Performance of equipment - challenges in exposure monitoring

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PURPOSE

When new equipment is installed in pharmaceutical industries an APCPPE[1] test should be performed to collect knowledge about the exposure profile of the equipment. In order to achieve the best possible results of an APCPPE test it should be performed when the pharmaceutical equipment is steady in its operation mode including the connections to additional attached equipment.

MONITORING STRATEGY

How to define the APCPPE monitoring strategy for a pharmaceutical equipment? According to the ISPE Manual[1] the monitoring strategy for APCPPE needs to be defined by an occupational hygienist. And the monitoring needs to be executed by an occupational monitoring experienced person.

Which decisions must be made for APCPPE monitoring for a pharmaceutical equipment? Many criteria must be considered when performing an APCPPE test e.g. choice of surrogate, enclosure environmental conditions, clothing, cleaning etc. Detailed knowledge about the pharmaceutical equipment and the standard operating procedure as well as the amounts and concentrations handled should be known.

RESULTS AND DISCUSSION

Example (A) – Test Enclosure Environmental Conditions

Temperature range, relative humidity, room pressure, air exchange rate and direction of air stream are parameters defined by the ISPE Manual for APCPPE monitoring. The pharmaceutical equipment is usually on the customers site and APCPPE test will be performed on site. Therefore, test enclosure environmental conditions can vary.

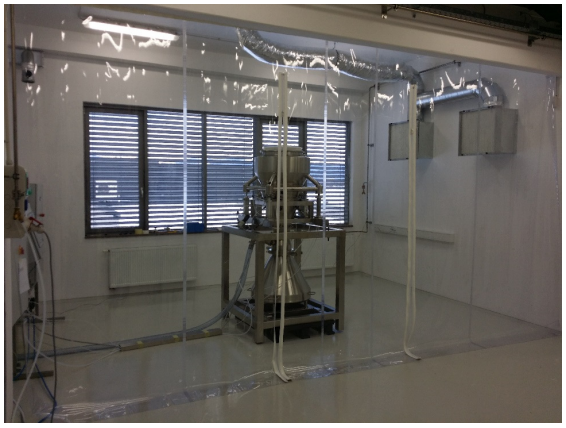

***Figure 1**: Temporary containment for performing APCPPE tests on customers site.*

Example (B) – Test Material

Test material should be representative of the actual process for which the pharmaceutical equipment is intended. Usually a surrogate is used when performing APCPPE tests. The ISPE Manual specifies a variety of surrogates. A surrogate should be chosen wisely because not every surrogate can be handled equally on every pharmaceutical equipment. Micronized material in a high percentage can cause agglomeration.

***Figure 2**: Agglomeration of test material when performing APCPPE tests*

RESULTS AND DISCUSSION (CONTD)

Example (C) – Clothing

The ISPE Manual also defines the clothing which should be worn during APCPPE tests by operators and the occupational monitoring experienced person. The difficulty with the clothing is the gowning and de-gowning procedure. In order to prevent carryover of the test material and thus, influencing the results of the APCPPE tests the gowning and de-gowning procedure must be clear to all participants prior to execution.

***Figure 3**: What to wear during APCPPE tests? When to wear which clothing during APCPPE tests?*

Example (D) – Cleaning

Cleaning of room and pharmaceutical equipment is a crucial part during APCPPE testing. An APCPPE test follows a certain defined protocol. Several exposure monitoring of air and surfaces will be done in a row in a short period of time. If cleaning of room and pharmaceutical equipment is not done properly it almost certainly influences the results of the APCPPE test.

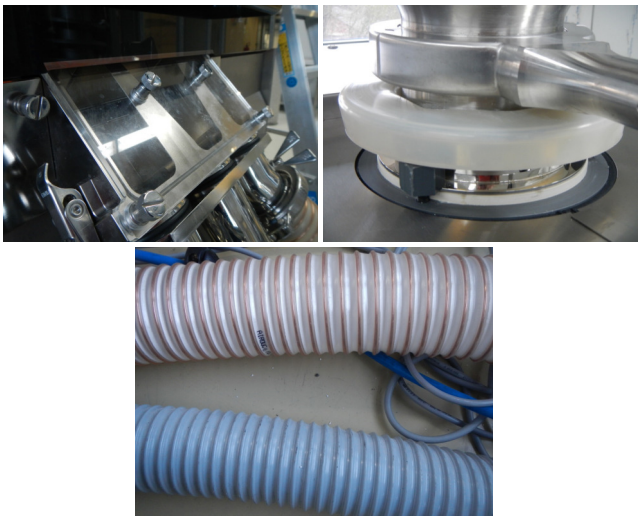

***Figure 4**: Surface contamination of pharmaceutical equipment and room after cleaning during APCPPE tests.*

CONCLUSIONS

In order to perform a successful APCPPE test at any pharmaceutical equipment a variety of factors have to be considered. In our experience the need to be guided through an APCPPE testing and address these factors is important for all participants. When performing an APCPPE test it is crucial that every participant understands its roles and responsibilities. When performing an APCPPE test it is crucial that the agreed scope of the test is understood by all participants. And most importantly that the participants know how to reach the scope in accordance with the ISPE Manual.

In our experience the execution of an APCPPE test has to be planned in detail. The lower the targeted limit value the more accurate the execution of an APCPPE test has to be. Otherwise, the results will be influenced by exposures that happened due to insufficient performing.

REFERENCES

[1] ISPE, Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment (Second Edition, Tampa, FL, 2012)