SmartNote: Risk-based approach to selecting environmental monitoring locations

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Part 2: Putting environmental monitoring theory into practice

Introduction

In the first part of our look at risk based approaches to environmental monitoring, we looked at the focal points that need to be considered. In this second part, we look at how we can put these ideas into practice.

As a reminder, the first stage is to look at people and equipment flows. For example, consider this dispensing room (Figure 1):

Once annotated maps and process descriptions have been produced, the HACCP approach involves:

- Considering where hazards could occur, and examining for both air and surface risks. Assessing the importance of these sources and if they are or are not hazards that need to be controlled. Examples include:
  - The amount of contamination on, or in, the source that is available for transfer.
  - Ease by which the contamination is dispersed or transferred.
  - The proximity of the source to the critical point where the product is exposed.
  - How easily the contamination can pass through any controls in place.

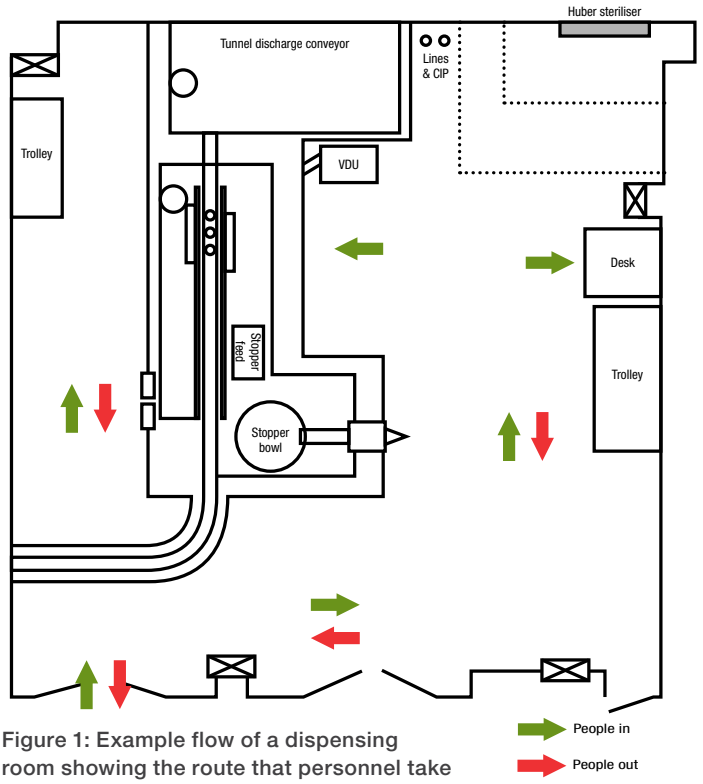

Figure 1: Example flow of a dispensing room showing the route that personnel take (source: Tim Sandle)

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- Assessing the risk of each hazard and where appropriate introduce a new, or seek to improve an existing, control method to reduce the risk.

Establishing Critical Control Points (CCP)

A CCP is a point where control can be applied and is assessed as being essential to prevent or eliminate a hazard or, alternatively, to reduce the hazard to an acceptable level. Here it is important to assess if there are sufficient controls in place to prevent (or reduce the likelihood) of the hazard from occurring.

This assessment falls under the area of risk control, which is a decision-making activity designed to reduce and/or accept risks. The fundamental purpose is to reduce the risk to an acceptable level. During risk control activities, the following key questions should be asked:

- What can be done to reduce or eliminate risks?
- What is the appropriate balance among benefits, risks and resources?
- Are new risks introduced as a result of the identified risks being controlled?

CCPs represent points in a process where controls should be measured and monitored to ensure risk is not realized. That is, they are invariably the suitable points where environmental monitoring should take place. A series of questions can be asked to help aid in making these assessments. For example:

- What locations are in close proximity to processing activity?
- What sites or equipment are contacted by personnel or gloves?
- What sites represent the most difficult areas to clean and disinfect?
- Where is the greatest amount of activity?
- What are the material and personnel flows?
- Where are the entry points where materials transfer from lower to higher classification?
- What are the dispersal mechanisms that could occur by the transfer of tools, supplies, or people?
- What happens in the room?
- How does equipment enter the room?
- How does equipment leave the room?
- What path does equipment take?
- What path does product take?
- How does material enter the room?
- How does waste leave the room?
- Is product ever exposed?
- Is anything stored in the room?
- Is there a water source in the room?
- Is the room a cold room, ambient or warm room?
- Do personnel enter and exit by the same route or a different route?
- What is the normal occupancy level in the room?
- Where do personnel tend to congregate (e.g. near a desk or a control panel?)
- How and when do cleaning personnel enter the room?
- How long does the process run for?
- Is any type of equipment likely to generate particles?
- Does water ever end up on the floor?
- Does the room contain a drain?
- Does the room have a safety shower?
- What is the frequency of cleaning and disinfection? (plus the effectiveness of these processes).
- Does the room contain difficult to clean areas? (such as small spaces, piping, conduits)
- Are there any airflow or air pattern concerns with the room, or areas that might accumulate contamination?

Upon selection of a CCP:

Establish appropriate limits. Establish system to monitor control of the CCP's. Establish the corrective action (when CCP is not under control). Establish procedures for verification to confirm that the HACCP system is working effectively. This can be by, for example, reviewing the contamination rate and by looking at environmental monitoring results and trending data. Establish documentation and reporting systems for all procedures. Train staff. Analyse collected data.

As an example, consider the same dispensing room with some locations marked (with focus in the figure on the room rather than the machine itself):

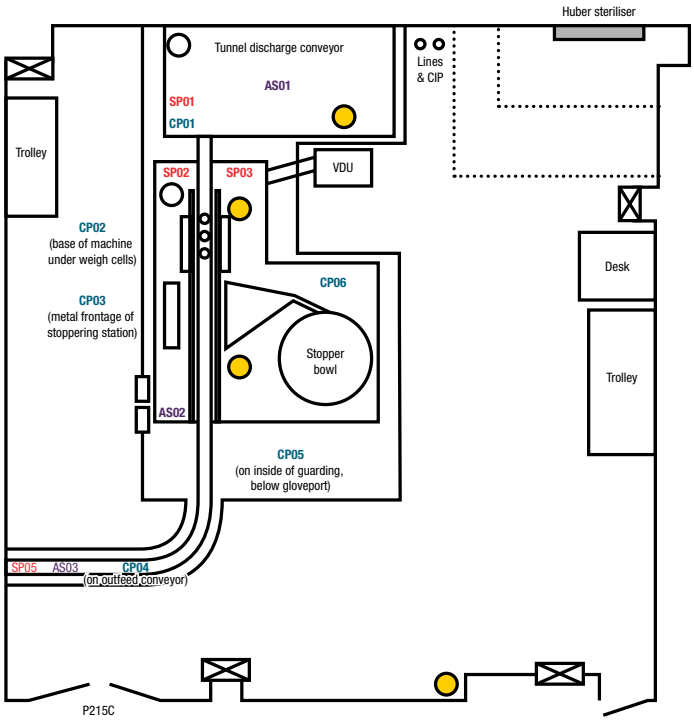

Figure 2: Dispensing area with monitoring locations marked (source: Tim Sandle)

Where:

SP = Settle plate

AS = Active air sampler

CP = Surface contact plate

The completed HACCP must be written up as a rationale and the locations described in procedures. With the rationale, it is important to define the locations and to describe the monitoring approach, together with the processes for reporting and data review.

Governance

On completion of the HACCP, it is important to verify that the samples are appropriate. One way to assess whether the system is working effectively is by reviewing key targets like product rejection rate and ask whether the environmental monitoring gave any forewarning?

This can be represented by:

Source: Tim Sandle

It is also important to periodically reassess hazards, effectiveness of control systems, frequency of monitoring, appropriateness of alert and action levels.

Developing a robust environmental monitoring program that stands up to regulatory scrutiny can be challenging. The two parts of this series have demonstrated how these challenges can be met by adopting risk-based approaches, including for the selection of environmental monitoring locations. Through this, by considering the severity of contamination, the likelihood of dispersal, and methods of detection, risk methodology can help guide towards a compliant and scientifically sound solution.

References and further reading

1. Sandle, T. (2006) Environmental Monitoring Risk Assessment, Journal of GXP Compliance, 10 (2): 54-73
2. Sandle, T. (2012) Environmental Monitoring: a practical approach. In Moldenhauer, J. Environmental Monitoring: a comprehensive handbook, Volume 6, PDA/DHI: River Grove, USA, pp29-54
3. Sandle, T. (2024) Biocontamination Control for Pharmaceuticals and Healthcare, 2nd edition, Elsevier, USA

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