

Comment Number	Section	Comment	Response
1	Table of Contents	1) The table of contents needs to be updated.	Agreed. The Table of Contents was updated.
2	Purpose	An explanation for the necessity of an analytical scheme should be added to the purpose of supplemental document SD-7 explaining why no singular analytical method is enough to make an identification. The purpose of SD-7 should also explain why structural information is of higher value than physical and chemical characteristics, especially if the physical and chemical characteristics are specific to targeted analytes.	No change made – this is a supplement to the core recommendation, and is not meant to stand on its own. A hyperlink was added to assist readers.
3	Definition	The beginning section is a repeat of the IIIB recommendations document. As a supplemental document, I don't think it's necessary to include again here.	Agreed. Much of the duplicative language from Part IIIB was removed.
4	Introduction	Add/clarify: Provided that the unused results do not support a different conclusion	Agreed. This language was moved to Part IIIB.
5	Introduction	From reading IIIB, it appears that quality practices outlined in IIIB.5.2 are always required. Clarify the intent of this sentence here – do you mean that since two samplings are not being used some other quality practices must be used to comply with IIIB.5.2?	Agreed. This language was moved to Part IIIB.
6	Introduction	Repeat of IIIB document.	Agreed. Much of the duplicative language from Part IIIB was removed.
7	Question 1	How is the analyst coming up with question that needs to be answered? Is the question being asked determined by the needs of law enforcement, the limitations of instrumentation being used by the laboratory, or both? We would assume that a laboratory would always strive for the highest level of identification possible at all times, but there are levels to identification. Both documents could be improved by adding more detail to the example given in the introduction of the Methods for Analysis and adding more information to the purpose of the supplemental document on the different levels of identification and the intended value of this information	The source of the question is based on the customer's request, the observations of the materials submitted, and jurisdictional requirements.
8	Question 2	Add word "either" here or add a note similar to Q3 explaining that in this scenario distinguishing between these two compounds is not necessary.	Agreed and corrected.
9	Question 3	Regarding isomers I miss the technique GC-IR that we often use after analysing with GC-MS to provide information on isomers. This is not mentioned. GC-IR used to be our screening method some 10-15 years ago but due to GC-MS being more sensitive we switched to this technique.	The source of the question is based on the customer's request, the observations of the materials submitted, and jurisdictional requirements.

10	Question 3	<p>This would be a more powerful example of limited A data still qualifying as a category A test if the GC technique were removed from the example. Or break it into 3a as is and 3b with LC and MS being sufficient (GC retention time not used).</p> <p>As it is, it doesn't clarify whether a limited A is still a category A since three tests are ultimately used. But if the limited A + one B were used it would highlight this quite well.</p>	<p>The purpose of the example was clarified. Examples of analytical schemes do not preclude the use of other valid schemes containing alternate techniques.</p>
11	Question 3	<p>Maybe add a delineating line in the tables after the initial selected scheme to highlight the additional testing from the original testing.</p>	<p>Agreed. Delineating line was added.</p>
12	Question 5	<p>Methamphetamine and phentermine need to be differentiated in scenario #5. Is considering GC-MS two tests really sufficient? Does this cover enough points in IIIB.5.2 to ensure that the results correspond to the sample tested if two aliquots cannot be tested, and there is not a second technique to ensure results are consistent?</p>	<p>It is noted at the beginning of the document that throughout the following examples, it is assumed that the laboratory is utilizing validated methods and employing quality practices to ensure the results correspond to the sample tested. In this example, it is assumed that the color test would be performed from a second sampling or that the appropriate QA procedures were performed. The example laboratory's method was expanded to include a requirement to run reference materials for both methamphetamine and phentermine.</p>
13	Question 5	<p>Does the mixed IR spectrum meet the level of a Cat C based on the significant peaks attributable to methamphetamine?</p> <p>If so, indicate this in the assessment and remove the category B GC test to illustrate this. If not, clarify in IIIB.3.1.2.2 that this data cannot be used towards the identification and explain that the IR test does not count toward the required number of tests.</p>	<p>Due to the potential for data variability, SWGDRUG cannot define the achieved category in this case, all we can determine is that it does not meet the expected selectivity of Category A.</p>
14	Question 5	<p>Consider adding a delineating line to separate the initial selected scheme and additional testing</p>	<p>Agreed. Delineating line was added.</p>
15	Question 6A	<p>I would define the term "reviewable data" as this may be slightly different for various techniques.</p>	<p>Agreed. Added a reference to appropriate section in Part IIIB.</p>
16	Question 7	<p>Is this type of MS a category B? It's listed as a B in the assessment below. Consider clarifying the MS and MS with fragmentation difference in the table of categories in IIIB.</p>	<p>Agreed, the table was clarified to match the consideration section of the question.</p>
17	Question 7	<p>Add a delineating line between original scheme and additional testing.</p>	<p>Agreed. Delineating line was added.</p>
18	Question 8B	<p>I think this example might be more powerful if the pharmaceutical identifier were consistent with a known pharmaceutical product such as OC80 tablets, but testing revealed the presence of fentanyl.</p>	<p>Agreed. The example was changed to include inconsistent pharmaceutical identifier information.</p>

<p>19</p>	<p>Question 9</p>	<p>Finally, NOW is the time for SWGDRUG to begin establishing or recognizing the need for new protocols/criteria governing the analysis of Charlotte Web and Medical / legal marijuana for those localities where such statutes exist. This should include a showing that TLC is or is not present in the resin, if present a quantitation should be done depending upon statutory requirements, and how the sampling and quantitation be done. How should the sample be collected and what components of plant material be included in the quantitative sample. Obviously, only leaf and flowering tops used with the exclusion of stem would give a higher percent then if stems included. How many samples need to be randomly selected for a proper "average percent" similar to the excel sampling for dosage units. How should the extraction be done. Etc.</p>	<p>Example #9B was added to provide further clarification and Part IIIB was updated to include a requirement to determine the THC level, where applicable.</p>
<p>20</p>	<p>Question 9A</p>	<p>Question #9A: Would all of the tests in the selected scheme for Question 9 be necessary if the analysis was performed by a trained botanist? I would say that an examiner with other education/background then botanist could as well be trained in recognizing features specific for cannabis, so using macroscopy combined with misroscopy could be performed by a person trained in the field. In the other document, part IIIB, this definition is used: In this context, competency exclusively applies to those examiners recognized as professional botanists or those who are appropriately trained in botanical identification. The two documents should be consistent</p>	<p>The language was clarified to mirror the language for Part IIIB.</p>
<p>21</p>	<p>Question 10</p>	<p>The scheme provided is not as clear as it could be and tackles two issues at once: can identifications be made without lab-owned reference materials AND what is the appropriate level of selectivity to determine a specific isomer.</p> <p>The specific question posed was "can 4-MMC be identified without reference standards" and the answer appears to be yes, since the examples are relying on comparison to SWGDRUG libraries and data. This would be the case for any substance in which the lab was not relying on in-house data so long as the appropriate scheme is selected.</p> <p>Would identification of 4-MMC be possible by GC/MS if the lab had a reference standard for only 4-MMC?</p>	<p>Without all the reference standards, GCMS can not provide an unambiguous identification of 4-MMC. The selection of NMR allows unambiguous determination of 4-MMC without the use of a contemporaneous reference material. The comparison of spectra from all three isomers was performed.</p>

22	Question 10	I do not have a problem with the use of the color test for psilocin in this case as a Category A and B were used and that the color test properly showed it to be an indication not consistent result. BUT, I have seen in at least one case a mass spectrum was used with a Marquis test to "identify" heroin.	No changes were made based on the comment.
23	Question 11	For Questions #11 and #12, it will be better to include the GC-MS technique to emphasize to the readers that GC-MS technique is not able to differentiate psilocin and psilocybin as psilocybin degrades to psilocin under thermal conditions.	Agreed. The example was changed.
24	Question 12	Any technique not utilizing a heated inlet could be used. Not everyone has MS/MS. Another technique would be use infrared spectroscopy to show the presence of psilocybin. In fact, a GC or UV consistent with Psilocin and the ir showing psilocybin would be acceptable. In fact, the scheme in #11 above with ir added would have been sufficient to identify Psilocybin in that sample.	No changes made – examples of analytical schemes do not preclude the use of other valid schemes containing alternate techniques.
25	Question 12	What is the proposal for beverage alcohol analyses; many perform 1) ID from container - can of beer and 2) GC-FID for characterization/identification and quantitation	Ethanol analysis is beyond the scope of this document and SWGDRUG.
26	Question 12	In general, it is not common to use XRD for identification (non-quantification) of common drugs, excipients and pharmaceuticals, although it may be used as a Category B (or even A) technique. In this new supplemental SD-7, there are no comments on that either. This may have been caused by the typical very slow acquisition and analysis, but the modern equipments are capable of performing much faster analyzes. Therefore, I guess it would be meaningful if there were some examples with this technique (exploring also its limitations).	Additional examples may be considered for future versions.

<p>27</p>	<p>Question 12</p>	<p>Question #4 & #6 & #6A: If Category C test (no reviewable data) is replaced by any Category A test (any of Raman, IR, MS, NMR, even if repeat) on separate, distinct, consecutive portion/aliquot, there will be an additional piece of reviewable data provided - stronger support for conclusion.</p> <p>Thank you again for the opportunity to provide feedback to SD-7 for Part IIIB. Please refer to my feedback for Part IIIB. Question 4: Instead of Category C Color Test, use another (distinct, respective, and/or consecutive on separate aliquot) Category A FT-IR. Blanks run before each Category A test, and included reviewable data. Same as previous line on table). Category A is superior to Category C anytime in this case.</p> <p>Question 6: Instead of Category C color test, allow for use of Category A Raman or FT-IR on another, separate (consecutive), distinct aliquot. In this case, either Category A would be superior to Category C any time. Question #6A: Two separate, consecutive Hand-held Raman (or FT-IR) on two separate respective aliquots would be acceptable, provided blank runs prior to each and reviewable data generated each test & blank. I bring up the suggested viability and acceptability of two separate, respective, consecutive Category A tests on two distinct aliquots, even if the same (IR or Raman or MS), provided blanks before each aliquot and reviewable data included given the examples in Question #8A, #8C and #9 which use only category B and C tests (two B + one C). Given that Category A is highest selectivity over B and C, using any two (2) Category A is superior, even if same two (conditions apply above).</p>	<p>Clarification has been added to Part IIIB to clarify that a second test must exploit different chemical and physical properties, which is not the same as repeating a technique on duplicate samplings.</p>
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