

## **Public Comments on ASTM E2329-17 Standard Practice for Identification of Seized Drugs**

Submitted on Behalf of

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January 6, 2018

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:

- (1) 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).
- (2) 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.<sup>1</sup>

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<sup>1</sup> 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, Hal Stern, and Sandy Zabell expressed their agreement with it. No commenter expressed any disagreement with it.

## Introduction

As is well known, NIST disavowed the part of ASTM E2329–14 that read:

It is expected that in the absence of unforeseen error, an appropriate analytical scheme effectively results in no uncertainty in reported identifications (see Practice E2764).

A joint statement from NIST and the Forensic Science Standards Board explained that

The FSSB and NIST agree that the term "effectively results in no uncertainty" means different things to different readers of the document. While this language was deemed appropriate by its authors, it was deemed inappropriate by others including NIST.<sup>2</sup>

The FSSB, NIST, and ASTM, Inc., promised “to work together on new language that conveys clear meaning.”<sup>3</sup> The new language appears in ASTM E2329-17, which is being considered as a replacement for ASTM E2329-14 on the OSAC Registry of Approved Standards. Unfortunately, the ASTM revision process does not seem to have reached the goal of a clear and scientifically acceptable meaning for this standard.

The revised Standard Practice for Identification of Seized Drugs (ASTM E2329-17) contains two major improvements.<sup>4</sup> They are shown in Table 1.

Section	2014 Standard	2017 Standard
4.2	Correct identification of a drug or chemical depends on the use of an analytical scheme based on validated methods (see Practice E2549) and the competence of the analyst. It is expected that in the absence of unforeseen error, an appropriate analytical scheme effectively results in no uncertainty in reported identifications (see Practice E2764).	Correct identification of a drug or chemical depends on the competence of the analyst and the use of an analytical scheme that incorporates validated methods (see Practice E2549). It is expected that in the absence of unforeseen error, an appropriate analytical scheme effectively results in reliable and scientifically supported identifications <u>5</u> / (see Practice E2764). 5. Milman, B. L., Chemical Identification and Its Quality Assurance, Springer-Verlag, 2011

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<sup>2</sup> Joint OSAC FSSB and NIST Statement on ASTM E2329-14, July 05, 2016, <https://www.nist.gov/news-events/news/2016/07/joint-osac-fssb-and-nist-statement-astm-e2329-14>.

<sup>3</sup> Id.

<sup>4</sup> Other parts of the standard which have not changed obviously raise the same problems noted in comments of the HFC and LRC members on ASTM E2329-14.

6.1.8	The chosen analytical scheme shall demonstrate the identity of the specific drug present and shall preclude a false positive identification and minimize false negatives. Where a scheme has limitations, this shall be reflected in the final interpretation (see Practice E2764).	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).
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### Comments on Section 4.2

The first sentence of Section 4.2 is incomplete. Correct identification (in a particular case) also depends on whether a competent examiner using validated methods applied these methods properly. The Federal Rules of Evidence and those of many states require a showing that validated methods have been applied properly in a particular case.

The second sentence uses the phrase “effectively . . . reliable and scientifically supported identifications.” In the statistical literature, a reliable measurement system is one that produces fairly consistent measurements.<sup>5</sup> In the broader scientific literature, “reliable” also can mean trustworthy, as it usually does in the legal system. The standard probably is referring to reliability in the broad sense of something that can be relied on to be correct. Inasmuch as neither ASTM E2329-17 nor the SWGDRUG glossary to which it points defines reliability, however, arriving at this conclusion takes some effort.<sup>6</sup> Further ambiguity results from the phrase “unforeseen error.” Identifications made pursuant to an analytical scheme that “incorporates validated methods” are, by definition, both statistically reliable and scientifically supported. Thus, readers are left to wonder whether “unforeseen error” refers to an analyst’s failing to follow the validated method, to making a clerical error (both of which are foreseeable), or to something else. If that is the point of the clause, words like “blunder,” “misapplication,” or “malfeasance” would achieve greater clarity.<sup>7</sup>

One could view these ambiguities as more or less harmless, but the additional reference to “Practice E2764” reinstates the original, unacceptable language of “no uncertainty.” Section 4.3.1 of ASTM E2764-11 is *identical* to the sentence in ASTM E2329-14 that the new version is

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<sup>5</sup> In analytical chemistry and engineering, the terms “repeatable” and “reproducible” are commonly used to indicate two types of reliability. E.g., Barry N. Taylor & Chris E. Kuyatt, NIST Technical Note 1297: Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results (1994), available at <https://www.nist.gov/pml/nist-technical-note-1297>. But see Nat’l Acad. of Sci., Engineering & Med., Statistical Challenges in Assessing and Fostering the Reproducibility of Scientific Results: Summary of a Workshop (2016) (discussing the variety of definitions of the terms “reproducibility” and “replicability” found in different scientific fields).

<sup>6</sup> Because statistical reliability is part of what makes identifications “scientifically supported,” the term would be superfluous if this were the intended meaning. Furthermore, the authority cited in this subsection defines “reliability of an identification” as the sensitivity and specificity of a binary classification. Boris L. Milman, *Chemical Identification and Its Quality Assurance* 64 (2011).

<sup>7</sup> The phrase was the subject of criticism in both HFC and LRC comments on ASTM E2329-14.

supposed to have fixed. Citing ASTM E2764-11 as a reference for readers to understand ASTM E2329-17 therefore allows analysts to continue to assert that there is “no uncertainty” in their identifications (unless they committed an unknown, unforeseen error).<sup>8</sup>

Of course, well trained, conscientious, and knowledgeable analysts would not testify in this manner, but it would be unfortunate if OSAC were to approve—for the second time—a standard that could be cited as supporting such assertions. NIST’s previous statement that “no measurement, qualitative or quantitative, should be characterized as without the risk of error or uncertainty”<sup>9</sup> was correct.<sup>10</sup> No standard that departs from this principle, explicitly or implicitly, has a place on the OSAC registry.

### Section 6.1.8

ASTM E2329-14 requires the laboratory to select the analytical scheme that will “preclude a false positive identification and minimize false negatives.” Apparently recognizing the impossibility of totally precluding false positives, ASTM E2329-17 requires the laboratory to choose the analytical scheme that will “minimize false positive and false negative identification.” But each scheme has to trade off reducing the risk of errors of one type for increasing the risk of the other type of error. There may be no analytical scheme among the alternatives that the standard provides that minimizes *both* false positive *and* false negative probabilities relative to the other schemes.

Thus, the professed requirement that laboratories adopt procedures that keep *both* false-positive and false-negative risks to their smallest possible values is not statistically defensible. We appreciate that the drafters of the standard may have meant to say that the laboratory must follow procedures that reduce both types of error to acceptably small values, resulting in statistically reliable and valid drug identifications. Expressing that idea more precisely (or simply dropping the sentence) would accomplish the objective of the standard and make it better suited for inclusion in the registry.<sup>11</sup>

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<sup>8</sup> The witness can truthfully testify that, according to ASTM E2329-17, the laboratory produced a “reliable” and “scientifically supported” identification, which means, as explained in the OSAC-approved reference to “ASTM E2764,” that there is “no uncertainty” in the finding. This problem could be solved either by revising the Standard Practice for Uncertainty Assessment (ASTM E2764) or by deleting the references to it. We understand that ASTM is revising E2749-11. Once a suitable version is made public, a reference to it could be appropriate.

<sup>9</sup> NIST Statement on ASTM Standard E2329-14, Mar. 17, 2016, <https://www.nist.gov/news-events/news/2016/03/nist-statement-astm-standard-e2329-14>.

<sup>10</sup> The uncertainty in the findings of some laboratories, especially those that exceed the minimum provided for in ASTM E2329, appears to be very small. See S.E. Rodriguez-Cruz & R.S. Montreuil, Assessing the Quality and Reliability of the DEA Drug Identification Process, 6 Forensic Chem. 36 (2017). However, it is not zero, and it is for a judge or jury to decide whether the risk of error in a particular case is negligible.

<sup>11</sup> The remaining sentence in § 6.1.8 also could be improved. Because every analytical scheme has limitations, the sentence should simply state, without referring to ASTM E2764-11, that reported findings shall be accompanied by a statement of those limitations or the uncertainty in the result as determined by empirical testing. This suggestion is editorial; in itself, it would not preclude registry approval.

## **Public Comments on ASTM E2329-17 Standard Practice for Identification of Seized Drugs**

Submitted by Lynn Garcia, Kent Cattani and Ron Reinstein

January 6, 2018

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.

The following is a consensus opinion of five (5) individual scientist. 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, 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.

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.

Looking at this from another perspective, emerging issues in drug identification provide an additional impetus not to place E2329-17 on the OSAC Registry. Historically, forensic evaluation of seized drugs entailed the reliable identification of one illicit substance. However, since the recent advent of more powerful and analytically more challenging synthetic drugs in routine case work, ASTM E2329-17 is no longer suited to the identification of the wide range of seized drugs. In this new challenge, small quantities of an active, illicit drug such as fentanyl (and related synthetic analogs) are encountered in conjunction with additives, which can be active drugs or inactive. The illicit ingredient(s) may only comprise 0.2% to 1% of a seized drug sample rendering the (formerly) most powerful bulk identification techniques such as X-ray diffractometry (XRD), Nuclear Magnetic Resonance Spectroscopy, (NMR), Infrared Spectroscopy (IR), unit-resolution Mass Spectrometry (MS), Microcrystalline tests, and Raman Spectroscopy (RS) of little or no use in *direct* identifications. Even tablet identification via visual inspection of "Pharmaceutical Identifiers" has limited utility with the advent of ever more sophisticated counterfeit color-matching dyes and pill pressing technology. Botanical identification of marijuana may miss the presence of added (and more dangerous) fentanyl (or other drug) analogs.

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."

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.

In the Interim, ASTM E2329-17 and the SWGDRUG recommendations remain available for laboratories making forensic drug identifications while a more suitable Standard is under development.

Submitted by:

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Origin	Category	Section	Page	Line	Subject	Comment	Proposal	Commenter
Public Review	Comment	NA			Approve	<p>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</p>		Amanda Shanbaum

Public Review	Substantive	6.1.2.1			Microscopical and macroscopical identification of cannabis	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.	Specify that this procedure is not applicable to cannabis.	Sarah Olson, NC Indigent Defense Services Comments (6 individual comments) Forensic Resource Counsel Indigent Defense Services Durham, NC 27701 Phone 919-354-7217 Sarah.R.Olson@nccourts.org
Public Review	Substantive	6.1.2.1			Acceptance criteria for features	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.	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 cannabis and should be specified in this document.	Sarah Olson, NC Indigent Defense Services Comments (6 individual comments) Forensic Resource Counsel Indigent Defense Services Durham, NC 27701

Public Review	Substantive	6.1.2.1			photographic documentation	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.	Specify that photographic evidence is required for microscopic and macroscopic analysis in addition to written descriptions of features.	Sarah Olson, NC Indigent Defense Services Comments (6 individual comments) Forensic Resource Counsel Indigent Defense Services Durham, NC 27701
Public Review	Substantive	6.1.3			THC concentration issue	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.	Specify that this procedure is not applicable to cannabis.	Sarah Olson, NC Indigent Defense Services Comments (6 individual comments) Forensic Resource Counsel Indigent Defense Services Durham, NC 27701

Public Review	Substantive	6.1.4.1			Lack of data in spectra and chromatograms	Spectra and chromatograms provided in laboratory discovery packets often do not provide enough detail to enable an expert to review them.	Require that reviewable raw data be provided rather than printed spectra and chromatograms alone.	Sarah Olson, NC Indigent Defense Services Comments (6 individual comments) Forensic Resource Counsel Indigent Defense Services Durham, NC 27701
Public Review	Substantive	6.1.6.3			Procedural blanks/blind proficiency testing	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.	Change to "procedural blanks between each evidence sample." Use of blind proficiency testing should be listed as a good laboratory practice.	Sarah Olson, NC Indigent Defense Services Comments (6 individual comments) Forensic Resource Counsel Indigent Defense Services Durham, NC 27701