SECTION S18- RISK IDENTIFICATION, ASSESSMENT & CONTROL

OBJECTIVE

To identify risks arising out of the organization's operations, conduct a risk assessment of the various processes and initiate actions to eliminate or minimize the risk.

RESPONSIBILITIES

The QE Manager is the Owner of this procedure and has overall responsibility and authority for its establishment and maintenance. Department Heads shall be responsible for the successful implementation of this procedure.

DEFINITION

1. Risk: Risk is the possibility of events or activities impeding the achievement of an organization's strategic and operational objectives. Risk can be expressed in terms of consequence, impact, or severity of the impact and its related likelihood of occurrence.

2. Severity: Severity can be assessed as the effect it has on the internal and external parties.

3. Likelihood: The likelihood levels can be described with respect to how easy it is for a person to exploit a threat.

PROCEDURES

1. Risk Identification

1.1 Department representative shall list critical activities, products or services including routine and non-routine processes for each work location.

1.2 Activities, products and services may be grouped such that those with similar characteristics can be evaluated concurrently.

1.3 While identifying risks, the following shall be addressed to:

(a) Give assurance that the quality management system can achieve its intended results
(b) Enhance desirable effects
(c) Prevent or reduce undesirable effects
(d) Achieve improvement

1.4 The possible impacts of risks identified shall be illustrated.

2. Risk Evaluation

2.1 Department representative shall identify the existing risk control measures in place by considering the following:

(a) The score for severity and likelihood shall be determined based on the guidelines illustrated in Table 1: Quality Risk Assessment Scoring Matrix in Evaluation Criteria for Quality Risk Assessment. (Form 1.A). The risk level shall be computed by multiplying severity and likelihood.

(b) The identified associated risks shall be recorded into the Quality Risk Assessment Form (Form 1.B).

3. Risk Control

3.1 The QE Manager shall assess the tolerability of risk using guidelines in Table 2 (Form 1.A), determine the significant risks and record in the Register of Significant Risks. (Form 1.C).

3.2 Additional risk control measures to eliminate or minimize the significant risks shall be taken with action leaders identified.

4. Review of Risk

5.1 The entire risk assessment process shall be reviewed or revised at least once every 3 years.

5.2 Department representative shall inform the QE Manager, employees or any other persons at the workplace of changes in the risk assessments.

REFERENCE

Form S18.A - Evaluation Criteria for Quality Risk Assessment

Form S18.B - Quality Risk Assessment Form

Form S18.C - Register of Significant Risks