Are you up to date on the components of an antineoplastic safety program? Examine your policies during this session on developing a comprehensive safety and health program, including engineering controls, competent personnel, safe work practices, personal protective equipment, evidence-based policies and procedures, and a medical surveillance program. You’ll review case studies on environmental and personnel monitoring and learn the actions you can take to minimize the adverse effects of exposure.

Content Area: General Content

Content Level: Intermediate

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Full Disclosure:
Nothing to Disclose

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Full Disclosure:
Nothing to Disclose

Objectives:
At the end of this session, participants will be able to:
1. Summarize recent and historical evidence for healthcare worker exposure to antineoplastic drugs.
2. Analyze the components of a safety and health program in one’s workplace aimed at preventing environmental contamination and personnel exposure to antineoplastic drugs.
3. Develop a plan to implement a medical surveillance program for staff who are occupationally exposed to antineoplastic agents.

Content Outline:
I. Health effects of occupational exposure
   A. Toxicity of cytotoxic agents
   B. Risks from targeted agents
   C. Healthcare worker exposure
      1. Incidence
      2. Health effects
   II. Components of a safety program
       A. Equipment and facilities
       B. Policies and procedures
       C. Education and training
       D. Medical surveillance plan
   III. Case studies in antineoplastic safety
       A. Evaluating and implementing safety equipment
       B. Lessons learned from environmental monitoring
       C. Implementing medical surveillance

Bibliography:


Concept of Risk

- What is the association between exposure & development of disease?
- If an association exists, how strong is it?
- Cohort study:
  - Select exposed & unexposed individuals: follow them to see if they develop the disease
- Case-control
  - Study begins with people who have the disease (cases) and non-diseased people (controls)

Measuring Risk

\[ \text{Relative risk} = \frac{\text{incidence in exposed}}{\text{incidence in non-exposed}} \]

- \( RR = 1 \) No difference in occurrence
- \( RR > 1 \) Occurrence in exposed is greater

\[ \text{Odds Ratio} = \frac{\text{Odds that a case was exposed}}{\text{Odds that a control was exposed}} \]

- \( OR = 1 \) No difference
- \( OR > 1 \) Exposure is positively related to disease

Gordis, 2004

Genotoxic Adverse Outcomes: Occupational HD Exposure

- Genotoxicity in exposed nurses
  - 50% increase in DNA single strand breaks
  - Significantly greater DNA tail length (Comet Assay)
- Chromosomal abnormalities in exposed nurses
  - Significant increase in structural chromosome abnormalities

Fuchs et al, 1995; Yoshida et al, 2006; Testa et al, 2007

Chromosome Abnormalities: Alkylating Agent Handling

<table>
<thead>
<tr>
<th>Location of Chromosome Abnormality</th>
<th>100 Event IRR*</th>
<th>200 Event IRR*</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chromosome 5</td>
<td>2.92</td>
<td>8.54</td>
<td>0.01</td>
</tr>
<tr>
<td>Chromosome 7</td>
<td>2.31</td>
<td>5.33</td>
<td>0.11</td>
</tr>
<tr>
<td>Chromosome 5 or 7</td>
<td>2.62</td>
<td>6.86</td>
<td>0.001</td>
</tr>
<tr>
<td>Chromosome 11</td>
<td>1.17</td>
<td>1.37</td>
<td>0.79</td>
</tr>
</tbody>
</table>

*IRR = Incidence Rate Ratio: Association between chromosome abnormality rates at select drug handling frequencies compared to zero drug handling events (controls).

McDiarmid, 2010

Cancer Occurrence: Occupational HD Exposure

- Increased occurrence of cancer in pharmacy technicians (RR = 1.1-3.6)
- Increase in acute leukemia in exposed nurses (RR = 10.65)
- Overall increased occurrence of cancer in exposed nurses (OR = 3.27, \( p = .03 \))

\[ \text{RR} = \text{Relative Risk}; \ \text{OR} = \text{Odds Ratio} \]

Hansen & Olsen, 1994; Martin, 2003; Skov et al, 1992

Adverse Reproductive Outcomes: Occupational HD Exposure

- Infertility (OR = 1.42-1.5)
- Spontaneous abortion/mis carriage (OR = 2-3.5)
- Premature labor (OR = 2.98)
- Pre-term birth (OR = 5.56)
- Learning disabilities in offspring (OR = 2.56)

Framson, 2007; Hansen & Olsen, 1994; Lawton, 2012; Martin, 2003; Skov, 1992
Potential Routes of Exposure

- **Dermal absorption:**
  - Direct drug contact
  - Contact with contaminated surfaces
- **Injection:**
  - Sharps
  - Breakage
- **Ingestion via contaminated:**
  - Food, gum
  - Hand-to-mouth transfer
- **Inhalation:**
  - Aerosols
  - Vapors

Summary of Published Evidence

- Contamination on external vial surfaces (>15 studies since 1992)
- Excretion of drugs and drug metabolites in urine of health care workers (>55 studies since 1992)
- Workplace surface contamination (>100 studies since 1994)

Oncology Nurses: Known Exposure

- **Sampling frame:** NC state RN registry
- **1339 nurses in outpatient oncology units**
  - Response rate of 30.5%
- **Major finding:**
  - 16.9% self-reported dermal or eye exposure to chemotherapy

Surface Contamination: Opportunity for Exposure

1999
- 6 sites, >200 samples
- 3 drugs
- Pharmacy: 75% wipe samples > LOD
- Nursing: 65% wipe samples > LOD

2010
- 3 sites, 143 samples
- 5 drugs
- Pharmacy: 75% wipe samples > LOD
- Nursing: 43% wipe samples > LOD

Implications for Practice

- Routine medication handling results in hazardous drug exposure
- Knowing what drugs are *hazardous* is essential
- Safe handling precautions reduce exposure
- Any worker who fails to follow precautions puts themselves and others at risk

Hierarchy of Controls

*Most Effective*

- Eliminate the hazard
- Engineering controls
- Administrative controls
- Work practice controls
- Personal protective equipment

*Least Effective*

U.S. Dept. of Labor, 1998
Engineering Controls: Highest Level Protection

- Machines or equipment
  - Biologic Safety Cabinet (BSC) or
  - Compounding Aseptic Containment Isolator (CACI)
  - Closed system transfer device (CSTD)
- Advantages:
  - Contain the hazard
  - Independent of the worker

Education, Training & Monitoring

- Education
  - Classroom instruction (90%)
- Training
  - Supervised practice with preceptor (100%)
  - Skill checklist (60%)
- Monitoring
  - Formal mechanism (25%)
  - Informal “spot checks” (50%)
  - None (25%)

Work Practice Controls

- Label HDs as hazardous
- Transport HDs in sealed bags
- Inspect HD containers for leaks
- Wash hands after removing PPE
- Avoid touching unnecessary items with contaminated gloves
- Avoid wearing PPE outside drug handling areas
- Avoid spiking & priming (without a closed system)
- Discard used IV equipment intact

Personal Protective Equipment (PPE)

- Gloves:
  - two pair, tested with hazardous drugs
  - powder-free
  - latex, nitrile, neoprene
- Gowns:
  - tested with hazardous drugs
  - disposable, single-use
  - cuffs
  - back closure
- Eye protection:
  - when splashing is possible
- Respirator:
  - aerosols & spills

Administrative Controls

- Written policies & procedures
- Hazardous Drug List
- Education & competency
- Medical Surveillance
- Alternative duty around pregnancy

Medical Surveillance

- What it is:
  - Collecting and interpreting health data
- Purpose:
  - Detecting changes in health status
  - Identifying & correcting prevention failures
  - Preventing adverse outcomes in other workers

ASHP, 2006; NIOSH, 2004; Polovich, 2011
Polovich & Clark, 2012
ASHP, NIOSH, OSHA, ONS
NIOSH, 2012
Medical Surveillance Program
- Initial & continuous health monitoring
- Routine collection of health information
- Acute exposure assessment & documentation
- Exposure control plan
- Occupational health follow-up & consultation

Alternative Duty
- What it is:
  - Temporarily reassigning workers to duties that do not include HD handling
- Purpose:
  - Reducing HD exposure during vulnerable periods in reproduction
  - Preventing adverse reproductive outcomes associated with HD exposure

Alternative Duty Plan
- Employers’ responsibilities
  - Inform employees of risks of exposure
  - Identify job tasks without exposure opportunity
  - Establish mechanism for providing protective reassignment
  - Honor employee requests
- Employees’ responsibilities
  - Inform supervisor of applicable situations
  - Request alternative duty according to policy

An Institutional Experience Outpatient Oncology Case Study

Problem
- Differences in practices related to handling of hazardous drugs existed between inpatient and outpatient areas
- Patients treated in both settings questioned these differences
- Staff cross trained in both settings questioned these differences

Significance
- 8 million HCWs potentially exposed to HDs
  - Pharmacy and nursing staff involved in mixing and administering at highest risk
  - In the United States, an estimated 22 million adult patient visits occur annually for chemotherapy
  - Approximately 18 million (84%) of those visits in ambulatory settings, largely by nurses
- By 2050, due to the aging US population, the number of cancer cases are expected to double, increasing the use of antineoplastic drugs
  - Increasing use of HDs in nonmalignant conditions
  - Increasing use of higher doses, more combinations
  - Many biologically engineered drugs exist with unknown health risks
  - No standard exists regarding drug contamination of environment
  - Regular monitoring of environment can assist with detection of problem areas or practices that are affecting exposure levels
  - Prudent practice requires that we reduce exposure as much as technically possible

Assessment Utilizing a Gap Analysis

- A technique used to determine what steps need to be taken to move from the current state to the desired, future state.
- Identification of “what is” versus “what should be”
- Clarify gaps or discrepancies
- Gap analysis can then drive content of educational plan and practice improvements

Barriers Identified

- Knowledge deficit regarding HD health risks and policy requirements
- PPE: hot and time consuming to apply
- Waste containers overfilled and some had broken feet/pedals/lids
- Supplies not readily available
- Staff felt they were too busy to leave work area to eat and drink

Strategies

- Evidenced based
- Customized to each specific outpatient environment
- Focused on overcoming barriers
- Realistic
- Involvement of frontline staff
- Involvement of interprofessional staff
- Support of leadership

Planning

- Supply Changes
  - Glove and gown evaluations completed
  - PPE stations standardized and stocked
- Cultural Changes
  - Implement food breaks (no food/drink in chemo work areas)
  - PPE Compliance: peer-monitoring, competency verification method

Planning

- Facility Changes
  - Designated bathrooms for patients receiving hazardous drugs
  - Designated chemotherapy checking stations
- Cleaning Changes
  - Ensure prompt removal and replacement of HD waste containers
  - Review practice for routine cleaning in all outpatient areas and bathrooms
  - Review practice for cleaning hazardous drug spill sites

Planning

- Practice Changes
  - Pharmacy
    - CSTD on chemo prior to dispensing
    - Eliminate glass bottles
    - Tighten connections
    - Do not overfill bags
    - Properly labeling all HDs
    - Pre-prime all HDs with a benign solution
  - Outpatient nursing
    - 100% compliance with PPE
    - Use multi-infusion sets to maintain IV pump tubing as closed system after initiating HDs; if this is not possible utilize CSTD
    - Develop standard pump set up procedures for complex regimens to ensure closed system
    - Never spike HD without a CSTD

Prevention of HD Spills

- Worst case scenario
- Risk of spreading HD from spill to larger areas
- Take every precaution to prevent spills
  - Tighten luer connections
  - Utilize gauze around connection when disconnecting
  - Maintain closed tubing system after hook up
- If spill occurs, conduct root cause analysis-record exact location

Evaluation of Antineoplastic Drug Exposure Among Health Care Workers at US Cancer Centers

- Objective:
  - Evaluation of HCW exposure to HD
- Methods:
  - Cross-sectional study examined environmental surface wipe samples, task diary, urine and blood samples
- Results:
  - Environmental surface contamination is widespread
  - Site that utilized a CSTD was the only area with no reported spills

Gown/Glove Evaluation

- Goals
  - Standardize gown and gloves for use across hospital for both isolation and HD handing
  - Ensure PPE complies with NIOSH recommendations
  - Improve staff satisfaction
  - Ensure adequate skin/body protection

Results of Surface Wipe Testing

- Inpatient vs. outpatient
- Areas tested
- Drugs tested

Terminal Environmental Cleaning

- Consultation with Health Safety Office to develop cleaning strategy
  - Scientific literature does not yet specify cleaning and decontamination procedure/agents
- Three time aggressive terminal clean of all surfaces in clinic (floors, computers, keyboards, counters, tables, chairs)
- Surface wipe studies repeated prior to staff and patient arrival the next AM

Lessons Learned

- All staff handling hazardous drugs or hazardous drug waste should be informed at the start of employment
- It takes time to change the culture
- Leadership support is crucial
- Each care environment has special circumstances and needs that must be identified
An Institutional Experience
Hospital Wide Implementation of Hazardous Drug Handling

Case Study

Problems

- Potential for staff exposure to hazardous drugs and environmental contamination existed across the institution
- Differences in practices existed in non-oncology areas

Drugs Considered Hazardous

- Universal approach to all HDs
  - Antineoplastics, antivirals, hormonal agents, immunomodulatory drugs, and others
- Evaluation of HDs is an ongoing process, as new drugs approved
  - NIOSH will review newly FDA-approved drugs on regular basis
- 26 drugs added to list; 15 removed
- Challenge: Drug package inserts not consistent, comprehensive, or standardized
- Hospital interprofessional workgroup developed institutional list

How will I know if a drug is hazardous?

- All hazardous drugs distributed by JHH pharmacy are labeled with a bright orange sticker.
- A JHH list** of hazardous drugs can be found at http://www.insidehopkinsmedicine.org/pharmacy/clinicalreferences/hazardousDrugs.pdf

- **All investigational medications will be labeled with the orange sticker and may not be on the list. Consider them hazardous until proven otherwise.

Safe Handling of Oral HDs

- Package oral agents in blister packs or foil packs
  - Uncoated tablets: Risk of exposure from dust inhalation or skin contact
- Utilize gloves when handling oral drugs
- Utilize full personal protective equipment (PPE) when handling liquid oral drugs
- Do not crush, break, or compound solutions outside biologic safety cabinet
- Do not place drugs in automated counting machines
- Dispose of unused drug as cytotoxic waste
- Educate patients and caregivers, provide written instructions


Hazardous drug Transport

- Preparation
- Transportation
- Administration
- Disposal of administration equipment
- Disposal of body excreta from patients who have received hazardous drugs

The pneumatic tube shall NOT be used to transport liquid hazardous drugs.

Disposing of Hazardous Drug Waste

- If there is more than 1 inch of free liquid or more than 3% of the original volume of material remaining in the container, dispose of as chemical waste in a black container.

- If there is less than those amounts, dispose of the materials as Residual/Trace waste in a yellow waste container.
<table>
<thead>
<tr>
<th>Evidence of Current Status</th>
<th>Y/N</th>
<th>Corrective Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Knowledge deficit/faulty belief systems</strong></td>
<td></td>
<td>1) Insufficient knowledge exists related to evidence of risk when handling hazardous drugs (dermal exposure, acute and late health effects, environmental exposure)</td>
</tr>
<tr>
<td>2) Lack of role modeling among experienced staff exists</td>
<td></td>
<td>3) Greater concern exists among younger staff/child bearing ages etc.</td>
</tr>
<tr>
<td>4) Peer pressure not to use PPE exists</td>
<td></td>
<td>5) PPE and CSTD perceived as optional by staff</td>
</tr>
<tr>
<td>6) Lack of leadership buy in</td>
<td></td>
<td><strong>Lack of compliance with new JHH hazardous drug policy</strong></td>
</tr>
<tr>
<td><strong>Lack of compliance with new JHH hazardous drug policy</strong></td>
<td></td>
<td>1) Noncompliance with my learning (RN and SA staff) (score NO if not 100%)</td>
</tr>
<tr>
<td>2) Knowledge deficit exists related to non-chemo hazardous drugs and the specific risks associated with those drugs</td>
<td></td>
<td>3) Staff crush, mix, or re-spike chemo</td>
</tr>
<tr>
<td>4) Pharmacy lacks consistency with labeling hazardous drugs and placing CSTD on every chemo dose</td>
<td></td>
<td>5) Lack of knowledge related to new requirements for covering toilet, handling excrement, and double gloving (ONS, 2011)</td>
</tr>
<tr>
<td>6) Lack of knowledge related to new requirements for covering toilet, handling excrement, and double gloving (ONS, 2011)</td>
<td></td>
<td><strong>Corrective Actions</strong></td>
</tr>
<tr>
<td><strong>Corrective Actions</strong></td>
<td></td>
<td>-- Develop plan for re-education of existing staff and comprehensive education of all incoming staff upon hire</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-- Establish % noncompliance with SKCCC chemo competency-2011/2012</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-- Develop a hazardous drug competency checklist-separate from chemo admin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-- Implement hazardous handling agreement- new and existing staff</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-- Conduct patient education- how can they help us?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-- Utilize simulated scenarios for education- ONS recommendations</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-- Consider unit super users and pay for them to attend the ONS hazardous handling-online course with a requirement to complete unit in-services on topics learned</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-- Establish % noncompliance with SKCCC mylearning- new policy education for hazardous handling</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-- Consider specific education based on unit administration of non-chemo hazardous drugs (eg. Transplant- immune modulators)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-- Meet with pharmacy to insure 100% compliance with hazardous drug labeling and CSTD application</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-- Conduct specific education regarding the rationale for cover toilets and double gloving</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-- Conduct meeting separate gap analysis of GS and meet with manager, pharmacy and nursing staff</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-- Ensure all staff know where to locate a chemo spill kit and how to use it. Utilize spill cleanup video made by SA staff for education of all RN/SA staff.</td>
</tr>
</tbody>
</table>
| 6) Greenspring noncompliance- incorrect PPE, no CSTD, chemo spill kits- cost barriers exist that create a barrier for nursing leadership at GS to initiate protocol requirements | --Ensure SA manager accountable for training and competency of all SA staff  
--Develop protocols for complex outpt regimens where pump channels are opened during chemo treatment and initiate CSTD for those situations. (otherwise maintained a closed system) |
| 7) Spills not always cleaned up per policy- policy change (no <5cc, all spills require same procedure with new policy) | |
| 8) Lack of knowledge (RN and CA) spill clean up procedure | |
| 9) Staff do not use CSTD with every dose of chemo | |
| 10) Outpt areas- staff do not keep a closed system for IV pump administration | |
| **PPE Equipment not readily available** | **PPE specific issues** |
| 1) Stored in nonstandard locations across 5th floor and OPD (Studies show staff less likely to use it if it is not easily accessible) | - Evaluate other potential gowns on market that meet NIOSH and ONS requirements  
- Re-educate re: double glove requirements  
- Conduct glove evaluation to find one glove that meets all safety recommendations to improve compliance and decrease confusion- already ongoing  
- Insure gown/gloves sizes are sufficient for all staff  
- Re-educate about need for hand washing with soap and water |
| 2) Supplies not correct- Greenspring only- wrong gowns, gloves etc | |
| **PPE specific issues** | |
| 1) Staff are not wearing gowns –hot, too small (one time use only (ONS, 2009)) | |
| 2) Staff are wearing incorrect gloves- gray chemo | |
| 3) Staff are not double gloving when handling hazardous drugs | |
| 4) Staff are not wearing mask with face shield | |
| 5) Staff do not wash hands with soap and water after handling hazardous drugs or excrement (hand gel not recommended) | |
| 6) Staff do not consistently wear PPE during | |
Olsen, M. Gap Analysis- SKCCC, Nursing- 2012©

<table>
<thead>
<tr>
<th>the 48 hr period post hazardous drug admin when handling excreta</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Identification of all HCW who are at risk</strong></td>
<td>-- Develop a plan for identifying all new and existing staff who are at risk</td>
</tr>
<tr>
<td>1) Every RN, CA, SA, students, MD, NP, visiting MD is not informed of risks in environment and educated</td>
<td>-- Education of all staff prior to working in the environment</td>
</tr>
<tr>
<td>2) Men or women trying to conceive or pregnant women are not offered alternate duty</td>
<td>-- ONS Guideline- comprehensive training upon hire and at least annually</td>
</tr>
<tr>
<td>3) Medical monitoring of staff at SKCCC does not occur</td>
<td>-- Review literature and consider a plan to monitor staff--medical monitoring</td>
</tr>
<tr>
<td><strong>Environmental Issues</strong></td>
<td></td>
</tr>
<tr>
<td>1) Food and drink exists in work areas where chemo administration occurs</td>
<td>-- Provide alternate location for staff to eat and break</td>
</tr>
<tr>
<td>2) Chemo is being dispensed in glass bottles and being vented</td>
<td>-- Provide adequate time for staff to eat and break</td>
</tr>
<tr>
<td>3) Chemo waste bins overflowing (especially in high use areas such as OPD)</td>
<td>-- Conduct meeting with pharmacy to eliminate ALL glass bottles for chemo administration. Direct nurses to return chemo dispensed in glass bottles</td>
</tr>
<tr>
<td></td>
<td>-- Develop plan for frequent checks by support staff of bins and emptying as appropriate--lid must remain closed at all times</td>
</tr>
</tbody>
</table>
Handling of Hazardous Drugs

All care providers (RN, MD, NP, PA, LPN CA, Clin Tech, SA, patient observer):

I have read the Johns Hopkins Hospital Handling of Hazardous Drugs policy and procedure, and I understand:

- There are possible risks to my health and the health of other staff members who work in the environment when I handle hazardous medications.
- Medications are classified as hazardous when they possess any of the following characteristics: genotoxicity, carcinogenicity, teratogenicity or fertility impairment. Investigational drugs are considered hazardous until proven otherwise.
- Material Safety Data Sheets (MSDS) are accessible within the Health Safety and Environment (HSE) website (www.hopkinsmedicine.org/hse) or on Oncology Clinical Tools.
- Proper application of personal protective equipment and safe handling are required when handling hazardous medications to avoid risk to my health and the health of other staff members working in the environment.
- Proper apparel and safe handling are required when handling body fluids during the first 48 hours following the administration of a hazardous medication.
- Immediate action must be taken if direct contact occurs with any medication that is labeled as hazardous. If skin or eye contact occurs, the employee must complete the Employee Report of Incident form and report to Occupational Injury Clinic (OIC) or the ED (if the OIC is closed) after following the washing procedure.
  - Johns Hopkins Hospital policy must be followed for the management and cleaning of any spilled hazardous medication.

RN, MD, NP, LPN Only

I have read the Johns Hopkins Hospital Handling of Hazardous Drugs policy and procedure and I understand:

- The procedures for the administration of hazardous medications
- The proper disposal of supplies used in the administration of hazardous medications
- The proper use of closed system transfer devices for hazardous drug administration
- The management of bulk waste for hazardous medications

Employee____________________________    ______________________________     _________   _______
Signature                                                          Printed Name                                                          Employee #      Date
Witness____________________________    ______________________________     __________________
Signature                                                            Printed Name                                                          Date

JHH Olsen, 2014 ©   Form to be filed in Personnel file
Outpatient Terminal Clean & PPE Compliance Plan

Assessment
- Gap Analysis
  - Identify organizational, educational, system, and structural changes necessary for clean work space and 100% PPE compliance
- Audit work practices
- Obtain feedback from staff related to barriers
- Perform baseline wipe studies

Inform/Educate
- Inform staff of baseline wipe studies
- Provide comprehensive education of HD handling
- Enroll designated super users in ONS Hazardous Handling Course

Terminal clean
- Terminal cleaning of outpatient clinic
- Environmental Services brought in weekend staff to conduct cleaning
  - Supervised by manager
- Conduct post cleaning wipe studies
- Conduct one year post wipe studies

Maintenance
- PPE & CSTD in place to support and monitor 100% compliance
- Conduct post cleaning wipe studies