



DOCUMENT CHANGE REQUEST

DCR number 407 Changes required for: N/A

Originator: lionel bonora

Date: 2008/05/19

Date sent: 2008/05/19

Organisation:

Status: IMPLEMENTED

Title: Minimum Requirements for Controlling Environmental Contamination of Components

Number: 24900

Issue: 2

Other documents affected:

Page:

Addition of sections 14 and 15

Paragraph:

Addition of sections 14 and 15

Original wording:

Proposed wording:

14. REQUIREMENTS FOR HUMAN CONTAMINATION CONTROL

Particles and chemical contamination from personnel e.g. skin and hair fragments, finger grease, exhalation aerosols and cosmetics residue shall be controlled. In general the requirements herein for airborne particle control cover this requirement. However, for all operations and inspections particular attention shall be given to personnel actions and protective measures so as to avoid component contamination.

This shall include the appropriate use of measures including:

- Clothing with particular reference to gloves or finger cots and masks,
- Screens and guards, e.g. spittle guards,
- Control of cosmetics usage,
- Post operation or inspection cleaning steps.

Each operation or inspection performed shall be assessed with regards to the personnel element and measures established to minimise the possibility for human contamination. Procedures, training and housekeeping measures shall be appropriate for the personnel measures put in place. Documented controls shall be established to monitor the continuing effectiveness of the preventive measures.

15. REQUIREMENTS FOR MACHINE CONTAMINATION CONTROL

Each equipment or machine utilised for a process or inspection step shall be assessed for the generation of contaminants such as particles and chemicals and the potential for these to be transferred to the component. Machine design, utilisation, cleaning and maintenance shall be appropriate to prevent such contamination. Post process step component cleaning shall



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be employed where necessary. Documented controls shall be established to monitor the continuing effectiveness of the preventive measures.

Justification:

Various findings/observations during ESCC audits

Attachments:

N/A

Modifications:

N/A

Approval signature:

Date signed:

2008-05-19