Adjudication of Public Comments received for E2329-17

Comment ID:	**1996**
Category:	Substantive
Section:	6.1.2.1
Subject:	Microscopical and macroscopical identification of cannabis
Comment/Proposals:	Identification of botanical material utilizing microscopical and macroscopical characteristics alone should not be used for the identification of cannabis because cannabis cannot be distinguished from hemp which can be legally grown in some jurisdictions so long as the concentration of THC does not exceed a specified level.
Proposed Solution:	Specify that this procedure is not applicable to cannabis.
SC Response:	E2329-17 does not advocate for the use of microscopical and macroscopical characteristics alone for the identification of cannabis. Only using these two tests would not fulfill the minimum analysis requirements stated in the document. Per the standard, cannabis can be analyzed with a macroscopical and microscopical examination and one other test (6.1.2). Hemp is a variety of cannabis with the same genus and species. It is known that hemp and cannabis have different concentrations of THC, however this document does not address quantitation of any seized drugs including cannabis. Requirements for determining the concentration of THC are beyond the scope of the document. This is a foundational document and not intended to provide specific jurisdictional requirements. Section 4.1.1 denotes the responsibility of individual laboratory's management to determine requirements of its jurisdiction.
Resolution:	Not persuasive
Notes:	Comment and adjudication language discussed with commenter (Sarah Rackley Olson) on March 21, 2018 via phone call with SC Chair Rodriguez-Cruz.

Adjudication of Public Comments received for E2329-17

Comment ID:	**1997**
Category:	Substantive
Section:	6.1.2.1
Subject:	Acceptance criteria for features
Comment/Proposals:	There should be a minimum standard for what macroscopical and microscopical features are required for identification of cannabis. The minimum standard should not be left to the individual labs to determine.
Proposed Solution:	The minimum standard for macroscopical and microscopical features are required for identification of cannabis should be based upon scientifically validated procedures for the identification of cannibas and should be specified in this document.
SC Response:	E2329-17 is a foundational document stating minimum requirements for the identification of seized drugs. It is not within the scope of E2329-17 to provide specific criteria for individual techniques for the identification of seized drugs. Therefore, specifying the particular features required for the identification of cannabis is outside the scope of this document.
Resolution:	Not persuasive
Notes:	Comment and adjudication language discussed with commenter (Sarah Rackley Olson) on March 21, 2018 via phone call with SC Chair Rodriguez-Cruz.

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Comment ID:	**1998**
Category:	Substantive
Section:	6.1.2.1
Subject:	photographic documentation
Comment/Proposals:	Documented details of botanical features should include photographs of the evidence material to preserve a visual record of the appearance and features for later review by another expert.
Proposed Solution:	Specify that photographic evidence is required for microscopic and macroscopic analysis in addition to written descriptions of features.
SC Response:	E2329-17 states minimum requirements (section 6.1.4.3) and does not preclude the implementation of additional laboratory procedures such as requiring the collection of photographic evidence during microscopic and macroscopic analyses. Mandating that reviewable data include photographs of microscope images would be a financial burden to laboratories and would significantly impact implementation of the minimum standards for identification.
Resolution:	Not persuasive
Notes:	Comment and adjudication language discussed with commenter (Sarah Rackley Olson) on March 21, 2018 via phone call with SC Chair Rodriguez-Cruz.

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Comment ID:	**1999**
Category:	Substantive
Section:	6.1.3
Subject:	THC concentration issue
Comment/Proposals:	Identification of botanical material utilizing morphological characteristics alone should not be used for the identification of cannabis because cannabis cannot be distinguished from hemp which can be legally grown in some jurisdictions so long as the concentration of THC does not exceed a specified level.
Proposed Solution:	Specify that this procedure is not applicable to cannabis.
SC Response:	The purpose of this clause is to allow those practitioners that have training and expertise in the field of botany, above and beyond the general training of chemists, to utilize their unique training to identify cannabis. Hemp is a variety of cannabis with the same genus and species. It is known that hemp and cannabis have different concentrations of THC, however this document does not address quantitation of cannabis or any other seized drug. Requirements for determining the concentration of THC are beyond the scope of the document. Section 4.1.1 denotes the responsibility of individual laboratory's management to determine requirements of its jurisdiction. A recommendation will be forwarded to the SDO task group to delete "(Category B)" from section 6.1.3 in a future revision of the document. This deletion will assist in emphasizing that this section only pertains to identification of cannabis by botany experts.
Resolution:	Not persuasive
Notes:	Comment and adjudication language discussed with commenter (Sarah Rackley Olson) on March 21, 2018 via phone call with SC Chair Rodriguez-Cruz.

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Comment ID:	**2000**
Category:	Substantive
Section:	6.1.4.1
Subject:	Lack of data in spectra and chromatograms
Comment/Proposals:	Spectra and chromatograms provided in laboratory discovery packets often do not provide enough detail to enable an expert to review them.
Proposed Solution:	Require that reviewable raw data be provided rather than printed spectra and chromatograms alone.
SC Response:	Section 6.1.4 already requires identifications to be supported with reviewable data. Sections 6.1.4.1 – 6.1.4.4 list examples of such reviewable data. The commenter intended to refer to both the availability of high-quality hard copy data, as well as access to raw electronic data. Raw data would enable an outside expert (with access to appropriate software) to reprocess the data during their assessment. The term "reviewable" as used in the document implies the hard-copy data provided is of acceptable quality. Otherwise, it should be deemed not reviewable. Policies and requirements pertaining to accessing raw electronic data are beyond the scope of this document, and are expected to be specified by individual laboratory jurisdictions.
Resolution:	Not persuasive
Notes:	Comment and adjudication language discussed with commenter (Sarah Rackley Olson) on March 21, 2018 via phone call with SC Chair Rodriguez-Cruz.

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Comment ID:	**2001**
Category:	Substantive
Section:	6.1.6.3
Subject:	Procedural blanks/blind proficiency testing
Comment/Proposals:	Procedural blanks needs to be more clearly defined so that it is clear how they should be employed (clarify whether a blank should be used once per day, once per run, once per analyst preparing samples in a batch, between each evidence sample, etc.). Use of blind proficiency testing is a good laboratory practice that should be included in this list.
Proposed Solution:	Change to "procedural blanks between each evidence sample."? Use of blind proficiency testing should be listed as a good laboratory practice.
SC Response:	The intent of section 6.1.6 is to offer examples of quality control measures laboratories shall employ to ensure analysis results correspond to a particular exhibit or laboratory submission. Defining how procedural blanks are utilized and how often is part of method validation and beyond the scope of this document. It is agreed proficiency tests are a part of good laboratory practice; however, they are part of the laboratory's quality assurance program and not part of quality control measures. The subject of proficiency tests is specifically discussed within the scope of a separate document, ASTM E2327-15, already referenced in the practice. A recommendation will be forwarded to the SDO task group to change the term "assurance" to "control" in section 6.1.6, to further clarify the intent of this section and prevent future misinterpretations.
Resolution:	Not persuasive
Notes:	Comment and adjudication language discussed with commenter (Sarah Rackley Olson) on March 21, 2018 via phone call with SC Chair Rodriguez-Cruz.

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Comment ID:	**2002**
Category:	N/A
Section:	N/A
Subject:	Comment on Intent to Add ASTM E2329-17 to the OSAC Registry
Comment/Proposals: 1	The following is a consensus opinion of five (5) individual scientists. This consensus comment represents these individuals' opinions and does not represent the position of NIST, the agency. We believe that ASTM E2329-17 should not be placed on the OSAC Registry because this Standard does not support the reliability of drug testing. Based on the Title: Standard Practice for Identification of Seized Drugs, this Standard is intended to clearly guide forensic laboratories in the identification of an unknown seized substance. As stated in the Scope "1.1. This practice describes minimum criteria for the qualitative analysis (identification) of seized drugs." However, 1. the Standard does not list the minimum performance criteria by which laboratory staff could reliably identify a drug. The Standard lists a suite of 18 analytical technologies and assumes the user will figure out how to use each technology and which specific method to use. Thus, the document provides little assistance to the examiner in selecting a specific analytical technology or how to use it. This allows for many different analyses to be conducted by different laboratories potentially resulting in a lack of consistency in the results. For example, there are 75 possible analytical technology combinations (not including visual examinations) allowed by this practice if at least one of them is a category A technology and 196 combinations if one chooses the 2B+1 approach, giving a total of 271 possible combinations of analytical technologies allowed by the practice. Since each analytical technology encompasses many different possible techniques, methods and instruments, the practice allows an unknowable number of approaches to drug analysis. **Not persuasive** – The seized drug sub-committee disagrees with the statement that E2329-17 is unreliable for drug identification. It is our assessment that the commenters' statements do not support their assertion. We respectfully request objective evidence to support their assertion. The issue of revising the title has been previously discussed between commenters, the seized drugs sub-committee and the SDO working group. It has been agreed on multiple occasions that a change in the title of the standard will be addressed in a future revision. E2329-17 is a foundational document designed to establish minimum criteria applicable to all identifications. The document is intended for analysts specialized in the analysis of seized drugs, competent in the discipline, and possessing the education, knowledge and experience to understand the operation of the different

	techniques included in the standard. Seized drugs submissions to laboratories are not uniform. They vary from day to day, from exhibit to exhibit, and from jurisdiction to jurisdiction. E2329-17 establishes criteria that can be applied to most, if not all, jurisdictions and types of submissions, while allowing the expert practitioners to apply their knowledge to the particular scenario at hand. The intent of E2329-17 is not to provide analysts with specific individualized protocols to identify each and every particular drug that could be possibly encountered, because the needs of analysis may vary depending on the substances present, the sample matrix, the laboratory's jurisdiction and the techniques available. 2. Of the 18 analytical technologies (not techniques or methods) listed in Table 1, the only *referenced technique* is microcrystal testing - no other technology-related methods are mentioned or delineated in the Standard. There are few explanations, references, performance criteria or explicit details of what the analytical technology is required to do - as an example - one of the category A technologies is mass spectrometry. This could be interpreted by the user as laser ablation ICP-MS, SIMS, Atom Probe MS, DART MS, LC-MS or GC-EI-MS or many other possible mass spectrometry techniques. Mass spectrometry is a technology made up of many types of instruments and techniques. **Not persuasive** – Table 1 provides 20 analytical techniques that can be utilized within an appropriate analytical scheme, utilizing validated methods, to identify a seized drug. All of the referenced standards in E2329-17, including those referencing microcrystal testing, were the only published ASTM standards at the time this standard was developed. It is the intent of the document to allow the use of any valid technique or its various applications. Depending on the chemical and physical properties of the questioned sample, the jurisdictional requirements, and the laboratory facilities, analysts have the option of using any of the above listed techniques for the case at hand. However, the requirements stated in sections 6.1.1 and 6.1.2 shall be fulfilled. 3. In addition to the new analytical identification challenges, there is an overarching new consideration - the safety of first responders and laboratory personnel. E2329-17 does not address such issues, but this issue must be *noted* in this new reality. A statement such as "Unidentified materials may be extremely dangerous to human health and appropriate material handling protocols and personal protective equipment shall be used." **Not germane** – Safety precautions and protocols for first responders is outside the scope of this document. **Not persuasive** – Section 1.5 of the standard indicates that specific safety

	precautions and protocols for laboratory personnel are the responsibility of the user and beyond the scope of E2329-17. Safety training is addressed in the referenced standard E2326-14, 6.3.6 and should be included in a laboratory training/orientation program. 4. To meet this growing current need and to prepare for the future of drug identification, a new Standard for the identification of seized drugs is required. Rather than addressing the evaluation of an unknown sample with a user-defined choice of analytical technologies as in ASTM E2329-17, the new Standard should evaluate the sample with a hierarchy of analytical techniques and defined methods that accomplish two goals: 1) make the analyst clearly aware of the category of hazard provided by the sample and 2) achieve a high level of confidence in the identification of small percentages of the illicit drug(s) in the sample. To have any utility, the bulk techniques will have to be used in conjunction with some form of pre-separation/drug isolation. Simple color forming tests are rendered even more unreliable with these complex samples. In this new Standard, chromatographic techniques such as GC, SFE, TLC, and LC will often be required to identify these 'minor constituent' drugs. High resolution mass spectrometry (HRMS) will also provide higher confidence in identifications. A recent SWGDRUG survey found that 90% of forensic drug labs are already using GC (and/or LC) MS and these techniques should be required for most samples. Of the 18 analytical technologies listed in Table 1, technologies that can separate all the components associated with the emerging synthetic drugs will prove more useful for reliable identification. **Not persuasive** – A hazard cannot be determined prior to identification. Laboratories utilize personal protective equipment (PPE) and engineering controls to reduce potential exposures to blood borne pathogens (BBP) and hazardous chemicals. Safety concerns are outside the scope of this document. Training programs are required to address safety concerns (see E2326-14, 6.3.6). Utilizing E2329-17 laboratories have successfully identified emerging drugs of abuse such as fentanyl analogs, synthetic cannabinoids and substituted cathinones, which are frequently found in low abundance. E2329-17 is a foundational document stating the minimum requirements for designing analytical schemes that can accomplish the identification of seized drugs. Using validated methods as referenced in E2549-14, 9.4.5 and designing analytical schemes and standard operating procedures fulfills the minimum requirements of the standard. Per the standard, a Category C technique cannot be used to identify a seized drug sample alone. However, a Category C technique provides direction for which analytical scheme to choose. 5. In the Interim, ASTM E2329-17 and the SWGDRUG recommendations remain available for laboratories making forensic drug identifications while a more suitable

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	Standard is under development. Submitted by: Thomas Bruno, Ph.D., Group Leader, Applied Chemicals and Materials Division, National Institute of Standards & Technology (NIST) Jeffrey Horlick, B.S., Physicist/Guest Researcher, Standards Coordination Office, National Institute of Standards & Technology (NIST) William MacCrehan, Ph.D. Research Chemist, Materials and Measurement Laboratory, National Institute of Standards & Technology (NIST) Eric Steel, B.S., Director, Material Measurement Laboratory Forensic Science Program, National Institute of Standards & Technology (NIST) Jennifer Verkouteren, M.S., Physical Scientist, Materials and Measurement Laboratory, National Institute of Standards & Technology (NIST)
Proposed Solution:	Do not add ASTM E2329-17 to the OSAC Registry.
SC Response:	See individual adjudication of comments above.
Resolution:	See individual resolution of comments above.
Notes:	These comments and the SC adjudication were also addressed and discussed on March 14, 2018 during the OSAC in-person meeting in Chicago, IL. Dr. William MacCrehan acted as representative of this group of commenters.

Adjudication of Public Comments received for E2329-17

Comment ID:	**2003**
Category:	Editorial
Section:	Full Document
Subject:	Support for Inclusion of E2329-17 on the OSAC registry
Comment/Proposals:	This comment is submitted on behalf of the Illinois State Police Forensic Sciences Command. The Illinois State Police Forensic Science Command is supportive of adding E2329-17 to the registry as a replacement for E2329-14. We have already adapted our own policies at facilities across the state of Illinois to align with the current standard. We view the new update as a positive improvement, especially regarding the uncertainty language. We have confidence in the standard as we already employ it in our analytical work on a daily basis. We encourage E2329-17 to be adopted by OSAC without reservation or disclaimer.
Proposed Solution:	Adopt as written, without disclaimer.
SC Response:	Commenter supports replacement of E2329-14 with E2329-17 without reservation or disclaimer.
Resolution:	No response needed
Notes:	N/A

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Comment ID:	**2004**
Category:	N/A
Section:	N/A
Subject:	Comment on E2329-17
Comment/Proposals:	This is a brief response to the comments made by 16 statisticians and attorneys submitted by David Kaye on January 6, 2018. The group makes valid observations, including but not limited to suggesting that problematic language in ASTM E2329-14 be removed in any document referenced internally by E2329-17, such as E2764-11. The Seized Drugs subcommittee in fact agrees and is currently in the process of removing the problematic language from all standards in which it appears. Removing the language from E2329-17 itself is an important improvement that should be communicated to forensic practitioners as soon as possible via publication of the standard on the registry. Hopefully, the subcommittee will be able to remove the problematic language from the standards referenced by E2329-17 before the FSSB votes on E2329-17. However, even if the language cannot be removed by that time, the FSSB should still include E2329-17 on the registry. The criminal justice community is better served by including the improved standard than delaying its approval to wait for similar edits to take effect in other referenced documents. The additional comments raised by the group should be addressed by the subcommittee in the next version of E2329. On balance and considering the timing constraints inherent in the SDO process, both the forensic community and the greater criminal justice system would be better served by including the improved E2329-17 on the registry; working to remove the problematic language from other standards as soon as possible; addressing additional comments in subsequent iterations; and supporting the good faith efforts of the subcommittee to publish standards that are urgently needed to ensure the integrity and reliability of criminal convictions involving seized drugs.
Proposed Solution:	None
SC Response:	No response needed
Resolution:	N/A
Notes:	N/A

Adjudication of Public Comments received for E2329-17

Comment ID:	**2006**
Category:	N/A
Section:	N/A
Subject:	Comment on ASTM E2329-17
Comment/Proposals:	Although ASTM E2329-17 is an improvement over E2329-14, we do not believe it should be placed on the OSAC Registry of Approved Standards for the following two reasons: Section 4.2 incorporates Practice E2764 to explain the statement that "It is expected that in the absence of unforeseen error, an appropriate analytical scheme effectively results in reliable and scientifically supported identifications." The current version of ASTM E2764 states: "4.3.1 It is expected that in the absence of unforeseen error, an appropriate analytical scheme effectively results in no uncertainty in reported identifications." Citing to this text allows analysts to assert that there is "no uncertainty" in their identifications (unless they committed an unknown, unforeseen error). Section 6.1.8 states that "[t]he chosen analytical scheme shall demonstrate the identity of the specific drug(s) present and shall minimize false positive and false negative identification." No analytical scheme can simultaneously minimize both the false-positive and the false-negative conditional error probabilities. The best that can be done is to adopt a scheme that achieves a scientifically and legally acceptable trade-off of error probabilities. An elaboration on these two comments and related issues follows. The full set of comments is intended (a) to assist the subcommittee in deciding whether the current wording is adequate to enable the FSSB to place E2329-17 on the Registry; (b) to contribute to further improvements in this standard and the connected one; and (c) to offer information to the FSSB if it is called on to place this standard on the Registry. The more complete statement explains the basis for the two conclusions stated above and gives specific suggestions for corrections and improvements.[1] [1] The explanatory document has the support of all the individuals named above. Page 1 was added for clarification at the end of the public comment period. David Banks, Georgiy Bobashev, Alicia Carriquiry, John Ellis, Jennifer Friedman, Karen Kafadar, David Kaye, Steven Lund, Cedric Neumann, Barry Scheck, Hal Stern, and Sandy Zabell expressed their agreement with it. No commenter expressed any disagreement with it.
Proposed Solution:	Solutions proposed in the attachment.

SC Response:	Regarding section 4.2 referencing E2764, the stated language in E2764 has been removed. It is currently under SDO revision. Regarding section 6.1.8, revisions to this language were already incorporated as a result of the first OSAC public comment period completed during the Fall of 2015. The intent of the new language was to emphasize the importance of devising analytical schemes that reduce both false positives and false negatives; however, it was never intended to be achieved *simultaneously*. From the attachment included by the commenters, it is noted that they do recognize the intent of the language in the document (see page 4, Section 6.1.8, last paragraph). However, besides suggesting the sentence be dropped, no alternative language is offered by the commenters. The subcommittee supports the original intent of the language, but also welcomes any suggestions for improvement, as long as any alternative language does not add ambiguity to the understanding of practitioners and main users of the document. In the interim, we assert this comment does not affect the overall appropriateness of inclusion of this document in the OSAC Registry. Based on discussions with commenters during the OSAC in-person meeting in Chicago, IL, revision recommendations will be forwarded to the SDO task group to further clarify the original intent of section 6.1.8. The following revisions may be proposed: (a) 6.1.8 The chosen analytical scheme shall demonstrate the identity of the specific drug(s) present ~~and shall minimize false positive and false negative identification~~. Where a scheme has limitations, this shall be reflected in the reported result (see Practice E2764). Suggestion from Dr. Cedric Neumann: (b) 6.1.8 The chosen analytical scheme shall have a combined selectivity such that seized drugs can be identified with as little error as possible.
Resolution:	Not persuasive
Notes:	The Seized Drugs subcommittee task group met with many of the commenters during the week of March 12-16 in Chicago, IL.