SWGDRUG Recommendations, Version 7.1

Public Comments and SWGDRUG Responses

SWGDRUG solicited comments on version 7.1 of the SWGDRUG Recommendations from November 12, 2015 to May 30, 2016.

SWGDRUG received 8 responses (all affirmative) which included the following comments. The comments have been organized for clarity. Each comment was considered by the committee and responses are below in red.

1. II.5(d) : Suggest to add in "Science and Justice" and "Drugs Testing and Analysis".

Response – The citations were added.

2. Concerning IIIA.2 Sampling strategy, I think it would be clearer to explain that there are several ways to do: - the sampling or selection part can be statistical (SS) or non-statistical (NSS). If SS then it is possible to infer about the population and you use a statistical model (SM) If NSS it is also possible to infer about the population BUT it is subjected to the condition that the selection is done RANDOMLY and only thus it is possible to operate in both ways: (1) apply a statistical model (SM) and determinate the resulting probabilities and level of confidence or (2) determinate and report a confidence interval for an inferred population parameter. If no random selection then no inference about the whole. If no inference about the whole population is necessary, it could also be possible to work in different ways which could be SS or NSS: in both cases, the conclusion can be made only on the selected specimen(s) even if with SS this allows for a certain degree of flexibility (you would be able to infer about the population if needed).

Response - We believe that the recommendations reflect the author's suggestion. No specific alternative language was provided.

3. The footers for parts IIIA and IIIB are not correct. The footer for Part IIIA should refer to sampling and Part IIIB should refer to Methods. Thanks!

Response - Changed footers for parts IIIA and IIIB.

4. Sections IIIA.2.2 and IIIA.4.1 have very similar wording. However in IIIA4.1 SWGDRUG recommends each unit be fully analyzed, in IIIA.2.2 each unit shall be fully analyzed. It seems that there could be a little fluctuation in interpretation with the wording not being exactly the same.

Response – Edited the sections for uniform and clearer verbiage.

5. IVA.3.3.4. NEW Supervisors Shall… While I understand that the intent of this addition is to account for those supervisors who may be grandfathered in to their position without meeting the criteria, it may portray that there are no requirements for a supervisor. My suggestion would be to add a statement that current supervisors shall meet a criteria set forth by the laboratory by which they are employed.

Response – Reverted to original language.

6. IVA.7.1.1: This sentence is not clear: "Monitoring shall include at least the use of blanks and reference materials, test mixtures, calibration standards." It seemed to imply all that is stated is required. Is that so? Suggestion : Monitoring shall include the use of blanks and appropriate reference materials, test mixtures or calibration standards

Response - Added "or" to harmonize sentence with ASTM E2327, to reflect blanks are required along with an additional reference material, test mixture, or calibration standard.

7. Section IVA.7.1.1 it appears that the “etc.” may have been deleted when it may still be needed.

Response - Added "or" to harmonize sentence with ASTM E2327, to reflect blanks are required along with an additional reference material, test mixture, or calibration standard.

8. IVA.7.1.1 Monitoring shall include, at least, the use of blanks and reference materials, test mixtures, AND calibration standards. Addition of the word "and" between test mixtures, calibration standards.

Response - The statement clarity was addressed by other means described above.

9. IVB.2.4.4.1.2 : For qualitative analysis, run the qualitative method, a minimum of ten times. I would like to know for a modified qualitative method e.g. GCMS method, is there still a need to run a minimum of ten times. Example: Current GC/MS method : 100 (ramp at 40/min) to 300; if this method is modified with a slower ramp rate e.g to 20/min or to 100 (ramp at 40/min) to 250(hold for 2 min) then ramp to 300 at 40/min, is there still a need to run it a minimum of ten times?

Response - This is not addressed in revision 7.1, but is being discussed by a SWGDRUG subcommittee.

10. With regards to category of testing. The instrumental technology has progressed where the discriminating power is increasing and the capital costs are decreasing. I recommend that Cat A class of testing includes Tandem Mass Spectrometry, High resolution Mass Spectrometry and NMR applications for drug identification purpose. Or that another category of testing is included. I note in the clan lab section techniques like NMR are listed for inorganic analysis. I reference the Euro Communities decision-6/23/EC "concerning the performance of analytical methods and the interpretation of results" which outlines the use of the above technology for the reporting substances

Response - This is not addressed in revision 7.1, but is being discussed by a SWGDRUG subcommittee.

11. The present recommendations are not taking in to account advances in technology which enable the use of single tests with highly discriminatory techniques to report drugs. QA aspects need to be considered to ensure that the result can be traced back to the exhibit. But there are other mechanisms to ensure the traceability besides multiple tests e.g barcode tracking. This recommendation appears to stem from the need to have independent tests due to the limited discriminating power of the techniques listed.

Response - This is not addressed in revision 7.1, but is being discussed by a SWGDRUG subcommittee.