

NIOSH 7400 PCM iDOC Requirements

NYS ELAP procedure for submitting initial Demonstration of Capability (iDOC) for analyst sample loads exceeding 2 samples per hour.

All labs must submit each new employee's iDOC to ELAP for approval (Certification Manual Item 231.1). Please email the iDOC package to elap@health.ny.gov. Continuing DOCs are to be maintained by the laboratory for review during assessments and **are not** to be submitted to the ELAP office.

Include in the email subject line "PCM iDOC" and the lab's ELAP #.

Laboratories must submit the following iDOC data to ELAP for review:

- 1) A cover letter summarizing the accepted counts for the analyst.
- 2) SOP for completing the DOC procedure, including a spreadsheet for performing required calculations.
- 3) Documentation for the samples (slide counts) used in establishing the DOCs. **Each slide may contain only one sample.** These slides may be a mixture of proficiency test (PT) samples and real-world samples. The slides shall cover the required ranges as found in the NIOSH 7400 method including approximately **equal** ratios of low (5-20 fibers), medium (>20-50 fibers) and high (>50- 100 fibers) fiber count ranges.
 - If PT samples are used, the mean fiber count from the PT report may be used, until in-house data can be generated.
 - For real-world samples with reported (known) results, standard deviations must be calculated using Section 14 of NIOSH 7400 method to assess usability in the iDOC. Laboratory mean values and standard deviation for each slide must be provided.
- 4) Full documentation for each analyst, including the individual results from the slides read for the iDOC. This shall include all bench sheets, including the stop and start time for each slide as well as the start time and stop time of the entire one-hour analysis period.

With respect to #2: Your SOP needs to address the requirements noted above. Also, for your calculations to be verified, provide the following information on the spreadsheet used to perform the calculations:

- Analyst name or initials
- Sample slide ID
- Date analyzed
- Start time and Stop time for each slide
- Overall start time and stop time
- Graticule field area
- Fibers/mm² for the original and the re-prep
- Absolute difference of the square root (SQRT) of the two fiber counts above

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- Calculation of $2.77(X)S'r$
- X (average of the SQRT of the two fiber counts),
- Sr value (intra-counter relative standard deviation)
- S'r value ($Sr/2$),

****Pass/Fail Criteria - (Pass = if $2.77(X)S'r$ is greater than (>) Abs. Difference****

The iDOC package will be reviewed by the ELAP technical staff and a letter will be sent to confirm acceptance or rejection of the slide count data and PASS/FAIL assessment. This letter should be kept in the analyst's training file so that it may be reviewed during an on-site assessment.

Reminder: New employees, following ELAP approval of the iDOC, must be challenged quarterly (i.e., 4 times a year) by laboratory management during the first year of employment at the approved laboratory. After the first year of employment, each analyst must perform a continued DOC semi-annually (i.e., two times a year) by laboratory management, and all records must be maintained at the laboratory for review during the on-site assessment.

The continuing DOC does NOT need to be sent to ELAP for approval. The ongoing DOC **DOES NOT** replace the routine QC that is to be performed by the lab throughout the rest of the year.