Implementation of a Professional Practice Assessment within a nuclear pharmacy

E. DE LANDTSHEER (1), C.JUUL (1), J. ROSE (1), G. PARISCOAT (1), J. LE GRAND (1)
1: Pharmacy Department, Hôpital Bichat Claude Bernard

Background

In **2023**, a new version of the french Good Compounding Practices (**GCP**) was issued, thus prompting our hospital to renovate the Radiopharmacy and reclassify the **cleanroom** to a **Grade C**. This requalification resulted in **adjustments to the hygiene and environmental control procedures**, followed by a presentation to the staff.

Objectives

Assess the **compliance** of the staff, operating in the cleanroom, with the **new hygiene processes**, separate from initial instructions.

Methods

Evaluation Tool development

Professionnal Practice Assessment (PPA) chart.
SoFRA (*French society of radiopharmacy*).

Sorting of pre-existing items to retain only those relating to hygiene.
Adaptation of this chart to **internal procedures** based on the 2023 GCP.

Development of the chart and validation by the hospital **I**nfection **C**ontrol **T**eam **(ICT)**

Scheduled assessments

Initial instructions

Hygiene cleanroom refresher meeting for the staff working within the nuclear pharmacy (Radiological technicians, Pharmacy technicians, Laboratory technicians)

Collection of **agar samples** during the assessments (aerobiocontamination and gloves)

Study: Monocentric, Prospective, Observational

Assessment Tool

4 distinct charts :
- Low and Medium Energy Hotcell (LMEH)
- High Energy Hotcell (HEH)
- Dispensation Automate (Trasis)
- Microbiological Safety Cabinet (MSC)

A total of **10** thematic index cards were evaluated, for an average number of **74** items (56-91), **17.5** of were not included in the original SOFRA chart

Index cards

1 - Entrance
2 - Reception and storage
3 - Controls
4- General Preparation procedures
5 - Generator elution
6-Preparation of radiopharmaceutical drugs
7 - Syringe filling and delivery
10 - Hygiene and Biocleaning
13 - Exit
14- Microbiological Sampling

Supplementary data Evaluation charts used

added item

Results

Table 1 : Overview table of evaluated staff

Work station	Trained personnel	Present personnel	Personnel assessed	Total (%)
LMEH	5	5	3	60%
MSC	2	2	1	50%
TRASIS	8	6	3	37.5%
HEH	2	2	0	0%

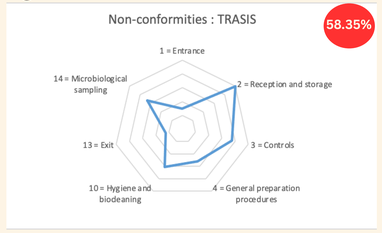
7 out of 15 trained personnel were evaluated **(47%).** Employees involved in the chart development were excluded from the evaluation (HEH).

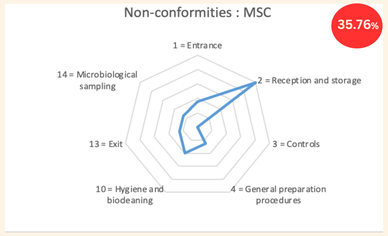
Table 2 : Monitoring microbial growth on sampled agar plates

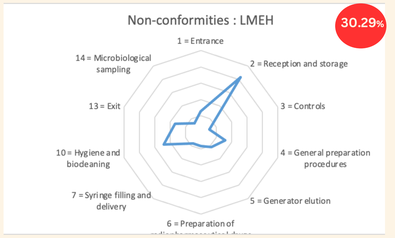
Work station	27/03	02/04	08/04	11/04	22/04
LMEH	/	0	/	2 UFC	0
MSC	/	/	0	/	/
TRASIS	0	/	0	0	/

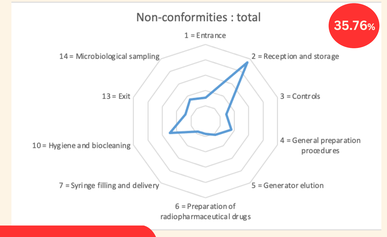
Microbial growths were observed on the agar collected on the LMEH on the 11/04 and are not correlated to the evaluation with the highest number of Non Conformities.

Figure 1 : Overview of recorded non-conformities









The index cards with the highest rates of non-conformities are: Reception and storage (**94.5%**), Hygiene and biocleaning **(49.7%)**, and General preparation procedure **(36.1%).**
In contrast, the index cards with the lowest rates of non-conformities are : Syringe filling and delivery **(16.7%),** preparation of radiopharmaceutical drugs **(16.7%**), and Generator elution **(22.22%),**
Across all index cards, the “Exit” one showed the lowest overall non-conformity rate at **(27.8%)**.

Discussion

The limits identified for this project included:
- An incomplete evaluation of the employees
- The pre-emptive announcement that the evaluation would take place thus skewing the observations
- The lack of scoring and the vast disparity within the number of items amongst the index cards complicating the interpretation of results.

Conclusion

This study helped identify **discrepancies to the GCP**, emphasizing the importance of **continuing the PPA** with the rest of the employees, as well as implementing **a training course concerning the items with the most NC**, and lastly to **conduct another PPA, remote** from the corrective measures.
Moreover, this PPA underlined the necessity of **evolving** current training methods, which are still based on a **peer-mentoring approach**.