Response to Public Comment on the Placement of ASTM E3255-21 "Standard Practice for Quality Assurance of Forensic Science Service Providers Performing Forensic Chemical Analysis" on the Registry

The OSAC Seized Drugs Subcommittee is appreciative of the insightful public comments received on ASTM E3255-21. After evaluation of the comments per the "OSAC Comment Adjudication Steps and Instructions for Subcommittees", the subcommittee has determined that the comments do not rise to the level of a "needed or critical revision that should be completed prior to addition of the document to the Registry" and continues to support the placement of ASTM E3255-21 onto the OSAC Registry.

This determination does not mean the subcommittee would have declined to implement some of the comments had they been provided at an earlier stage in the Registry approval process. At this late stage, however, the subcommittee cannot simply make the suggested revisions, a frustrating aspect of the current process that is expected to be improved with the upcoming changes to the OSAC process. On balance, members believe it is more beneficial to the community to move the standard forward to the Registry rather than hold the document back at this stage.

In an effort to address some of the valuable comments, the subcommittee proposes the following:

- Upon discussion of the comments from one of the signatories to response 2, additional valuable input was received, specifically regarding including minimum frequencies for technical case file review as well as recommending the following additional quality assurance measures be considered:
  (1) Re-review of a random selection of technical case files,
  (2) Reanalysis of randomly sampled case samples, and
  (3) Blind quality control testing.

  ASTM standard E2327-15e1 Standard Practice for Quality Assurance of Laboratories Performing Seized-Drug Analysis is due for revision and may be incorporated into the seized-drugs annex of E3255. The suggested edits for frequency of technical case file review and additional quality assurance measures will be provided to the task group undertaking the revision of that standard for consideration. The commenters are invited to participate in the OSAC and SDO revision and balloting processes of this annex prior to final publication of the revised standard.

- As an interdisciplinary quality assurance standard, E3255 appropriately requires method validation and verification. Specific details on what method validation and verification testing includes is being addressed in other standards. An interdisciplinary standard on method validation and verification for forensic science service providers performing forensic chemical analyses has been developed within OSAC's Seized Drugs and Ignitable Liquids, Explosives, & Gunshot Residue subcommittees and is currently under review at ASTM. We believe this standard will provide the detailed guidance the commenters are requesting. The commenters' feedback would be greatly appreciated during the ballot process at ASTM for this standard (currently cited in Annex A1 as ASTM E2549; revisions documented under Work Item WK72631 at ASTM). Once this standard is published at the SDO, E3255 may be revised to include a reference to this standard.

- Similarly, two standards dedicated to testimony and reporting are currently under development within OSAC's Seized Drugs subcommittee. We are confident these standards will provide the detailed guidance the commenters are seeking for testimony monitoring and report content, in large part because a member of the LTG has been involved during all stages of the drafting

process, and the subcommittee has used the National Commission documents as guideposts for standard development. The commenters are invited to participate in the process for developing these standards within OSAC or the SDO prior to those standards being published. Once these standards are published at an SDO, E3255 may be revised to include a reference to these standards.

Specific public comments received have been transcribed below along with the subcommittee adjudication and response to each item.

Adjudication of Public Comments:

Response 1

For any method or technique there are two critical aspects of reliability – the scientific testing to establish the limits, repeatability, reproducibility and accuracy of the method or technique and the quality assurance program under which the method or technique is employed. The first addresses whether the results are based on "reliable principles and methods" and the second helps ensure that the method or technique has been "reliably applied". FRE 702. Thus, we view a standard for quality assurance as a critical pillar in ensuring that the results or opinions presented in criminal cases can be relied upon by all the parties when making liberty and life altering decisions. As a critical pillar a standard for quality assurance must be well defined and rigorous. Sadly, this is not the case for ASTM E3255 and thus we respectfully request that it not be added to the registry at this time.

Task Group Response: This overarching standard is a very important step in improving quality assurance in forensic chemical analysis. In many instances, the standard itself either addressed the point or referred the reader to another standard which addressed the topic in more detail. This comment is non-persuasive and the task group recommends that this standard be added to the OSAC registry.

As we have reviewed more ASTM documents we recognize that upon occasion the guidance we sought was contained in another ASTM standard. But access to all of the relevant standards is not simple and absent a specific reference to the additional standard within the text of the document many readers may miss that essential guidance. Thus, to the extent that any of our concerns are addressed elsewhere the standard should be revised with a specific reference to that standard.

Task Group Response: This standard references 10 international standards in section 2.1 and an additional 11 standards within the annexes. All concerns raised are either addressed directly in the standard itself, one of the referenced standards or further delineated within one of the referenced standards. No other references need to be added to this standard at this time. However, as future standards are developed that are significantly related to this standard, the task group will revise this standard accordingly. This comment is non-persuasive.

Next, we would note that as we review both the ASB and ASTM standards there is a noticeable pattern that is troubling. Despite calls from consensus committees of the National Research Council and independent scientists for more science in forensic science and despite the work of the National Commission on Forensic Science to bring together stakeholders, forensic practitioners and research scientists to produce consensus recommendations to the forensic science community at large, those recommendations have been consistently ignored. ASTM E3255 is no exception.

Task Group Response: There are many instances in which this standard does in fact incorporate other consensus committee recommendations. Take for example the use of NCFS defined terms and requirements for method validation/verification, report writing and review, etc. While the exact language was not incorporated in all instances, this standard does incorporate the overarching thoughts and expressions raised by many of these consensus committees. It is also true that other standards currently under development, especially expert testimony and report writing, rely heavily on guidance from the NCFS. The subcommittee hears and appreciates

the LTG feedback on this subject and is working to incorporate the guidance as appropriate. This comment is non-persuasive.

Specifically, section 9, "Method Validation and Verification" fails to require that validation and verification data and documentation be maintained and be available for review upon request as recommended by the NCFS in its Recommendation to the Attorney General Transparency of Quality Management System Documents. https://www.justice.gov/archives/ncfs/page/file/839706/download

Task Group Response: Section 9.6 specifically states that "Validation and verification data and documentation shall be maintained." The task group appreciates the need for transparency, and believes the maintenance of the information carries with it the logical implication that it is available upon request. This comment is non-persuasive.

Section 13 "Casework Documentation, Report Writing, and Review" in its entirety ignores the NCFS Recommendation to the Attorney General Documentation, Case Record, and Report Contents https://www.justice.gov/archives/ncfs/page/file/905536/download, without explanation and to its detriment.

Task Group Response: This standard addresses the vast majority of the NCFS recommendations as delineated in the table below. As such, this comment is non-persuasive. Specifically, the five NCFS requirements are addressed in this standard as follows:

NCFS Views Requirements	E3255 Standard Citation
1	13.1.1
2	13.1.2 & 13.1.3
3	13.3.1 & 13.3.2
4	13.3.1 & 13.3.2
5	In part, 13.3.1 & 13.3.2

Section 13.1.1 fails to require as recommended by the NCFS that "Records [] be created contemporaneous with the examination of evidence and the technical review that, along with the FSSPs' quality management system documents relating to the forensic work performed, would allow another analyst or scientist, with proper training and experience, to understand and evaluate all the work performed and independently analyze and interpret the data and draw conclusions." This language was developed by the NCFS to address both the needs within a crime lab for verification and technical review and for the stakeholders or customers within the criminal justice system including investigators, prosecutors, judges, victims and their families and defendants. Instead of adopting the NCFS language ASTM E3255 13.1.1 states "[m]aintain documentation that contains sufficient information and clarity to allow another properly trained forensic science practitioner the ability to evaluate the notes, interpret data, and verify whether the original result is accurate." This language limits the usefulness of this documentation to verification and foregoes documentation that allows for an independent practitioner to come to an independent conclusion. In addition, section 13.1.1 oddly seems to suggests that an assessment can only be conducted by someone meeting the definition of FSP rather than the equally qualified "properly trained scientist" identified in the NCFS language.

Task Group Response: For context, the approved NCFS recommendation is worded exactly as follows: "Records should be created during the examination of evidence and during the technical review that would allow another analyst or scientist with proper training and experience to understand and evaluate all the work performed and to independently analyze and interpret the data and draw conclusions." The task group did review the NCFS language prior to developing this standard. A few reasons that the NCFS language was not adopted verbatim is first, the NCFS recommendation is not written to be compulsory with use of the word "should." Secondly, through technology (e.g., information management systems), the scientific chemical testing processes, and existing requirements for recording dates of testing, records are created during the examination of evidence. As such, it is not necessary to further require when records are created. In this standard, the language was intentionally written in the imperative, making it a requirement. This standard was written with the NCFS language in mind, but

not all aspects were adopted by the task group or ASTM. Lastly, with regards to who can review the documentation, this is a forensic standard written specifically for FSSPs, see scope in section 1.1. Adding additional language to include other "properly trained scientists" would be out-of-scope. That said, as written, it would not preclude a "properly trained scientist" the ability to evaluate records. This comment is non-persuasive.

Correctly section 13.2.3 requires that "[f]orensic science service providers shall have a documented procedure for resolving instances where forensic science practitioners and reviewers disagree. The procedure shall include instruction to document the disagreement and corresponding resolution." However, requiring the procedure to "include instruction to document" is vague and potentially permissive; the language should be changed to read "The procedure shall require documentation of the disagreement…" Further, section 13.2.3 fails to include a critical requirement that the documentation be maintained and disclosed with the results as called for by the NCFS. Disagreements could be Brady evidence, are likely evidence covered by ABA Model Rule 3.8 and are critical information in any scientific endeavor and thus any final report should disclose such disagreements.

Task Group Response: All comments are addressed through reading sections 13.2.3, 13.2.4 and reference to section 16. Specifically, documentation is required in 16.1.1. However, the task group will consider revising this language in future revisions to this standard. This comment is non-persuasive.

Section 13.3 "Report Writing" also fails to follow the NCFS's recommendations. Instead it just refers to Practice E620 *1 and ISO/IEC 17025 without addressing any shortcomings in either document. For example, Practice E620 permits critical information to be placed in the case file and not in a final report. And we, and the NCFS, recognized that not all information needed for an independent assessment could be placed in a report. But ASTM E3255 fails to require as the NCFS recommended that reports state that "the report does not contain all of the documentation associated with the work performed. In order to understand and evaluate all the work performed, and independently analyze and interpret the data and draw conclusions, a review of the case record is required."

Task Group Response: E620 does incorporate specific language about referring the reader of the report to other facts and data when rendering an opinion. For example, E620 section 4.7.13.2 states that a report shall "Identify other facts and data relied upon in rendering an opinion." In addition, reports are required to contain additional information (e.g., sampling, methodology, uncertainty, etc.), which automatically triggers the reader of the report that other information is available. This part of the NCFS recommendation was not supported by the task group for these reasons. This comment is non-persuasive.

Section 13.3.2 instructs that "reports issued by the forensic science service provider shall be accurate, clear, objective, and meet the requirements of the jurisdictions served." Once again the proposed standard ignored the language developed by the NCFS. The language here is vague, conclusory and not particularly instructive to the practitioner and not grounded in science or the scientific method. By contrast the NCFS recommended that "[r]eports should clearly state: the purpose of the examination or testing; the method and materials used; a description or summary of the data or results; any conclusions derived from those data or results; any discordant results or conclusions; the estimated uncertainty and variability; and possible sources of error and limitations in the method, data, and conclusions." This provides substantially more guidance to the practitioner and mirrors the requirements of scientific research.

Task Group Response: All of what is stated in this comment is captured within 13.3.1. Specifically, 13.3.1 indicates that reports shall include relevant elements described in E620 and ISO/IEC 17025. These international standards require that everything listed in the comment and more be provided in reports. It would be duplicative to restate all of the requirements directly in this standard when other standards cover the topic in much more detail. As such, this comment is non-persuasive.

Correctly section 16.1.1 requires that "[w]hen nonconforming work is encountered or discovered, the cause and the impact on past work shall be determined. Corrective measures shall be documented to minimize the likelihood of recurrence." But the standard should also require that "nonconforming work" be reported to the parties in

interest (the prosecuting authority, the court and any potentially impacted defendants). See NCFS Recommendation to the Attorney General National Code of Professional Responsibility for Forensic Science and Forensic Medicine Service Providers ("16. Appropriately inform affected recipients (either directly or through proper management channels) of all nonconformities or breaches of law or professional standards that adversely affect a previously issued report or testimony and make reasonable efforts to inform all relevant stakeholders, including affected professional and legal parties, victim(s) and defendant(s).") https://www.justice.gov/archives/ncfs/page/file/839711/download

Task Group Response: 16.1 includes language that says "Nonconforming work shall satisfy the requirements of ISO/IEC 17025." ISO/IEC 17025 covers this concept in much greater detail, see section 7.10.1.e, "where necessary, the customer is notified…" As ISO/IEC 17025 already covers this concept, it would be duplicative to restate the same requirement in this standard. This comment is non-persuasive.

The next category of problems we see in this proposed standard is a failure to provide minimum requirements despite its claim to do so in section 4.1. For example:

Task Group Response: This standard was written to specifically set minimum requirements. The task group will make future revisions to this standard as new requirements and suggestions are considered. This comment is non-persuasive.

Section 10.1.2. allows a lab deviate from the "recommended" use of "published or standardized methods" without any guidance about when or under what circumstances. Nor does it require that if a lab chooses not to use published or standardized methods, that it document that fact, explain why the deviation occurred and disclose the deviation to the end users of the report, including the defense. Allowing flexibility is not unreasonable but flexibility should not be untethered from any standards and must be accompanied with documentation of the circumstances and justification.

Task Group Response: This particular language was revised several times during the development and ASTM balloting process. As originally written, the language was too restrictive. There are many methods that are developed by FSSPs that have not been published/standardized, but that does not make them any less useful/worthy provided validation of the method is conducted. Laboratories are required to follow method validation/verification procedures prior to use, see section 9. This language was purposely chosen to encourage the use of published/standardized methods, but also allow the use of laboratory specific validated methods. The ASTM standard E2549 is currently under revision to become an interdisciplinary method validation/verification standard. The commenter is invited to participate in the SDO revision and balloting process of that standard, which goes into much more detail on the method validation and verification requirements. As such, this comment is non-persuasive.

Section 10.1.2.1 correctly requires that "[t]he forensic science service provider shall verify published or standardized methods by inhouse performance testing." But this section fails the harder but as important task of establish minimum standards for in-house performance testing begging the question what are the parameters/requirements for in-house performance testing?

Task Group Response: The requirement as written is self-explanatory. Specifically, see E1732 for the definition of verification and what it entails. Additionally, ASTM standard E2549 is currently under revision to become an interdisciplinary method validation/verification standard. The commenter is invited to participate in the SDO revision and balloting process of that standard, which goes into much more detail on the method validation and verification requirements. It is beyond the scope of this standard to further specify how a laboratory conducts a verification test. That said, the task group will consider adding language in future revisions of this standard as appropriate. As such, this comment is non-persuasive.

Section 10.1.2.2 suffers from the same problem as 10.1.2.1. it correctly states that "[t]he use of laboratory-developed or modified methods shall be validated and approved by the technical leader or other designated

individual according to forensic science service provider policy." But once again sets no minimum standard for validation. Requiring that a method be validated is meaningless in the absence of any standard for validation.

Task Group Response: The requirement as written is self-explanatory,. Specifically, see E1732 for the definition of validation and what it entails. Additionally, ASTM standard E2549 is currently under revision to become an interdisciplinary method validation/verification standard. The commenter is invited to participate in the SDO revision and balloting process of that standard, which goes into much more detail on the method validation and verification requirements. It is beyond the scope of this standard to further specify how a laboratory conducts a validation. In addition, each forensic chemical analysis discipline has their own specific validation procedures. For example, see Annex A1.1.1 for an additional reference for validation of seized-drug analytical methods. This comment is non-persuasive.

ASTM E3255 also fails to incorporate three essential quality assurance measures – testimony reviews, blind verification and doubleblind proficiency testing.

Task Group Response: This standard does incorporate blind verification and blind proficiency testing concepts. The standard does not include language specifically for testimony monitoring, however the task group will consider adding language in future revisions to this standard and reference additional relevant standards as they are published. This comment is non-persuasive.

Section 1.1 does not make any reference to testimony reviews. Section 15.1 does state that [i]nternal audits of the forensic science service provider's operations shall be conducted at least once a year", but provides no guidance on the scope or nature of these audits. Audits should include testimony and reporting reviews and that should be made explicit and the minimum requirements for such a review should be stated.*2

Task Group Response: Testimony monitoring was considered out-of-scope for this standard; an entire standard related to testimony which includes testimony monitoring is in progress within OSAC Seized Drugs Subcommittee. However, the task group will consider adding language in future revisions to address testimony monitoring. In reference to 15.1, the language does require that record keeping satisfy the requirements of ISO/IEC 17025, which provides substantial detail of what needs to be audited each year. In reference to reporting reviews, this standard does include language in section 13.2.1 to have FSSPs have a documented policy for reviewing and authorizing reported results. The task group will consider adding language in future revisions of this standard to address testimony and reporting reviews as appropriate and reference additional relevant standards as they are published. This comment is non-persuasive.

Section 13.2.2 calls for blind review "when achievable". It is hard to imagine when this is not "achievable" which begs the question why blind review is not required. But for those rare circumstances when it is not achievable this standard should require that the absence of a blind review be documented, explained and disclosed to the parties.

Task Group Response: As this standard is written to apply to all forensic chemistry disciplines, it is not possible/practicable to implement blind review in all cases given the current resources of forensic laboratories in the United States, as well as the nature of the science and the data and notes generated. Take for example drug analysis, when a practitioner conducts their analysis, they generate notes and data with the results listed next to each particular test (e.g., GC-MS indicates cocaine). In order to make that a blind-review, the results of every test would have to be redacted, which would be extremely arduous. In comparison, a fingerprint examiner records/notes characteristics, not results, this would be much more conducive to blind-review. Ultimately, this language was specifically crafted with help from a Human Factors representative to encourage, but not require blind reviews. As such, this comment is non-persuasive.

Likewise, in section 14 "Competency and Proficiency Testing" should require double blind proficiency testing programs or require an explanation why such a program cannot be established. We appreciate the current difficulties in establishing a double-blind program, though we note the Houston example to demonstrate that it can be done, but blinding participants to the fact that they are being tested is a long-established best practice in

science. The failure to apply it to forensic science is part of the forensic culture that needs to be reformed and brought in line with science. And if there is a demand for such testing it is likely that private enterprise will adjust to meet that demand.

Task Group Response: This topic was discussed at length during the development and several balloting steps at ASTM. Ultimately, it was decided to encourage but not require the use of blind proficiency testing for several of the reasons stated in the comment above. The task group appreciates the highlighting of the Houston lab as an example to emulate with respect to blind quality control, but please understand the majority of laboratories do not have the resources the Houston lab currently has, *especially* the human resources in its current quality division. Also, please note section 14.3.1.2 addresses this point directly. The task group will consider changes in future revisions of this standard. In the interim, this comment is non-persuasive.

There are two additional issues with section 14; the first is that testing that covers the entire range of case work is not mandatory. In 14.2.2 and in 14.3.2 "should" must be replaced with "shall". Testing that does not encompass the more difficult cases to be encountered provides no quality assurance with respect to those cases. Second, section 14 needs language requiring FSSPs to maintain documentation of any errors or other discrepancies caught by reviewers (e.g. administrative or technical) before submission to the proficiency test provider for scoring, and make that a part of the proficiency test file, to be disclosed along with proficiency test records upon request.

Task Group Response: This topic was discussed at length during the development and several balloting steps at ASTM. In fact, the proposed language included in the comment "entire range" was balloted at ASTM and did not pass, many negatives were received and found persuasive. Additionally, making this a "shall" would make it too restrictive or near impossible to meet. As such, the language was revised accordingly to encourage the FSSP's range of casework. With reference to maintaining documentation, those requirements are found in Section 14.1. Additionally, Section 13 applies to requirements associated with what is maintained in the documentation. This comment is non-persuasive.

Finally, OSAC should press for greater transparency for forensic results and opinions in its standards. While forensic results are used in adversarial proceedings, transparency is a hallmark of science and scientific results or opinions should be neutral and equally available to all the parties. Thus, for example, section 13.1.3 which correctly calls for the maintenance of communication logs should require both that documentation should be maintained and provided to the parties upon request. Similarly, in 13.1.4.1 any deviations should be both documented and reported in any final report. And in section 13.1.5 and section 17.1 documentation should not only be maintained but should be provided to the parties upon request.

Task Group Response: Each of the requirements listed in the comment require that documentation be maintained. The fact that documentation is maintained, it is automatically available upon request. As such, this comment is non-persuasive.

We encourage OSAC to make clear in its review of standards being considered for the registry that NCFS recommendations be incorporated into all standard development, that best practices be made mandatory except under identified and documented circumstances and that transparency be encouraged. Thank you in advance for considering the above comments.

Task Group Response: This standard meets the request being made, it incorporates best practices with mandatory requirements including documentation and record keeping. It also includes requirements for what information is required in reports to be transparent. This comment is non-persuasive.

*1 We have heard on occasion that the answer is then to revise E620. This appears to allow standard after standard to dodge the issue while nothing is done and there is no guarantee that E620 will ever be properly revised. Further few proposed standards just cite E620 and say nothing further. Most seem to add something to what is required (for example see section 13.3.2) and thus there seems to be no principled reason why the changes that the NCFS recommended are not being made.

Task Group Response: The rationale for revising E620 is sound and nothing is being dodged. By referring to E620, this actually helps prevent standards from contradicting each other. Reasons for not including the exact language offered by NCFS is provided above in the various task group responses. This comment is non-persuasive.

*2 This is an example of a section where, if another ASTM standard addresses testimony monitoring and audits in detail, or such standard is currently under development, the standard(s) should be referenced.

Task Group Response: The task group is aware of a standard in development regarding testimony monitoring, specifically within the seized drugs subcommittee, however reference cannot be made to a draft standard. The task group will consider adding language in future revisions to address testimony monitoring and reference additional relevant standards as they are published. This comment is non-persuasive.

Response 2

1. Scope
1.1 This practice discusses procedures for quality assurance of forensic science service providers performing forensic chemical analysis. This practice provides a framework of quality in the processing of evidence, including: maintaining a quality management system; personnel duties, qualifications, training, and education; facility considerations; evidence handling; analytical procedures; instrument and equipment performance; chemicals and reagents; casework documentation and reporting; proficiency and competency testing; method validation and verification; audits; deficiency of analysis; and documentation requirements. Annex A1 – Annex A3 provides additional procedures that are discipline-specific.

COMMENT:
The standard seems to omit quality assurance through testimony monitoring and review of reports. Quality managers should establish that testimony and lab reports are scientifically acceptable, perhaps by periodic random sampling and review. Section 15.1 does state that "[i]internal audits of the forensic science service provider's operations shall be conducted at least once a year, but it gives no indication of the scope or nature of these audits. If the audits pertain to testimony and reporting, that should be made explicit and the minimum requirements for auditing should be stated. [If a separate standard addresses testimony monitoring in detail, such as the standard currently under development by the seized drugs subcommittee, the standard(s) should be referenced here.]

Task Group Response: Testimony monitoring was considered out-of-scope for this standard. However, the task group will consider adding language in future revisions to address testimony monitoring and reference additional relevant standards as they are published. There is a standard in development regarding testimony monitoring within the seized drugs subcommittee, however reference cannot be made to a draft standard. In reference to 15.1, the language does require that record keeping satisfy the requirements of ISO/IEC 17025, which provides substantial detail of what needs to be audited each year. In reference to reporting reviews, this standard does include language in section 13.2.1 to have FSSPs have a documented policy for reviewing and authorizing reported results. The task group will consider adding language in future revisions to address reporting reviews as appropriate. This comment is non-persuasive.

1.2 This practice cannot replace knowledge, skills, or abilities acquired through appropriate education, training, and experience (see Practice E2917), and is to be used in conjunction with professional judgment by individuals with such discipline-specific knowledge, skills, and abilities.

COMMENT:
This use of boilerplate language is not instructive to practitioners.

Task Group Response: At this time, this language is a requirement of the E30 committee at ASTM. E30 has recently adopted revised language and it will be incorporated in the next revisions of this standard. This comment is non-persuasive.

3.2.11 standardized method, n—a method published by a recognized international, regional, or national standard development organization (for example, ASTM, ASB, AOAC, etc.).

COMMENT:
The fact that a "method" is published by a "recognized" SDO means that it is published as a "standard," not that the "standard" prescribes a standardized method. The ASTM style manual (March 2008) defines "test method" as "a definitive procedure that produces a test result" and gives an example of "identification." The ASB style manual (March 2018) does not define "method" and uses the word only once, as a synonym for "technique." It is not apparent that every standard or best practice recommendation for a technique lays out a detailed set of steps for analysts to follow when making an "identification" or producing another result. Standards that lack sufficient specificity should not be regarded as "standardized."

Task Group Response: The use of the term "*standardized method*" was defined specifically for interpreting requirements set forth later in this standard. The task group will consider if a revision is necessary in future revisions to this standard. This comment is non-persuasive.

6. Personnel

COMMENTS:
•Many of the subsections here lack appropriate specificity and substance and are also inconsistent with each other. Examples are listed below.
•Additionally, all of the positions listed should be required to conform to the requirements of E2917.
•Specific comments about the subsections:

Task Group Response: Specificity is provided within the standard and any perceived inconsistencies are further delineated within the language or the requirement to conform to E2917. The suggestion that all positions listed should be required to conform to E2917 would not be appropriate because E2917 is written specifically for Forensic Science Practitioners. This comment is non-persuasive.

◦6.4, 6.5. Many "key personnel" positions listed include that such personnel must have certain education, skills, and training. However, the director and quality assurance manager subsections do not state that those holding these positions must have "education, skills, and abilities commensurate with their responsibilities." This language, as well as what such "education, skills, and abilities" would constitute, should be added.

Task Group Response: There is a requirement for all positions to have defined responsibilities, duties, educational requirements and required skills, see section 6.1. The task group specifically did not further define any additional requirements for these positions intentionally. That said, the task group will consider if a revision is necessary in future revisions to this standard. This comment is non-persuasive.

◦6.6.1, 6.7.1. What are the "education, skills, and abilities commensurate with" the responsibilities of technical support personnel and technicians? Baseline parameters should be set out technicians? Baseline parameters should be set out.
◦6.6.2. What "on-the-job" training is necessary for technical support personnel? Baseline parameters should be established.
◦6.8.1. What type and quantity of lab classes are required or appropriate? Baseline parameters should be set out.

Task Group Response: Technical support personnel perform a wide variety of tasks within a laboratory (e.g., evidence handling, glassware washing, making solutions, etc.). As the various tasks are vast, and with each requiring a different level of knowledge, skills and abilities, it was decided to leave this decision to each FSSP. For

example, someone who washes glassware will not need the same baseline parameters or on-the-job training as someone who makes chemical solutions. In reference to 6.8.1, this section refers specifically to a Forensic Science Practitioner. The type and quantity of lab classes are defined in E2917 which is required in 6.8.3. This comment is non-persuasive.

6.7 Technician –
COMMENT:
Why would this be a defined position? Are there staff who analyze evidence but do not issue reports? Why would such individuals then require training on providing testimony? Whatever the explanation, this position should not be exempt from all the training required by E2917.

Task Group Response: FSSPs commonly employ technicians to perform a number of tasks. There is no specific degree requirement for a technician, as they only perform basic duties, they do not render interpretations, issue reports or provide opinions through reports or testimony. However, technicians that have access to evidence can perform basic tasks such as running instrumental tests (e.g., GC-MS) under the direction of the FSP. By nature of their job, they do not have the training and education, but they can be part of the chain-of-custody of the evidence. As such, they are subject to being called to testify, hence the reason to require testimony training. E2917 is specifically written for FSPs, it would be inappropriate to hold technicians to this level of training, continuing education and professional development. This comment is non-persuasive.

7. Physical plant
COMMENTS:
•Many terms here are not defined or requirements are otherwise lacking specificity.

◦7.1.3. What constitutes "[s]uitable space?" This should be defined.
◦7.14. What constitutes adequate "[e]nvironmental and procedural controls to prevent incidental contamination?" This should be defined.
◦7.1.5 serves as a helpful juxtaposition. Unlike 7.1.3 and 7.1.4 which do not explain "[s]uitable space" or "[e]nvironmental and procedural controls," 7.1.5 provides helpful examples of devices and equipment that can protect from chemical hazards.

Task Group Response: Perhaps the commenters did not realize that there was a citation specifically for section 7 provided at the bottom of the page, referenced below:

[5]*Forensic Science Laboratories: Handbook for Facility Planning, Design, Construction, and Relocation*, June 2013, available from https://tsapps.nist.gov/ publication/get_pdf.cfm?pub_id=913987.

This reference goes into significant detail as to required space, environmental and procedural controls, etc. This standard was not intended to be all-inclusive, especially when so much work was already provided in the referenced citation. This comment is non-persuasive.

9. Method Validation and Verification

COMMENTS:
•9. Method Validation and Verification – 9.6 should be drafted as follows: "Validation and verification data and documentation shall be maintained and be available for review upon request." See NCFS, Recommendation to the Attorney General Transparency of Quality Management System Documents (recommending that "Summaries of internal validation studies, including at a minimum (i) the scope of the study, (ii) summaries of major events/experiments performed, results, major conclusions and methods implemented or approved by the forensic provider" be made readily available to the public)
https://www.justice.gov/archives/ncfs/page/file/839706/download

Task Group Response: Section 9.6 specifically states that "Validation and verification data and documentation shall be maintained." The fact that documentation is maintained, it automatically makes it available upon request. As such, this comment is non-persuasive.

10.1.1.5 When applicable, forensic science service providers should employ a statistically based protocol when an inference is to be made regarding a specified proportion of a submission for qualitative or quantitative determinations.

Comment:
The sampling requirement is obscure. What is "a statistically based protocol"? Some form of random sampling of the "submission"? When would probability sampling not be "applicable"?

Task Group Response: When making an inference regarding a specified proportion of a submission, the FSSP must use some form of statistically based protocol (e.g., frequentist or Bayesian). There are many statistical models that can be employed, hence why this standard does not mandate one specific method. It is intended that each FSSP performing forensic chemical analysis develop their own probability reporting criteria, for example see Annex A1.1.1. Probability would not be applicable for instance if the submission is heterogeneous or can be made so, or if the customer does not require an inference of the proportion (e.g., 1 tablet out of 100 tested and found to contain XX). Additionally, 10.1.1.5 meets the scope as originally intended for this standard, being more specific was not intended. That said, the task group will consider if a revision is necessary in future revisions to this standard. This comment is non-persuasive.

10.1.2. COMMENTS: First, under what circumstances may a lab deviate from use of published or standardized methods? Second, when a lab does not use published or standardized methods, it must document that fact as well as explain why the deviation occurred. Third, failure to use published or standardized methods must be disclosed to the end users of the report, including the defense. The intent may have been to allow labs reasonable flexibility, but, as written, it risks allowing labs to deviate from standards that should be followed, with no explanation or justification. The standard should instead note: (1) the circumstances and 2) an explanation for choosing an alternative analytical procedure.

Task Group Response: This particular language was revised several times during the development and ASTM balloting process. As originally written, the language was too restrictive. There are many methods that are developed by FSSPs that have not been published/standardized, but that does not make them any less useful/worthy. Laboratories still have to follow required method validation/verification procedures prior to use, see section 9. This language was purposely chosen to encourage the use of published/standardized methods, but also allow the use of laboratory specific methods. Additionally, ASTM standard E2549 is currently under revision to become an interdisciplinary method validation/verification standard. The commenter is invited to participate in the SDO revision and balloting process of that standard, which goes into much more detail on the method validation and verification requirements. As such, this comment is non-persuasive.

10.1.2.1 The forensic science service provider shall verify published or standardized methods by in-house performance testing.

COMMENT:
What does verification consist of? Section 4.1 states that this standard provides minimum requirements. What is the minimum inhouse performance testing that is required under this standard? What are the parameters/requirements for in-house performance testing?

Task Group Response: The requirement as written is self-explanatory, especially for the target audience for this standard. Specifically, see E1732 for the definition of verification and what it entails. It is beyond the scope of this standard to further specify how a laboratory conducts a verification test. That said, the task group will consider adding language in future revisions of this standard as appropriate. Additionally, ASTM standard E2549 is currently under revision to become an interdisciplinary method validation/verification standard. The commenter is invited

to participate in the SDO revision and balloting process of that standard, which goes into much more detail on the method validation and verification requirements. As such, this comment is non-persuasive.

10.1.2.2 The use of laboratory-developed or modified methods shall be validated and approved by the technical leader or other designated individual according to forensic science service provider policy.

COMMENT:
Section 4.1 states that this standard provides minimum requirements. What is required in the way of a policy for validation? Stating that there must be a laboratory policy for validation offers no standardization or guidance.

Task Group Response: The requirement as written is self-explanatory, especially for the target audience for this standard. Specifically, see E1732 for the definition of validation and what it entails. It is beyond the scope of this standard to further specify how a laboratory conducts a validation. In addition, each forensic chemical analysis discipline has their own specific validation procedures. For example, see Annex A1.1.1 for an additional reference for validation of seized-drug analytical methods. Additionally, ASTM standard E2549 is currently under revision to become an interdisciplinary method validation/verification standard. The commenter is invited to participate in the SDO revision and balloting process of that standard, which goes into much more detail on the method validation and verification requirements. This comment is non-persuasive.

10.1.6.2 Comparison of instrumental test/case sample data to external reference data when a reference material is unavailable. External reference data shall be assessed and demonstrated to be fit for purpose. Factors include:
(1) Origin of the data;
(2) Validation of the data;
(3) Peer review of the data; and
(4) Comparability of analytical conditions.

COMMENT:
Normally, one validates methods for generating data or making inferences from data. What is validation data and peer review of data? The use of the terms “peer review” and “validation” here is not ideal, but the underlying idea is good.

Task Group Response: Please note that the primary way to demonstrate reliability of the test results is to compare to a reference material as delineated in 10.1.6.1. 10.1.6.2 is specific to when a reference material is not available. If an FSSP chooses to use an external source for comparison purposes, they have to assess the veracity of information they are using. Essentially, this section says the FSSP has to verify that the data is genuine by reviewing any available validation documentation (e.g., structural elucidation, comparison to other certified reference materials, etc.) and whether it was peer reviewed (e.g., published in scientific literature). That said, the task group will consider if a revision is necessary in future revisions to this standard. This comment is non-persuasive.

10.6.2. COMMENT: How are the listed factors satisfied/how is assessment by satisfaction of these factors conducted? The draft is silent on this and does not explain in any meaningful way how external reference data is supposed to be established as fit for purpose.

Task Group Response: The vast majority of the time, FSSPs follow the requirements found in 10.1.6.1. Further delineating requirements for using reference data is beyond the scope of this standard. However, the task group will consider if a revision is necessary in future revisions to this standard. This comment is non-persuasive.

10.2.2.4. COMMENT: Should be modified to require certified reference materials when available.

Task Group Response: This language was revised several times at OSAC and ASTM, the result is what was published. It is important to note that a CRM is not required for all purposes. For example, a CRM would be required for performing quantitative analysis, but may not be required for performing qualitative analysis. CRMs

are costly and it would not be appropriate to require in all instances. The language as published does prefer the use of CRMs. The task group will consider if a revision is necessary in future revisions to this standard. This comment is non-persuasive.

11.2 Instrument Performance—Instruments shall be routinely optimized and monitored to ensure that proper performance is maintained.

COMMENT:
Section 4.1 states that this standard provides minimum requirements. What are the minimum requirements to achieve this outcome?

Task Group Response: The requirements for proper performance are published by the specific instrument manufacturer. Each instrument manufacturer requires various levels of maintenance. It is beyond the scope of this standard to provide specific requirements for the vast number of instruments used in forensic chemical analysis. This comment is non-persuasive.

11.2.1 Acceptance criteria for monitoring instrument performance shall be defined and documented.

COMMENT:
What is the minimum required when monitoring instrument performance? The subsections only refer to "the use of reference materials, test mixtures and blanks when applicable" and documenting and retaining " instrument performance monitoring."

Task Group Response: The requirements for monitoring instrument performance are dependent on the instrument and method being used. It is beyond the scope of this standard to provide specific requirements for the vast number of instruments used in forensic chemical analysis. As written, this section does set the minimum requirements. This comment is non-persuasive.

13. Casework Documentation, Report Writing, and Review
13.1 Casework Documentation:
13.1.1 Maintain documentation that contains sufficient information and clarity to allow another properly trained forensic science practitioner the ability to evaluate the notes, interpret data, and verify whether the original result is accurate.

COMMENTS:
Section 13.1.1 limits the usefulness of this documentation to verification and foregoes independent judgment. It should be replaced with the language developed by the NCFS that focused on the ability for a full and fully independent assessment by another properly trained scientist (not necessarily meeting the definition of FSP). Replace with: "Records should be created contemporaneous with the examination of evidence and the technical review that, along with the FSSPs' quality management system documents relating to the forensic work performed, would allow another analyst or scientist, with proper training and experience, to understand and evaluate all the work performed and independently analyze and interpret the data and draw conclusions."

Particularly with respect to documentation these standards need to address the needs of the criminal justice system and not just internal reviews.

•Documentation must be sufficient to allow an external, independent practitioner to come to an independent conclusion, not just verify
results. Review the NCFS language for possible adoption.

Task Group Response: This standard as written addresses the vast majority of the NCFS recommendations as delineated in the table below. Specifically, the five NCFS requirements are addressed in this standard as follows:

NCFS Views Requirements	E3255 Standard Citation
1	13.1.1
2	13.1.2 & 13.1.3
3	13.3.1 & 13.3.2
4	13.3.1 & 13.3.2
5	In part, 13.3.1 & 13.3.2

For context, the approved NCFS recommendation as written is not compulsory ("Records should be …"). The task group reviewed the NCFS language prior to developing this standard. A few reasons that the NCFS language was not adopted verbatim is first, the NCFS recommendation is not written to be compulsory with use of the word "should." Secondly, through technology (e.g., information management systems), the scientific chemical testing processes, and existing requirements for recording dates of testing, records are created during the examination of evidence, hence making it not necessary to further require when records are created. In this standard, the language was intentionally written in the imperative, making it a requirement. Not all aspects of the NCFS recommendation were adopted by the task group or ASTM. Lastly, with regards to who can review the documentation, this is a forensic standard written specifically for FSSPs, see scope in section 1.1. Adding additional language to include other "properly trained scientists" would be out-of-scope. That said, as written, it would not preclude a "properly trained scientist" the ability to evaluate records. This comment is non-persuasive.

13.1.2 Evidence handling documentation shall establish chain-of-custody.
13.1.3 Case related communications shall be maintained.

COMMENT:
Such documentation should be maintained and provided to the parties upon request.

Task Group Response: Section 13.1.3 specifically states that "Case related communications shall be maintained." The fact that documentation is maintained, it makes it automatically available upon request. As such, this comment is non-persuasive.

13.1.4 Analytical documentation shall include observations, methodology, blanks, controls, test results, and supporting documentation. Examples of supporting documentation are instrumental data, sequence files or run logs, charts, graphs, and spectra generated during analysis.

COMMENT:
Such deviations must be documented but also must be disclosed to the parties.
13.1.4.1 Any deviations from required analytical procedures shall be documented (see 10.1.1).

Task Group Response: Section 13.1.4.1 requires documentation. Disclosure is covered in section 13.3.1 which requires that reports include relevant elements described in E620 and ISO/IEC 17025. Specifically, refer to E620 section 4.7.14.1 which states that where necessary for the interpretation of the results, the report shall include "Statement(s) on deviations, additions, or exclusions from the test method, and information on the specific test conditions." This comment is non-persuasive.

COMMENT:
The following phrase should be added to this sentence: "and explained."

Task Group Response: Documentation and disclosure is already required in Sections 13.1.4.1 and 13.3.1. As such, an "explanation" is available upon request. In addition, the "and explained" language was balloted at ASTM and did not pass. This comment is non-persuasive.

13.1.5 Casework documentation shall be retained according to the forensic science service provider's policy or jurisdictional regulations or laws.

COMMENT:
Such documentation should also be provided to the parties upon request.

Task Group Response: Section 13.1.5 specifically states that "Casework documentation shall be retained…" The fact that documentation is maintained, it makes it automatically available upon request. As such, this comment is non-persuasive.

13.2 Case Review:
13.2.1 Forensic science service providers shall have a documented policy for reviewing and authorizing reported results.
13.2.2 When achievable, reviewers should not be privy to analysts' results when conducting reviews.

COMMENTS:
Blind review should be required. If not required then the standard should make clear that blind review is a best practice and should be conducted by an FSP if such a review is achievable." Additionally, when blind review is not conducted, this should be documented, explained and disclosed to the parties.

Task Group Response: As this standard is written to apply to all forensic chemistry disciplines, it is not possible/practicable to implement blind review in all cases, especially due to the nature of the science and the data and notes generated. Take for example drug analysis, when a practitioner conducts their analysis, they generate notes and data with the result listed next to each particular test (e.g., GC-MS indicates cocaine). In order to make that a blind-review, the results of every test would have to be redacted, which would be extremely arduous and unnecessary. In comparison, a fingerprint examiner records/notes characteristics, not results, this would be much more conducive to blind-review. Ultimately, this language was specifically crafted with help from a Human Factors representative to encourage, but not require blind reviews. As such, this comment is non-persuasive.

13.2.3 Forensic science service providers shall have a documented procedure for resolving instances where forensic science practitioners and reviewers disagree. The procedure shall include instruction to document the disagreement and corresponding resolution.

COMMENT:
Add the following sentence to this section: "This documentation shall be maintained and disclosed with the results." This is consistent with the NCFS Recommendation to the Attorney General Documentation, Case Record, and Report Contents. https://www.justice.gov/archives/ncfs/page/file/905536/download. Alternatively, section 13.3.1 should be amended as suggested below.

Task Group Response: This particular comment was received during the balloting steps at ASTM. A ballot was initiated to consider this revised language in the standard, however, it was not adopted by the ASTM membership. Documentation is available upon request and will be disclosed accordingly based on the particular jurisdiction. This comment is non-persuasive.

13.2.4 Identified deficiencies shall be resolved in accordance with Section 16.
13.3 Report Writing:
13.3.1 Reports shall include relevant elements described in Practice E620 and ISO/IEC 17025.

COMMENT:
Because Practice E620 permits putting so much critical information into the case file and not in the report, this standard should specify the following in addition to compliance with E620 and ISO 17025: "Reports should clearly state: the purpose of the examination or testing; the method and materials used; a description or summary of the data or results; any conclusions derived from those data or results; any discordant results or conclusions; the estimated uncertainty and variability; and possible sources of error and limitations in the method, data, and conclusions."

Task Group Response: All of the elements stated in this comment are captured within 13.3.1. Specifically, 13.3.1 indicates that reports shall include relevant elements described in E620 and ISO/IEC 17025. These international standards require everything listed in the comment and more be provided in reports. It would be duplicative to restate all of the requirements directly in this standard when other standards cover the topic in much more specific detail. As such, this comment is non-persuasive.

Because not all material required for an independent evaluation is in a report the report should also state that "the report does not contain all of the documentation associated with the work performed. In order to understand and evaluate all the work performed, and independently analyze and interpret the data and draw conclusions, a review of the case record is required."

Task Group Response: E620 does incorporate specific language about referring the reader of the report to other facts and data when rendering an opinion. For example, E620 section 4.7.13.2 states that a report shall "Identify other facts and data relied upon in rendering an opinion." Additionally, reports are required to contain additional information (e.g., sampling, methodology, uncertainty, etc.), which automatically triggers the reader of the report that other information is available. This part of the NCFS recommendation was not supported by the task group. This comment is non-persuasive.

Finally the standard should require that "[t]he case record should be organized and made available." This is consistent with the NCFS Recommendation to the Attorney General Documentation, Case Record, and Report Contents. https://www.justice.gov/archives/ncfs/page/file/905536/download

Task Group Response: Section 13.1.5 specifically states that "Casework documentation shall be retained…" The fact that documentation is maintained, it makes it automatically available upon request. As such, this comment is non-persuasive.

13.3.2 Reports issued by the forensic science service provider shall be accurate, clear, objective, and meet the requirements of the jurisdictions served.

COMMENT:
The NCFS recommendation should be incorporated here as well.

Task Group Response: The NCFS language was considered. As a result, everything in the NCFS language is captured within 13.3.1. Specifically, 13.3.1 indicates that reports shall include relevant elements described in E620 and ISO/IEC 17025. This comment is non-persuasive.

14. Competency and Proficiency Testing
COMMENTS:
•14.2.2. "Should" should be changed to "shall."
•14.3.1.2. If blind proficiency testing programs cannot be implemented, this should be documented and explained. This section should define and require double blind testing proficiency testing.
•14.3.2. The requirement that proficiency test samples be representative of the full range of casework should be mandatory – replace "should" with "shall."

Task Group Response: This topic was discussed at length during the development and several balloting steps at ASTM. Ultimately, the revised language did not pass ASTM, it was decided to encourage but not require the use of blind proficiency testing and the full range of casework. As suggested, the language would be too restrictive and make it nearly impossible for labs to meet. This comment is non-persuasive.

16.1.1.
COMMENT:

This standard should include a provision that discovery be reported to the parties in interest (the prosecuting authority the court and any potentially impacted defendants). See NCFS Recommendation to the Attorney General National Code of Professional Responsibility for Forensic Science and Forensic Medicine Service Providers ("16. Appropriately inform affected recipients (either directly or through proper management channels) of all nonconformities or breaches of law or professional standards that adversely affect a previously issued report or testimony and make reasonable efforts to inform all relevant stakeholders, including affected professional and legal parties, victim(s) and defendant(s).") https://www.justice.gov/archives/ncfs/page/file/839711/download Nonconformities must be disclosed to the parties, to include the defense.

Task Group Response: 16.1 includes language that says "Nonconforming work shall satisfy the requirements of ISO/IEC 17025." ISO/IEC 17025 covers this concept in much greater detail, see section 7.10.1.e, "where necessary, the customer is notified…" As ISO/IEC 17025 already covers this concept, it would be duplicative to restate the same requirement in this standard. In addition, proposed language addressing this comment was balloted at ASTM, it was not adopted. As such, this comment is non-persuasive.

17.1. COMMENTS:
•Records should not only be maintained, but disclosed upon request to the parties.
•Non-conformances and disagreements and resolution of disagreements, while they should be in each specific case file, they should be added to this section so they are maintained collectively as part of the quality assurance record.

Task Group Response: Each of the requirements listed in the comment require that documentation be maintained. The fact that documentation is maintained, it is automatically available upon request. As such, this comment is non-persuasive.

OSAC Registry Approval (Legacy) 1.5, Comment Adjudication Response Template

Document Title	ASTM E3255-21: Standard Practice for Quality Assurance of Forensic Science Service Providers Performing Forensic Chemical Analysis (ASTM International)
Requesting Unit	Seized Drugs

Unit Chair		**Unit Technical Contact**	
Name:	Agnes Winokur	Name:	Anne Slaymaker
Affiliation:		Affiliation	

Beginning Comment Period Date	4/6/21			
End Comment Period Date	5/6/21			
Comment Adjudication Meeting Dates	06/08-22/2021	07/01/2021	07/01-26/2021	07/26/2021
# of Members Present	Entire SC review and comment	Entire SC discussion	Entire SC review and comment	7Entire SC invited to discussion
Resolution Date and Vote Outcome	Electronic ballot. 17 approve; 0 reject; 0 abstain; 2 did not vote.			

Note: This template is intended for use by all Units considering a new document for addition into OSAC Registry

#	Person	Section	Editorial or Technical	Attached File
1	Jessica Willis	9, 10, 13, 14, 16		Open Comment Response 1 - for easier reading
	OSAC Legal Task Group	Scope, 1.2, 3.2.11, 6,7, 9, 10, 11, 13, 14, 16, 17		Open Comment Response 2 - for easier reading

scientific testing to establish the limits, repeatability, reproducibility and accuracy of the method or technique and the qua
the second helps ensure that the method or technique has been "reliably applied". FRE 702. Thus, we view a standard for qu
altering decisions. As a critical pillar a standard for quality assurance must be well defined and rigorous. Sadly, this is not th
that upon occasion the guidance we sought was contained in another ASTM standard. But access to all of the relevant stand
the extent that any of our concerns are addressed elsewhere the standard should be revised with a specific reference to that
committees of the National Research Council and independent scientists for more science in forensic science and despite th
recommendations to the forensic science community at large, those recommendations have been consistently ignored. AS
maintained and be available for review upon request as recommended by the NCFS in its Recommendation to the Attorney G
Documentation, Report Writing, and Review" in its entirety ignores the NCFS Recommendation to the Attorney General Do
Section 13.1.1 fails to require as recommended by the NCFS that "Records [] be created contemporaneous with the examina
another analyst or scientist, with proper training and experience, to understand and evaluate all the work performed and in
verification and technical review and for the stakeholders or customers within the criminal justice system including investig
that contains sufficient information and clarity to allow another properly trained forensic science practitioner the ability to
foregoes documentation that allows for an independent practitioner to come to an independent conclusion. In addition, s
trained scientist" identified in the NCFS language. Correctly section 13.2.3 requires that "[f]orensic science service provi
document the disagreement and corresponding resolution." However, requiring the procedure to "include instruction to d
section 13.2.3 fails to include a critical requirement that the documentation be maintained and disclosed with the results a
endeavor and thus any final report should disclose such disagreements. Section 13.3 "Report Writing" also fails to follow
Practice E620 permits critical information to be placed in the case file and not in a final report. And we, and the NCFS, recog
reports state that "the report does not contain all of the documentation associated with the work performed. In order to ur
Section 13.3.2 instructs that "reports issued by the forensic science service provider shall be accurate, clear, objective, and
conclusory and not particularly instructive to the practitioner and not grounded in science or the scientific method. By cor
of the data or results; any conclusions derived from those data or results; any discordant results or conclusions; the estimate
practitioner and mirrors the requirements of scientific research. Correctly section 16.1.1 requires that "[w]hen nonconfo
likelihood of recurrence." But the standard should also require that "nonconforming work" be reported to the parties in in
Professional Responsibility for Forensic Science and Forensic Medicine Service Providers ("16. Appropriately inform affected
previously issued report or testimony and make reasonable efforts to inform all relevant stakeholders, including affected pro
this proposed standard is a failure to provide minimum requirements despite its claim to do so in section 4.1. For example:
circumstances. Nor does it require that if a lab chooses not use published or standardized methods, that it document that fa
this standard on the registry, as well. COMMENTS REGARDING ASTM E3255-21 1. Scope 1.1 This practice discusses pro
of evidence, including: maintaining a quality management system; personnel duties, qualifications, training, and education
reporting; proficiency and competency testing; method validation and verification; audits; deficiency of analysis; and docu
through testimony monitoring and review of reports. Quality managers should establish that testimony and lab reports are
operations shall be conducted at least once a year, but it gives no indication of the scope or nature of these audits. If the aud
testimony monitoring in detail, such as the standard currently under development by the seized drugs subcommittee, the s
experience (see Practice E2917), and is to be used in conjunction with professional judgment by individuals with such disci
method published by a recognized international, regional, or national standard development organization (for example, AS
prescribes a standardized method. The ASTM style manual (March 2008) defines "test method" as "a definitive procedure th
synonym for "technique." It is not apparent that every standard or best practice recommendation for a technique lays out a
regarded as "standardized." 6. Personnel COMMENTS: •Many of the subsections here lack appropriate specificity and sul
requirements of E2917. •Specific comments about the subsections: ◦6.4, 6.5. Many "key personnel" positions listed inc
holding these positions must have "education, skills, and abilities commensurate with their responsibilities." This language
with" the responsibilities of technical support personnel and technicians? Baseline parameters should be set out. ◦6.6.2.
required or appropriate? Baseline parameters should be set out. 6.7 Technician – COMMENT: Why would this be a de
the explanation, this position should not be exempt from all the training required by E2917. 7. Physical plant COMMENT
What constitutes adequate "[e]nvironmental and procedural controls to prevent incidental contamination?" This should b
provides helpful examples of devices and equipment that can protect from chemical hazards. 9. Method Validation and V
maintained and be available for review upon request." See NCFS, Recommendation to the Attorney General Transparency o
summaries of major events/experiments performed, results, major conclusions and methods implemented or approved by t
forensic science service providers should employ a statistically based protocol when an inference is to be made regarding a s
protocol"? Some form of random sampling of the "submission"? When would probability sampling not be "applicable"?
standardized methods, it must document that fact as well as explain why the deviation occurred. Third, failure to use publis
as written, it risks allowing labs to deviate from standards that should be followed, with no explanation or justification. The
provider shall verify published or standardized methods by in-house performance testing. COMMENT: What does verifica
standard? What are the parameters/requirements for in-house performance testing? 10.1.2.2 The use of laboratory-devel
COMMENT: Section 4.1 states that this standard provides minimum requirements. What is required in the way of a policy f
sample data to external reference data when a reference material is unavailable. External reference data shall be assessed and
analytical conditions. COMMENT: Normally, one validates methods for generating data or making inferences from data. W

Response
See attached document for a detailed response to each comment submitted.

See attached document for a detailed response to each comment submitted.

Reason	Resolution
See attached document for a detailed response to each comment submitted.	Not persuasive
See attached document for a detailed response to each comment submitted.	Not persuasive

No response needed

Categories for adjudication of negative public comment for addition to registry

Term	Definition
Not Germane	Comment is not relevant to the subject of document being considered
Persuasive - review required	General agreement with comment given, further review by subcommittee
Withdrawn by submitter	Comment withdrawn by submitter
Not persuasive	Justification for non persuasive rationale is indicated by committee action
Previously considered	Topic of comment was previously discussed and resolved by subcommittee*
No response needed	Comment does not require a response

*If all commenters express the same or similar reasoning for not moving a document forward, the OPO looks to confirm that all similar comments have the same adjudication response (e.g. Persuasive, Not Persuasive, etc.). We also look to confirm that the response provided by the unit is the same or similar. This is to ensure that when the final comment(s) and response(s) are published to the OSAC website, that viewers have a clear understanding of the unit's perspective on a given issue.