ISO 14644-2:2000	ISO 14644-2:2015	Impact of Updates on Current Monitoring
Headings: Section 4: Demonstration of continued compliance • Principle • Testing for continued compliance • Monitoring • Documentation • Records	Headings: Section 4: Creating, implementing and maintaining a monitoring plan • Principle • Risk Assessment • Monitoring Plan • Calibration • Review & Approval • Response to deviation during monitoring Section 5 Periodic Classification of air cleanliness by particle concentration	N/A
4.3.1 Routine monitoring of airborne particle concentration and other parameters shall be performed according to a written plan. 4.3.2 This plan shall be based on risk assessment related to the application of the cleanroom. References Annex B which lists items that the risk assessment will influence such as the frequency of sampling, locations, interpretation of data, actions if OOS results, other tests such as airflow volume, pressure differentials (Table 2), air flow visualization, filter leakage, recovery and containment (Table A.1) that may have an impact on the particle concentrations within the room.	4.1 also looks for a documented monitoring plan which is based on risk assessment, reviewed and approved, implemented, data analysed for trend analysis, actions documented where necessary and the plan periodically reviewed. 4.2 talks in general terms about risk assessment but references Annex A. Annex A has a list of considerations that should be taken into account when performing the risk assessment.	Need to review the current plan/procedure for routine monitoring of particulates in order to see if there is justification based on risk assessment for the monitoring that is being performed.

Table 1: Schedule of testing to demonstrate compliance with particle concentration limits. Table 2: Schedule of additional tests for all classes Table A.1: Schedule of Optional tests	These tables have been removed for the 2015 edition. These tests and the schedule of them is now based on risk assessment taking into consideration the purpose of the cleanroom. 4.3 lists items that should be included as part of the output of the risk assessment. These outputs will be reviewed periodically and so can changed pending historical data and more information being gained on the cleanroom.	As above
Table 1, Table 2 details that these tests are normally performed in the operational state but can be performed in the at rest state. 4.3.1 details that monitoring is normally performed in the operational state.	There is no reference to the cleanroom state for monitoring however ISO 14644-1 does take into consideration the required ISO class in the in-operation state when performing calculations around the particle monitoring (Annex B 14644-1)	This should be taken into consideration in the risk assessment
N/A	For processes that produce particles as part of the process and where these particles do not have an impact to the process or product, it may be an option to rely on periodic at rest classification, or operational classification of simulated operations, rather than monitoring the particles in operation. Other performance & cleanliness attributes may still have to be monitored.	Review to see if options are needed.

4.2.6, 4.3., 4.4.1 (f) Where instruments are used for testing they shall be calibrated in accordance with current industry practice. Proof of calibration is required.	4.4 Calibration: Instrumentation shall: • be adequate to perform monitoring required • have a valid calibration cert meeting current accepted frequency & method of calibration For particle counters this should be based on ISO 21501-4. If this standard cannot be met a decision to use this particle counter must be documented.	Check that all instrumentation has a valid calibration cert. Check if the particle counters used are calibrated in accordance with ISO 21501-4. If not document a justification for use.
4.2.7 If test results exceed the limits specified, the cleanroom is not in compliance and appropriate remedial action shall be taken. Following remedial action requalification shall be undertaken. 4.2.8 details four main occurrences that require a requalification of the cleanroom	4.6 If monitoring results exceed limits, an investigation is required and action taken. If the action requires significant changes to the cleanroom or its operation, then classification as per ISO 14644-1 shall be performed. The monitoring plan also needs to be reviewed to reflect the changes.	Review the protocol for when OOS results are achieved to ensure it includes an investigation and an impact assessment as to whether or not requalification is required.
Table 1: particle counts taken annually if >ISO class 5 cleanroom and particle counts taken 6 monthly if ≤ISO class 5. Extension of testing time intervals was only documented for cleanrooms that had continuous or frequent monitoring systems in place.	Section 5: Classification testing shall be performed annually as per ISO 14644-1. This frequency can be extended based on risk assessment, historical data that has been in compliance.	No change for > ISO class 5 cleanrooms. For ≤ISO class 5 cleanrooms this may be a change or it may be decided to leave it at the current frequency based on risk assessment.
No mention of limits. It details if limits are exceeded steps that should be taken, but it doesn't detail specific limits, alert or action limits or how to set limits.	Annex B details information on setting alert and action limits. It details information on setting limits for pressure differential monitoring & particle count monitoring.	Review current limits for pressure monitoring & particle monitoring. Ensure they meet the relevant regulations complied with and ensure they are explainable as to where they came from. It is good practice to have an alert limit in place to trigger if you are heading out of control.

4.4 Documentation Included criteria that shall be fulfilled in the test reports. This was a good list of requirements and was useful in particular if external reports were generated or were been reviewed.	This criteria is not listed in the 2015 edition.	N/A

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