ISO 14644-1:2015 Key Updates

ISO 14644-1:1999	ISO 14644-1:2015	Impact of Updates on Current Monitoring
ISO Classification Table	ISO Class1, 0.2 µm limit of 2 pt/m^3removed ISO Class 2, 0.5 µm limit of 4 pt/m^3removed ISO Class 3,1.0 µm limit of 8 pt/m^3removed ISO Class 5, 5.0 µm limit of 29 pt/m^3 removed. The removal of these limits was due to sampling and statistical limitations for particles in lower concentrations made classification inappropriate and for particles greater than 1 µm there can be issues with particle losses in the sampling system. All other particle concentration limits /m^3 of air remain the same as previously. Limits for ISO Class 9 are now only applicable in the 'in operation' state.	No impact for an ISO class 8, 7, 6 or 4 cleanroom. For an ISO class 1, 2, 3 and 5 cleanroom the acceptance criteria for the larger size particles have been removed. Before eliminating these from your monitoring it is worth reviewing the impact of these particle sizes on your process and if removed the lack of potential knowledge that may be lost. For example 5.0 µm particles can be a good indicator of personnel contamination in an ISO class 5 cleanroom and therefore potential risks to the product. For an ISO class 9 cleanroom the limits specified in the standard only apply to the 'in operation' state.
Annex B: Determination of particulate cleanliness classification using a discrete particle counting, light scattering instrument B.2.2 Instrument Calibration refers to the instrument having a valid calibration cert and the frequency and method of calibration based on current accepted practice.	Annex A: Reference method for classification of air cleanliness by particle concentration. A.2.2 Instrument Calibration refers to the frequency and method of calibration based on current accepted practice as specified in ISO 21501-4. However, there is a note stating that if the particle counter cannot meet all the requirements of ISO 21501-4, a justification must be documented in the test report.	Review the calibration certs of the particle counter used to ensure that it can conform to the requirements set out in ISO 21501-4. If not ensure there is a rationale for use documented.

B.4 Sampling The number of sampling locations was derived from the equation: $\sqrt{A}$ m^2 i.e the square root of the area of the room in metres squared, which was then rounded up.	A.4 Establishment of Sampling Locations Table A.1 lists the different cleanroom areas (m^2) up to 1000m^2 and defines from this the number of sampling locations that are required within this cleanroom area. If the cleanroom area is greater than 1000m^2 formula A.1 is applied to determine the minimum number of sampling locations. Additional sampling locations can be used to facilitate sub division of the cleanroom area into equal sections if preferred. Sampling volume and time requirements remain the same.	The use of this table defining the number of sampling locations required will in many cases increase the number of sampling locations to be monitored compared to the previous standard requirements.
B.5 Recording of Results If the number of sampling locations was ≤1 or >9 the average of the results was calculated and it is this average that must have met the specification If the number of sampling locations was ≥1 and <10, the average, standard deviation and 95%UCL was calculated and it is this figure that must be within the specification for the specific lass of cleanroom.	A.6 Processing of Results If two or more results are gained from 1 sampling location they will be averaged. This will depend on the sampling volume and time. Perhaps only one result will be required. The cleanroom has met its classification requirements if the average particle concentrations at **each sampling location** are within specification.	The processing of results will be easier as there are less statistical calculations to be performed. However, there is a big change on how the acceptance criteria is met. Now all individual locations or the average of individual locations within the cleanroom will have to meet spec before the cleanroom can be deemed to meet the specified classification.

In summary if the averages or 95%UCL (pending the number of locations) was within the acceptance criteria for that particular class of cleanroom then the cleanroom had met its acceptance criteria and was deemed to meet that ISO class.		
B.6.2 Treatment of Outliers There was a section dealing with outliers and listing criteria to be reviewed if an outlier was identified as causing the final 95% UCL result to be out of spec.	Sampling Procedure A.5.5 & A.5.6 There is an allowance that if an out of spec result is observed at a location due to an abnormal occurrence that count can be discarded, a new sample taken and noted on the test report. There is also a paragraph detailing if an out of spec is observed due to a technical failure of the cleanroom or equipment, it identifies a list of criteria to be reviewed.	While there is an allowance for an out of spec result to be resampled, this means that now each individual result will have to be examined at the time of sampling in order to identify if an out of spec result has occurred.
N/A	A.6.1.2 Calculate the concentration per cubic metre. There is a formula detailing how to convert results to cubic metre.	This calculation will help ensure that the conversion of results (pending the sample volume taken) to cubic metre will be performed correctly.

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