No.	Comment for IVA 2020	Assessment	Decision
1	Section IVA.3.3.4 Supervisors shall B) have a minimum of two (2) years experience as an analyst in the FORENSIC analysis of drugs This is the first reference to FORENSIC in the context of analysis of drugs. Recommendation: The introduction to this document, IVA.1 should include a reference to the forensic nature of the work. Unable to access “Part II – Education and training (section 2, 3 or 4)” to see what the training requirements are.	Beyond scope of proposed amendments. No change. Part IVA is a subsection of the Recommendations. The term "forensics" first appears in the Forward and Mission Statement and is subsequently used throughout the document. It is excluded from Annex A (glossary) as it is considered to be a common/non-scientific term meaning related to matters of law.	Rejected
2	In relation to section IVA.3.2.3 and IVA.3.2.4 it appears to preclude Analysts technically peer reviewing each others work. I feel this may not be practicable in many laboratories, as supervisors or managers may not have the capacity to review the work of a team of Analysts. Can some clarity around this requirement please be provided?	Beyond scope of proposed amendments. No change. Part IVA.3.2 is prefaced with the language "An individual (however titled) may be responsible for one or more of the following duties". The term *may* was deliberately selected to indicate that the listed responsibilities are not exclusive for the corresponding title but rather a guideline for minimum responsibilities to be considered. Section 3.2 does not dictate who, specifically, performs technical reviews but rather states that the supervisor (technical leader) has the overall responsibility for technical operations such as technical reviews.	Rejected
	IVA. 2.3 A) A Quality Manual must be in place explaining the general characteristics (Quality Policy, List of SOPs, responsibilities of QM personnel) of the Quality system, B) a policy must be in place describing the plan for the improvement of the quality system (e.g. quality goals).	No change. A) Current language requires a documented quality management system. A "quality manual" is not the only means to achieving a successful quality management system. B) The proposed revision included a mandate for the quality management system that achieves improvements.	Rejected
	IVA.3.2.7 Quality Control Analyst: A designated person who independently has access and check the generated data and the chain of custody.	Beyond scope of proposed amendments. No change. This document is indented to require oversight and maintenance of the quality management system, not specify who performs checks.	Rejected
	IVA.5.1 The below information are recommended to be included: a) the process of reporting the receipt of evidences, b) the physical nature and the weight of the evidence at the time of receipt.	Beyond scope of proposed amendments. No change. A) Intake and reporting processes may be in manuals/SOPs apart from the case file or record. Centralized records are not part of IVA.5.1. Additionally, Part IVA.9.2 requires reporting a descriptive list of submitted evidence. B) Satisfied by "description of the items of evidence submitted". Weight is not mandated upon receipt. Part IVA/9.1.2 requires a weight/count in casework documentation upon opening evidence packaging.	Rejected
	IVA.5.4 Records regarding any used amount of the evidence for testing purposes must be kept.	Beyond scope of proposed amendments. Changed 5.4 to clarify the intention of the requirement. Sampling is generally not considered in disposition of evidence. Disposition is intended to let the customer know where the evidence resides after analysis. At a minimum, records shall be kept when the evidence is wholly consumed during testing.	Clarification provided

	IVA.5.5 A statement is recommended to be included describing the time period that the documents must be retained. If that varies, then a statement can be included explaining that the retention period can be decided by the labs according to local regulations or jurisdictional requirements.	Beyond the scope of proposed amendments. No change. The phrase "…in accordance with jurisdictional requirements" exists in the current language.	Rejected
	IVA.6.1.6.1 The comparison of data between reference material and the case sample, obtained from different instruments is not recommended. The comparison should be done at the same instrument.	No change. Reference materials run on different instruments can be valid for the comparison to an unknown with appropriate information (performance checks, validation, etc.) showing both pieces of equipment produce comparable data. For example, if a laboratory has 2 of the same ATR IRs and an in-house library is built on 1 of the 2, it can be transferred for use with the second assuming the parameters are validated to be comparable. Another example would be a mass sprectrum for a case sample produced on one GC/MS can be compared to a reference material spectrum produced on another GC/MS provided that both intruments are verified to produce comparable data.	Rejected
	IVA.7.2.3 A maintenance schedule of the instruments must be in place and the tasks must be recorded.	Beyond the scope of proposed amendments. No change. Intuitively, if instrument performance is monitored and documented (IVA.7.1.2), so shall maintenance. Requiring a planned schedule is not mandatory and is up to the laboratory to determine. Additionally, "equipment calibration and maintenance" records are required in IVA.15.	Rejected
	IVA.8.6 A procedure for the selection of vendors based on certain criteria must be in place.	Beyond the scope of proposed amendments. No change. This document ensures the appropriateness of chemicals and reagent but is not intended to address specific purchasing protocols such as vendor evaluations.	Rejected
	IVA.9.2 A procedure describing the process for controlling the documents and a list of the current documents must be in place. The reports are recommended also to include the following: 1) The identity of the method used. 2) Information regarding special conditions of the method, like environmental conditions. 3) Where interpretation is included, this should be scientifically justified.	No change. Part IVA.9.2 requires, at a minimum: 1) a list of analytical techniques employed. This does not preclude a laboratory from reporting the specific instrumental method used but it would not be mandatory per ISO/IEC 17025:2017 Section 7.8 2) such information is required to be monitored and documented per ISO/IEC 17025:2017 Section 6.3 but reporting is not mandatory. SWGDRUG is in agreement that reporting is not required. 3) It is up to the laboratory to determine what information constitutes a result, opinion or interpretation based on their workflow (see ISO17025:2017 section 7.8.7).	Rejected
	IVA.12.3 External audits of laboratory operations are recommended at least once a year.	Beyond the scope of proposed amendments. No change. Annual external audit are not necessary/mandatory.	Rejected
3	IVA.13 The policy shall also include a requirement for the establishment of preventive actions.	Beyond the scope of proposed changes. Recommendation in line with risk based thinking of ISO/IEC 17025:2017. Expanded the language in IVA.13.1 to include the opportunity for preventative measures in light of an analytical deficiency. May be considered in furture revision.	Accepted

	(A) Since there are differing interpretations and some confusion within the community, consider explicitly spelling out the hierarchy of recommended practices in IVA.6.1.6. Specifically IVA6.1.6.1 contains many options, but that also have a hierarchy of reliability/risk and it would be helpful to spell it out. Also consider mentioning the decreasing order of preference corresponds to a decreasing order of reliability /increasing risk. Suggestion: IVA.6.1.6.1 ... Reference material may be analyzed according to the following options within this clause, in order of decreasing reliability/increasing risk: (1) Coanalysis with test/case sample; (2) Contemporaneously with test/case sample (e.g. within 24 hours of test/case sample); (3) On the same method and instrument as the test/case sample, at a laboratory defined time interval from the test/case sample. IVA.6.1.6.2 Comparisons to external reference data may be used where a reference material is unavailable. External reference data includes data collected within the laboratory on a different method than the test/case sample, data collected at another laboratory on the same and/or different method than the test/case sample, published literature data, spectral libraries, published monographs.	No change. Language includes "In descending order of preference..." Summary of preference: 1. Comparison to in-house reference material 2. Comparison to external reference material 3. Structural elucidation (no reference material) SWGDRUG does not intent to be more prescriptive on the nature of comparisons.	Rejected
4	(B) IVA.9.2. - consider expanding the 'conclusions' bullet to recommend reports clarify between the possible results such as (1) a positive identification, (2) possible presence of substance, but no identification made due to lack of reference material, (3) possible presence of substance, but no identification made due to poor quality data is made, and (4) no substance of interest observed.	No change. Part IVC.2.2.2 recommends testing limitations to be documented and potentially reported. It is up to the laboratory to determine relevance of a limitation and whether it shall be reported. May be considered in furutre revisions.	Rejected
5	IV.A.6.1.6.1 - What does "comparable" data mean? Should this have some elaboration or definition to clearly articulate what acceptable comparable data represents?	No change. This document allows the laboratory the freedom to determine such decision points. Subsequent examples are intended to clarify that method validation or internal reference collection compilation are ways in which a lab may choose to achieve comparable data.	Rejected
6	No suggestions.	No change.	Accepted
7	The additional explanation of the quality management system makes job duties more clear. The received and opened dates of chemicals and reagents being listed is necessary to maintaining their efficiency. The dates should be documented incase of re-analysis of a case where testing procedures produce varying results. Furthermore, the additions to the report writing section are beneficial. It allows for information to be clearly formatted and the additional information that would be in the reports allows for less questions after a report is released to the appropriate party. I think the changes made to this document are clear and useful and I do not recommend any other changes.	No change.	Accepted
	Overall the document is good and well constructed, but a few suggestions for consideration: IVA.2 Place more explicit emphasis on review of the quality system eg. "A documented quality management system shall be established, maintained and regularly reviewed."	Beyond scope of proposed changes. No change. Review is inherent to maintaining a quality management system. Additionally, IVA.3.2.5 defines the Quality Manager's role which includes an annual review of the quality management system.	Rejected

	IVA.3.2.5 and IVA.3.2.6 Both mention an annual review (one of quality, one of health and safety) .. would this more appropriately "require regular review as document, but at least annually (or some other specified frequency)"	Beyond scope of proposed changes. This document recommends that annual audits include a quality management system as well as a health and safety review, at a minimum. Per the Forward, these recommendations "are recognized to be minimum standards that may be modified to address unique jurisdictional requirements". This does not preclude more frequent/regular review.	Rejected
	IVA.3.3.4 Although desirable, will a supervisor always necessarily be qualified as an analyst? Particularly in a small organisation, they may have a broader remit, or in a larger organisation they may be technically qualified but not have completed all in house requirements. Sub paras a) and b) are very prescriptive	Beyond scope of proposed changes. Changed. "Supervisor" title updated to "Technical Leader" with the understanding that supervisors may manage a unit, staff, etc. and may not be technically competent. These requirements are intended for personnel making decisions on testing schemes, results, etc.	Accepted
	IVA.4.5 Proper safekeeping must include measures to maintain integrity and prevent cross-contamination .. include ref to IVA.5.2	Beyond scope of proposed changes. No change. Part IVA.4.2 requires the laboratory facility to prevent contamination.	Rejected
	IVA.6.1.6.1 last dot point .. if reference material is analysed at a previous date there must be documented evidence to demonstrate the validity of the comparison	Beyond scope of proposed changes. No change. Agreed. Part IVA.6.1.6.1 requires the same analytical conditions or comparable data, IVA.6.1.6 states a positive test result shall meet the acceptance criteria defined in the method validation and operating protocol and IVA.6.1.5, requires laboratories to monitor the analytical processes using appropriate blanks, controls and reference materials. Thus, changes invalidating the comparison shall be realized and the IVA.13 (Deficiencies of analysis) requirements should be met, if neccesary.	Noted
	IVA.7.1 and IVA.7.2 Routinely monitored performance of instruments and equipment needs to have at least some frequency guidance - routinely could be annually!!!! Needs to appropriate to the instrument/equipment and documented in a schedule	Changed. Incorporating risk-based thinking into determining the frequency of performance checks is in agreement with the proposed changes.	Accepted
8	IVA.9.2 Reports should also include any assumptions made or limitations on the results and opinions expressed and documented. Wher elements are not included in the treport the reportmay offer advice as to where or how that information can be accessed eg. "dates of analyses available on request"	No change. Part IVC.2.2.2 recommends testing limitations to be documented and potentially reported. It is up to the laboratory to determine relevance of a limitation and whether it shall be reported.	Rejected
	IVA.8.4 The efficacy of all reagents shall be checked prior to or concurrent with their use in casework. Results of these tests shall be documented. Proposed wording: IVA.8.4 The efficacy of all reagents shall be checked prior to and concurrent with their use in casework. Results of these tests shall be documented.	No change. Per the Forward, these Recommendations "are recognized to be minimum standards that may be modified to address unique jurisdictional requirements". This document recommends reagent checks be performed prior or concurrent with casework however, this does not preclude more frequent checks. For example, a laboratory may choose to check a color test reagent monthly rather than with each case based on the level of risk a laboratory is willing to assume.	Rejected

9	IVA.9.2 Report writing; Reports issued by laboratories shall be accurate, clear, objective, and meet the requirements of the jurisdictions served. These reports shall include the following information: * additions to, deviations or exclusions for the method Proposed wording: * additions to, deviations or exclusions from the method	Changed.	Accepted
10	I have reviewed the proposed changes and am in agreement with the revisions.	No changes.	Accepted
11	1) Section IVA.6.2.7.1 - Suggest to use 're-analysis' instead of 'analysis' Proposed change: The laboratory protocol for extending expiration dates shall be documented and should include re-analysis of the the material"	Beyond scope of proposed changes. Changed. Extension of expiration date criteria amended to a separate requirement. If the expiration date is based off manufacturer's specifications, then the extension assessment may be the first analysis. Otherwise, it would be a reanalysis.	Accepted
	2) Section IVA.8.6 - Suggest to include date of preparation or lot number Proposed change: Chemical and reagent containers shall be labeled as to their contents and date of preparation or lot number.	Beyond scope of proposed changes. No Change. May be considered for future revision.	Rejected
	3) Section IVA 13.1 - Suggest to include technical review in c) Proposed change: c) a requirement for administrative and technical review of the activity or work of the individual involved	Beyond scope of proposed changes. No Change. Per the Forward, these are minimum recommendations which does not preclude a laboratory from including additional review(s) in thier policy. Technical review may not be necessary for simpler administrative errors lending to analytical deficiencies.	Rejected
	4) Section IVA.14- Suggest to include risks and opportunities related to health and safety Proposed change: Laboratories shall have a documented health and safety program in place. Risks and opportunities related to health and safety shall be considered.	Changed. Incorporating risk-based thinking into programs and procedures is in agreement with the proposed changes.	Accepted
	5) Section IVA.15 - Suggest to add in the following topics into the list of additional documentation: - control of records (identification, storage, protection, back-up, archive, retention, retrieval and disposal of records) - risks and opportunities - corrective actions - customer feedback	1. The requirement for maintenance of documentation in IVA.15 implies a laboratory has a method in which to "control" such records. 2. While it is agreed that risk assessment shall be documented, simply stating "risks and opportunities" is too broad to be meaningful. Documentation of nonconformities, preventative measures, uncertainty, etc. are a means to documenting such assessments. 3. required as part of IVA.13.1 e). 4. Amended requirements to include customer feedback.	Accepted (partial)
12	I don't understand why the dates of lab activity are important in the report and I think it makes the report cluttered and harder to read. Reports should be clear and concise.	No Change. "[D]ate(s) of performance of laboratory activity" are required under ISO/IEC 17025:2017 7.8.2.1. Supplemental Document SD-5 (in revision) provides examples of a consolidated approach to satisfying this international reporting criteria.	Rejected

13	For the following: Section "IVA.9.2 Report writing" and the statement "a statement to the effect that the result relates only to the items tested or sampled." it appears, at least to me, to preclude making inferences to some larger proportion (even 100%) of a population from sample items tested. Could an alternate statement read, "in instances where inferences of identity, made from a tested sample to some larger proportion of a population, are not statistically based, a statement will be issued to the effect that test results apply only to the items tested or sampled."	Consistent with the language in ISO/IEC 17025:2017 7.8.2.1 (l). The bullet point does not preclude inferences but rather ensures the report is clear that only a sample was analyzed. Section IIIA.2.1.1.2 requires the plan to be either statistically based or have an appropriate statistical analysis completed and limits of the inference shall be documented if an inference about the whole population is to be drawn from a sample.	Rejected
	VA.6.1.6.1 "The reference material may be analyzed: • contemporaneously with test/case sample (e.g. same sequence/batch) • as part of routine quality control (e.g. daily check solutions) • at a previous date (e.g. method validation, internal reference collection)" --> If reference material is analyzed at a previous date, it should be required that there be an assessment of the instrument or parameters to ensure changes have not been made which may invalidate the comparison. For example, if retention time is to be compared to a standard run two weeks prior, it should be assessed whether maintenance has been performed that may invalidate the comparison including a change in GC/MS liner, tune, or column adjustment.	Beyond scope of proposed changes. No change. Agreed that changes which may invalidate comparisons should be documented. Per IVA.6.1.5, "laboratories shall monitor the analytical processes using appropriate blanks, controls and reference materials." Thus, changes affecting analysis should be realized and the IVA.13 - Deficiencies of analysis requirements should be met.	Rejected
	IVA.6.1.6.3 "When neither reference materials nor external reference data are available, structural elucidation techniques may be employed providing the analyst has the appropriate skills for their interpretation. Such interpretations shall be made only by analysts competent in structural elucidation interpretation." -->When the term competent is used, are you mandating documented competency of the analyst in a technique which can be used for structural elucidation? With new ANAB criteria, "competent" assumes a level of documentation and some defined criteria of obtaining such competency. If this is not the intention, perhaps a different term such as "experienced" would be best fit.	Beyond scope of proposed changes. No change. Identifications made by structural elucidation shall only be made by competent analysts. As such, the laboratory must have a means to evaluate and document competency.	Agreed
14	IVA.6.2.6.1.1 "For reference materials obtained from a provider not accredited under ISO 17034 the identity and purity information supplied by the provider shall be verified by analysis. When verification by analysis is not possible, this shall be documented and where applicable the limitation expressed within the report. Other information may be evaluated as needed." At this time, it is difficult to find ISO17034 vendors for all quantitative preparations. If the laboratory could also perform a risk assessment based on previous performance of standards, and that could be a sufficient avenue as well. It is recommended to add a risk component to this standard since ISO 17034 is now specifically referenced.	No change. The hierarchy and language of IVA.6.2.6.1 inherently incorporates risk assessment. Part IVA.6.2.6.1 discusses reference materials from an ISO 17034 accredited provider. 6.2.6.1.1 is embedded in 6.2.6.1 to emphasize ISO 17034 accreditation but requires verification of identification and purity when an ISO 17034 accredited vendor is not available. Lastly, documentation is required if analysis is not possible as this assumes the most risk when assessing the reliability of the information supplied with a reference material.	Rejected

15	IVA.6.1.6.1: Is there a documented benefit for running reference materials contemporaneously with the test/case sample compared to within a certain time frame? Our current policy for retention time comparison is within a five day window and that has seemed sufficient. We have gathered data that shows retention time does not significantly drift unless maintenance is performed, so in my opinion, that five day window could be extended, not reduced, without reducing the quality of data. We currently compare mass spectra to an in-house or peer reviewed library, or we can compare directly to the standard(s) run for retention time.	No change. A laboratory should select the frequency for analysis of reference materials based on method performance and risk.	Agreed
16	Section IVA.9.3, the sections that follow should be renumbered to IVA.9.3.1 and IVA.9.3.2	Beyond scope of proposed changes. Changed.	Accepted
17	In section IVA.9.2: One of the bullet points states that reports should have an unambiguous descriptive list of all submitted evidence. Having a detailed description requires that all evidence would need to be opened and viewed by the analyst. Not every piece of evidence submitted is opened and analyzed. Is this asking to refer to item numbers or is it expected that all submitted evidence is opened and described?	Clarified requirement for a description of relevant evidence and unambiguous identification of tested items.	Accepted