EVALUATION OF THE SURFACE CONTAMINATION IN A CHEMOTHERAPY PREPARATION UNIT BEFORE A PROCESS CHANGE

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BACKGROUND

Preparing cytotoxic drugs is at high risk of toxicity for health care professionals and the environment. That's why in a chemotherapy preparation unit (CPU), it is essential to control the contamination with these cytotoxics.

Until April 2016, in our CPU, cytotoxic drugs were prepared in isolators placed in a controlled atmosphere area (ISO 7). Since May 2016, part of the preparations is compounded with the robot Kiro Oncology® (Kiro robotics, Spain) in a laminar air flow hood. In order to analyse the impact of this process change on the surface contamination, this preliminary study was conducted in April 2016.

OBJECTIVES

- **To identify critical sampling points with high risk of chemical contamination in the CPU**
- **To assess the contamination before the start of the automated compounding**

MATERIALS AND METHODS

Risk analysis thanks to « Failure Modes, Effects and Criticality Analysis » (FMECA) → risk mapping to determine sampling points

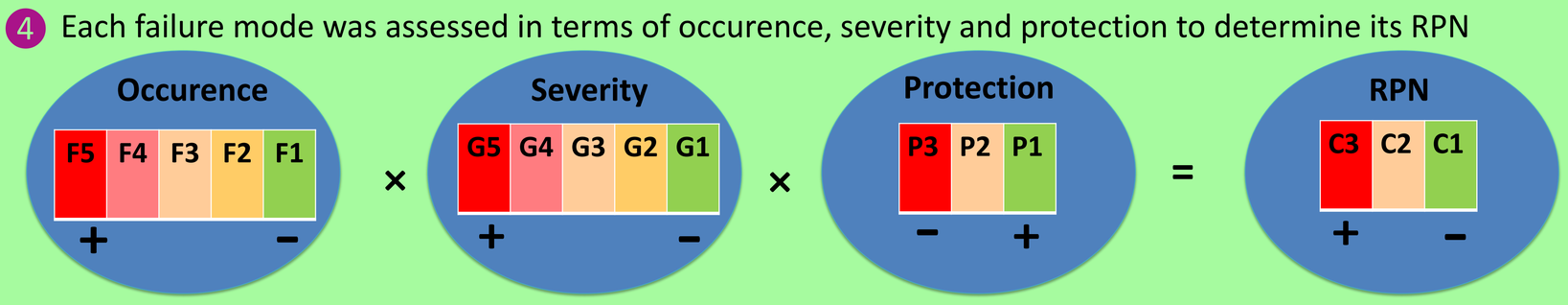
1. Formation of a multidisciplinary working group
2. Description of the preparation process in the CPU
3. Hazard identification
4. Risk assessment: Occurence X Severity X Protection = Risk priority number (RPN)
5. Choice of sampling locations

- Samples were collected by wiping down the surfaces at the end of a working day before general cleaning
- The presence of the 9 following cytotoxic drugs were tested using LC-MS/MS in each sample: **Cyclophosphamide*, Ifosfamide*, 5-fluorouracil*, Gemcitabine*, Etoposide*, Methotrexate, Paclitaxel*, Docetaxel and total platinium (Cisplatin, Carboplatin, Oxaliplatin*)**

* Drugs which are compounded by the robot

RESULTS

1. Working group: 3 hospital pharmacists, 1 pharmacy resident, 2 pharmacy technicians, 1 laboratory technician, 1 hospital assistant → 4 meetings of 1 hour with 4 to 8 members per meeting and 6 personal interviews of 30 minutes were conducted
2. The CPU was divided in 6 areas → 19 preparation process steps were described
3. 22 failure modes were specified
4. Each failure mode was assessed in terms of occurence, severity and protection to determine its RPN



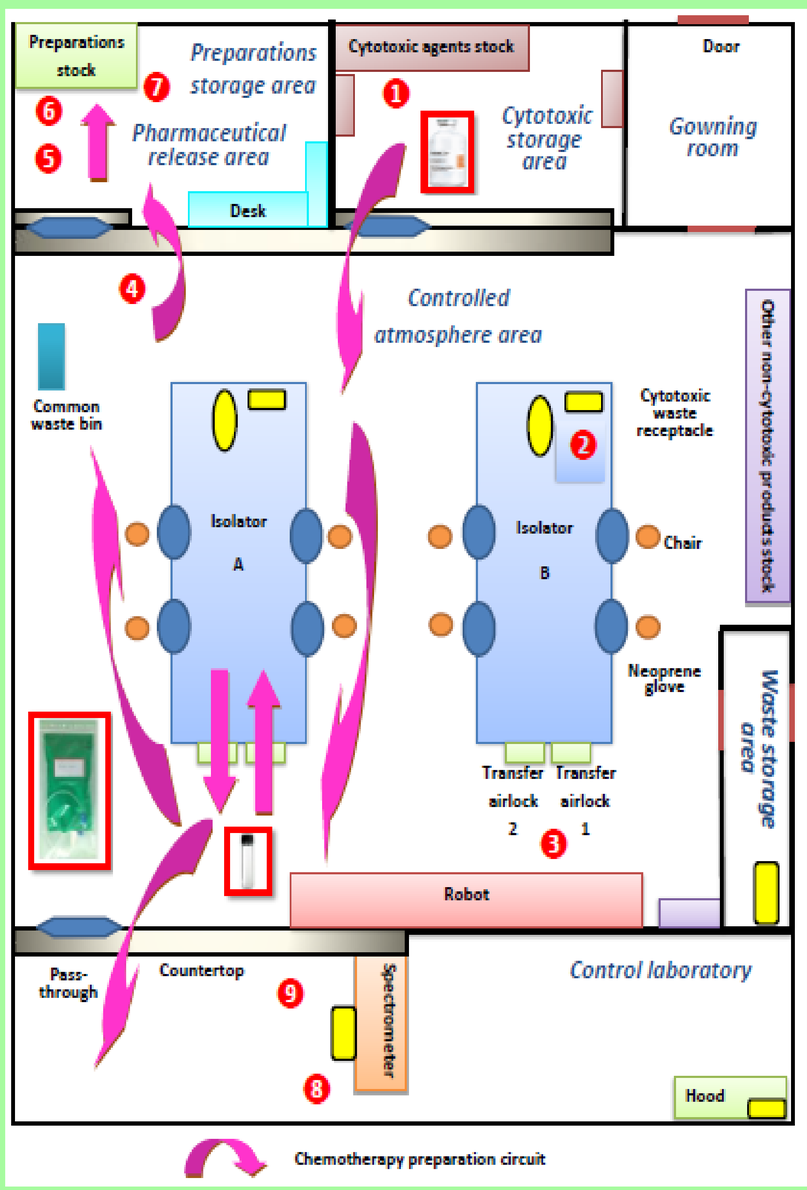
Class	Criticity level	Decision	Number of failure modes
C3	[75 ; 20]	Collect these areas firstly	13
C2	] 20 ; 10]	Collect these areas secondly or only if they require special attention	5
C1	] 10 ; 1]	No need to collect these areas	4

5. 9 Sampling areas were defined

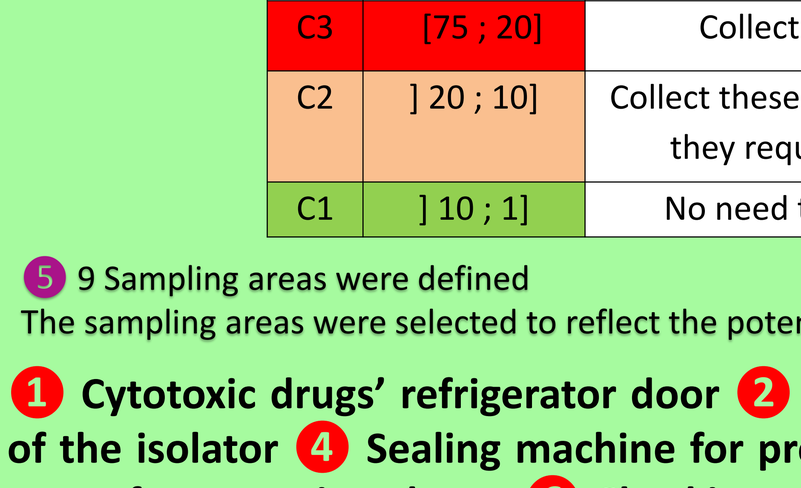
The sampling areas were selected to reflect the potential effects of the most critical failure modes.

1 Cytotoxic drugs' refrigerator door 2 Work surface of the isolator 3 Basket rack of the isolator 4 Sealing machine for preparations' secondary packaging 5 Storage area of preparation sheets 6 Checking area of finished preparations 7 Storage area of finished preparations 8 Control laboratory's computer 9 Spectrometer

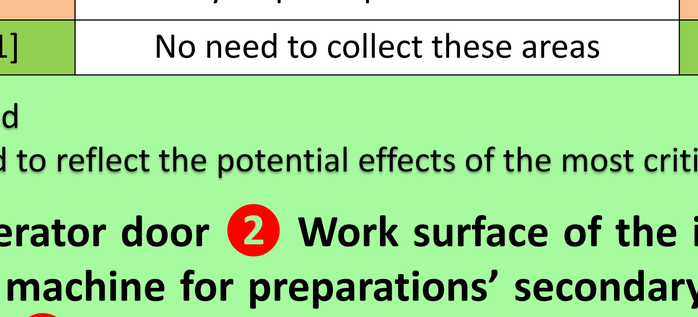
Plan of the CPU with the 9 picked sampling areas



Distribution of 81 analysis results (9 samples – 9 cytotoxic drugs) depending on the cytotoxic amount in ng/cm² in the CPU

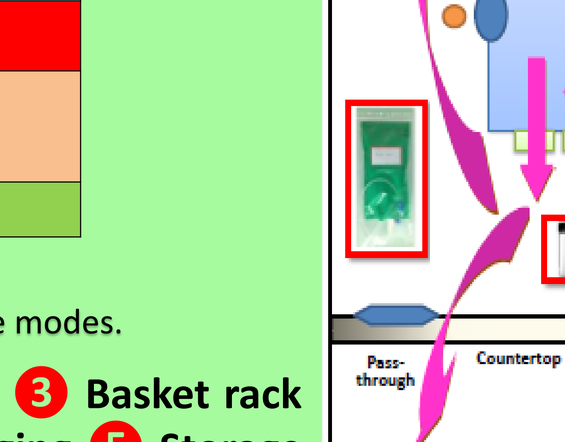


By comparison, the study conducted by ESOP1 (part 1-Pharmacy) [1] got the following distribution:
(888 results – 5 samples – 15 hospitals - 12 cytotoxic drugs)



*LOD : Limit of detection

2 areas highly contaminated



All **other samples < 0,2 ng/cm²**

All areas contained **platines.**
8/9 areas contained **gemcitabin and ifosfamide**.

The **highest value** was recorded for **5-fluorouracil** (8.6 ng/cm²) and **total platinum** (7.3ng/cm²).

[1] **Contamination with cytotoxic drugs in the workplace ESOP pilot study,** E. Korczowska, H. Jankowiak-Gracz, J. Tuerk, T. Hetzel, K. Meier, E.Grześkowiak

CONCLUSION

The FMECA risk analysis method enabled us to select the most critical sampling points. The spectrometer as the most contaminated area was an unexpected result. The robot's gravimetric analysis may reduce the number of cytotoxic samples analysed by the spectrometer and thus its contamination. A whole package of prevention and protection measures will be required throughout the preparation circuit to reduce the risk of contamination.

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PP - 021
ATC: All other therapeutics - V03