and worldwide as well, to give tranquility life to muslim society, and becoming the world halal center which extends information, solution and halal standard admitted both in national and international level (Indonesian Council of Ulema 2012). It also has missions for making and developing proper standard in halal auditing system; conducting halal certification process for products marketed and consumed by muslim society; educating and realizing the society concern to consume halal product; and providing comprehensive and accurate information as well on halal products and various related aspects (Indonesian Council of Ulema 2012) by establishing LPPOM MUI (Lembaga Pengkajian Pangan, Obat-obatan dan Kosmetika Majelis Ulama Indonesia). LPPOM MUI recognize halal certificates issued by approved halal certification body only for product produced in the country where the halal certification body located, except for product produced in Europe can be used halal certificate by any approved halal certification body located in Europe. The MUI decree regarding list of approved foreign halal certification body is effective for two years as of the date it is stipulated and will be monitored and evaluated once a year (Indonesian Council of Ulema 2012).

3.8 Compliance

An effective compliance program is needed by organizations to ensure that its employees meet all current legal and regulatory requirements. A compliance program has been described as a commitment by an organization’s top management to ensure that the organization plays by the rules (University of Mississippi Medical Center 2004). Compliance is a critical issue, it is either a state of being in accordance with established guidelines, specifications, or legislation of the process. Based on Harvey (2004), compliance is undertaking activities or establishing practices or policies in accordance with the requirements or expectations of an external authority. University of Melbourne (2004) mentioned that compliance is what we do to ensure that we meet the requirements under the law relating to our activities. Compliance needs to be seen less as a function and more as an institutional state of mind, helping organizations to anticipate risk as well as to avoid it (Micallef 2007).

The Federal Sentencing Guidelines for Organizations (FSGO) mentions key components for effective compliance program (Silverman 2008):
1) Organizations must establish compliance standards and procedures to be followed by employees and agents of the organization.

2) The program must be administered and overseen by “high-level” personnel within the organization.

3) Organizations must ensure that substantial discretionary authority is not delegated to employees with a propensity toward criminal conduct. 

4) Organizations must provide training programs and effective communications about their compliance standards and procedures.

5) Monitoring and auditing systems must be implemented, and a reporting system must be established through which employees can report wrongdoing without fear of retribution.

6) Organizations must provide incentives for employees and others to come forward to report issues and must establish disciplinary policies for those involved in wrongdoing.

7) After an offense has been reported, organizations must take reasonable measure to respond and prevent future incidents from occurring.

The process which ensures that a set of people are following a given set of rules is called compliance management. The rules are referred to as the compliance standard or compliance benchmark, while the process is what manages their compliance. Compliance management can take many forms of a mix of policies, procedures, documentation, internal auditing, third party audits, security controls, and technological enforcement. There are two recognized models for implementing compliance management that are mentioned in HCi Journal (2001):

1) Model 1: The ‘Ten Commandments’ model

   This model sets forth the rules and actively punishes those who do not comply with the rules. This model works well where there is a simple set of rules that everyone can understand. It breaks down completely where there is a complex set of rules which need interpretation, or are just too large to memorize or access.

2) Model 2: Quality Management

   The Quality Management model has been widely adopted and has been largely successful. This model is especially important because many companies which are required to follow a compliance standard often have multiple standards to follow, some of which may overlap or conflict with one another. This model allows for some flexibility on the part of the company implementing the standards to make those judgement calls without being harshly penalized for something that may not make sense for the company.