Chapter28: Significant ChangES

0. General:

Change is the only constant as far as management system is concerned. An organization shall review the key processes/controls and system when there is a significant change. Significant change shall be informed to BIS and this may trigger a Stage-I audit before Stage-II audit.

1.0. A change **can** be considered significant when **there is**:

a) Change in technology;

b) Change in regulations;

c) Change in product design to meet new regulatory requirements;

d) Change in machinery;

e) Relocation of machinery;

f) Deployment of new process;

g) Shutdown for a prolonged period and need to re-evaluate;

h) Change in plant location resulting the need for a re-evaluation and

i) Major accidents etc.

1.1. A significant change calls for Stage–I audit before the recertification audit. The renewal application shall indicate any significant changes compulsorily. In addition, during surveillance audits if there is a significant change then the audit need to cover the impact to changes which may require increase audit time. This shall be clearly reported in audit reports.

2.0. Recertification audit after six months from validity incase of lapse more than six months after the validity instead of carrying out re-certification audit, Stage-I shall be carried out even if there is no significant change.