COMMENTS BY THE OSAC LEGAL RESOURCE COMMITTEE (LRC)

TO: Seized Drug Subcommittee of the Chemistry-Instrumental SAC

FROM: Lynn Garcia, LRC Liaison to Chemistry-Instrumental SAC

RE: LEGAL RESOURCE COMMITTEE (LRC) COMMENTS ON E2329-14

Response from the Seized Drugs Subcommittee

The OSAC Seized Drugs subcommittee recognizes and appreciates the comments received from the Legal Resource Committee (LRC) pertaining ASTM E2329-14, Standard Practice for Identification of Seized Drugs. The following responses attempt to address and clarify some of the issues brought to our attention by the LRC.

The document in review (E2329-14) was original published by ASTM in 2004. The document was originally published as Part IIIB of the Scientific Working Group for the Analysis of Seized Drugs (SWGDRUG) Recommendations, which are intended to assist forensic analysts and managers in the development of analytical techniques, protocols and policies. The SWGDRUG Recommendations are internationally recognized as minimum standards that may be supplemented to address unique jurisdictional laboratory requirements.

The document under consideration is neither a test method nor a prescriptive standard. Therefore, many of the comments provided by the LRC members are not considered applicable. Also, this document is not intended to encompass all other related standards, terminology, validation documentation, etc. that may assist in its application. The field of seized drug analysis is an extensive one encompassing the subjects of sampling, chemical identification, presumptive and confirmatory analytical techniques, method validation, quantitative procedures, structure elucidation, measurement uncertainty, reporting protocols, and many others. It is unrealistic and impractical to attempt to include all these subjects into one single document, as the result would be an ineffective standard that would not be useful for practitioners. Efforts are already underway to address some of the aforementioned subjects via the publication of separate documents on the OSAC Registry.

There appears to be some misconceptions and misunderstandings regarding the OSAC process as well as the process in use by the standard development organization (SDO) under which this standard is published (ASTM). We believe that it would be useful to provide additional training regarding these procedures to not only members of the LRC but also members of other resource committees and individual discipline subcommittees.

We understand the desire for these documents to be written such that they are more comprehensible to lawyers and judges. However, many of these documents under review have already been in the forensic community for over ten years and they were originally drafted with the goal of providing useful minimum standards for seized drug analysts. In fact, there are many seized drug laboratories throughout the world that use this document (as well as the SWGDRUG Recommendations) as a foundation for their policies and procedures. It is our strong belief that attorneys and judges have the ability to consult scientists in order to interpret a scientific document, much in the same way as a scientist would consult an attorney to interpret a legal document. Serious consideration is being given to all the comments provided by the LRC members. However, we believe that making significant changes to the document in order to address the resource committees would take away too much from the original technical and scientific intent of the document.

The Seized Drug Subcommittee of the Chemistry-Instrumental SAC is proposing that ASTM E2329 − 14 ("Standard Practice for Identification of Seized Drugs") be placed on the OSAC Repository of Standards and Guidelines.

Our comments are primarily intended to enhance the value of the Standard to the legal community. This Standard will be most helpful if it not only helps assure high quality results in the laboratory, but also is written to show how work performed in accordance with the Standard is both well grounded in theory and data and that it is presented within the boundaries of "the knowledge and experience of [the expert's] discipline."[1] Consequently, the comments are intended to address four questions that are important to the legal reception of the Standard:

(1) Is the Standard written as clearly as possible, and without undefined technical terms and symbols, so as to enable lawyers and judges to grasp the main ideas and requirements set forth?

(2) Does the Standard describe in detail how the peer-reviewed and readily available scientific literature establishes the validity of the assumptions underlying the scientific tests and the interpretation of test results?

(3) Does the Standard list the limitations of the tests and results and provide for expressions of the uncertainties in measurements and inferences drawn from them?

(4) Does the Standard include recommendations or requirements for the creation and retention of documentation of the test and the contents of reports, including the scientific limitations of the tests and related conclusions or inferences? These are matters of both technical merit and legal

[1] Kumho Tire Co. v. Carmichael, 526 U.S. 137, 148 (1999) (quoting Daubert v. Merrell Dow Pharms, Inc., 509 U.S. 579, 592 (1993)).

importance. Although the LRC is not able to assess the scientific merit of a Standard, our review encompasses whether a Standard makes a prima facie case for the validity of the methods and legal utility of the kinds of expert opinions that a Standard contemplates.

The LRC received feedback from the FSSB recently that it would be more useful for LRC members to provide consolidated comments as opposed to providing the comments of individual members and indicating which other members of the LRC join in the comments. We did not have sufficient time to attempt this before comments on E2926-13 were due. However, we have been discussing possibilities for meeting this request and will strive to make our comments as useful as possible to the FSSB and other interested readers.

Comments by LRC Member Jennifer Friedman:

I do not believe this standard is ready to be published in the OSAC registry. My reasons for this opinion are set forth below.

1.4 This is a proposed standard therefore it should be described as a standard not a practice. Additionally, this seems to suggest that it would be appropriate not be follow the standard if the analysts "experience, education, or training dictated it should not be followed.

Not persuasive. This is standard language incorporated into ASTM documents. The intent is to prevent an individual, not possessing the appropriate "experience, education, or training," from using the document without proper scientific judgment. Neither is this section meant to imply that the standard should be ignored, but rather that the standard should be used in conjunction with existing knowledge. Describing something as a "Standard Practice" should not preclude it from moving forward to the OSAC Registry of Standards.

3.1 I believe there should be a standard glossary of terms used by all committees in generating standards. To the extent a term is not included in this glossary, it should be included in the standard or if the glossary defines a term differently than is used in the standard, it should be defined in the standard.

Not persuasive. Separate on-going efforts within the OSAC are geared towards the development of a general Terminology document that would include many of the terms in this Standard Practice. The current absence of such document should not preclude others from being added to the OSAC Registry.

4.2 this standard references other standards that may or may not be included in the OSAC registry. This is a problem. Additionally, this statement makes no sense," in the absence of unforeseen error, an appropriate analytical scheme effectively results in no uncertainty in reported identifications." Errors are always unforeseen. This does not tell the reader anything about error rates or limitations of the technique.

Not persuasive. It is unrealistic to expect all references found in a document to be already included in the OSAC Registry, as submissions have only started. In addition, not every document that is of value to forensic chemists is expected to be included in the registry, e.g., textbooks, published papers, etc. To disallow reference to other technically sound and useful documents, just because they are not placed in the registry yet, would not be of service to the forensic or legal communities.

Editorial. The Seized Drug subcommittee intends to clarify the quoted language pertaining to uncertainty and error during the next ASTM revision of this document.

6.1.6 If this standard is going to include a direction that a lab use quality assurance measures, the measures that should be used must be specified. Additionally, the use of two samplings, bar codes, witness checks, good laboratory practices such as the use of controls should not be suggestions they should mandatory.

Not persuasive. This is a document stating minimum requirements, not a prescriptive standard. Quality assurance measures depend on laboratory, jurisdiction, and accreditation. The intent of the current document is to require laboratories to implement quality assurance measures as part of their quality system. The specific listing of such measures would fall under the scope of a separate document, most likely generated by the specific laboratory.

6.1.7 and 6.1.8 should cite to published validation studies in which the various techniques were tested and the limits and error rates of the techniques described.

Not persuasive. Again, this document is not a prescriptive standard. Citing published validation studies for all the dozens of possible and scientifically valid techniques a laboratory could use is outside the scope of the document. The vast majority of these techniques have been in use for decades, extensively published and strongly based on physical scientific principles. In addition, validation documentation is the responsibility and accreditation requirement of the laboratory performing the analysis, and it would vary from laboratory to laboratory in order to be fit-for-purpose and to fulfill jurisdictional requirements.

The following members of the LRC agree with comments made by Jennifer Friedman:

Barry Scheck joins in Jennifer Friedman's comments.

Comments by LRC Member David Kaye:

This ASTM Practice prescribes some "uniform methods, actions, practices, or processes, protocols" (or some parts of them). Being ASTM-approved, it is included in "the OSAC Catalog of External Standards and Guidelines [which] is a collection of standards, guidelines *and other documents* applicable to forensic science." NIST, OSAC Catalog of External Standards and

Guidelines, Dec. 10, 2014 (updated May 15, 2015), http://www.nist.gov/forensics/osac/standards-guidelines-catalog.cfm (emphasis added). I am informed that this fact makes it appropriate to consider the Practice for inclusion in the Registry even if it lacks the specificity and terminology for Standards and Guidelines discussed in previous OSAC meetings.

The Practice does offer some useful guidance, but it lacks the detail and specificity to be a "controlling legal standard" within the meaning of *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). Consequently, I do not see that much is to be gained by placing it in the Registry. To be sure, OSAC approval would signal that the methods alluded to are generally accepted, but the methods in question are hardly novel.

Perhaps I am underrating the power of the document to improve laboratory practices, but rather than place this particular Practice on the Registry, I believe that the SAC's expertise and efforts would better be devoted to producing a controlling standard that specifies more fully how analytical procedures are to be performed and that supplies advice on reporting and testifying.

In the hope that the SAC will accept the challenge to "develop new standards and guidelines for the OSAC registries to replace current documents in the catalog," NIST, *supra*, more detailed comments follow. Some suggestions as to revisions that simply would improve clarity are placed at the end.

1. Concerns About Content

Part 2 (referenced documents) is limited to a set of "Guides" and one SWGDRUG document. Are no other publications on the test procedures worth referring to? The Standard should show how it flows from and is supported by a body of cited scientific studies. (Even if the Practice were to be incorporated into the Registry as an off-the-shelf product to be replaced later, the SAC and the FSSB should consider including an appendix or introduction to the Standard as it appears in the registry. Presumably, that explanatory document would not have to be approved by ASTM.)

Not persuasive. It appears the intent of section 2 is misinterpreted. This is not a prescriptive standard; therefore, the inclusion of references to "other publications on the test procedures" is not applicable, because this document does not describe a specific test procedure. Section 2 is standard in ASTM documents, intended to provide the reader with an easy-to-find location where all documents referenced in a standard are listed. Interestingly, the Seized Drug subcommittee considers this comment (requesting inclusion of further references) somewhat contradicting the comment provided by the previous LRC reviewer who was critical of including references to documents that are not in the OSAC Registry yet.

Not sure what is being requested by "FSSB should consider including an appendix or introduction to the Standard as it appears in the registry". We believe this document stands on its own and is comprehensible to practitioners, the intended audience. E2329 is a broad document that provides laboratories with a framework to select an appropriate analytical scheme that includes all techniques and methods needed to effect a drug identification. While

there may be other documents to cite, SWGDRUG was the leader in identifying the need for providing this guidance. Indeed the SWGDRUG Recommendations are cited by state legislatures, other professional working groups and governments around the world as an authoritative guideline for the practice of drug analysis. Before the SWGDRUG publication, there were no equivalent guidance documents that unified the profession. It is appropriate to cite it as it was the first to cohesively identify paths toward robust drug analysis.

Section 4.1.1 states that "As these are minimum requirements, it should be recognized that they may not be sufficient for the identification of all drugs in all circumstances. Within these requirements, it is up to the individual laboratory's management to determine which combination of analytical techniques best satisfies the requirements of its jurisdiction." The meaning of "minimum" is unclear. Presumably, it points to a set of conditions that are necessary but not sufficient for a drug identification. But where is this minimum stated? Or is the idea that at least one of the techniques that are described must be used? That none of them need be used if management has something better in mind? That if any of them are used, the "practice" specifies a minimum set of requirements for using it? A Standard or Guideline should be clear about what must be done when. Section 6 is very useful in this respect, and might be referred to here, but it has some limitations noted below.

Not persuasive. The intent of section 4.1.1 is to emphasize the requirements listed which establish the minimum amount of testing a laboratory must do. In addition, the subsequent caveat further clarifies that the minimum testing may in fact not be enough for a particular drug identification and the laboratory must do more testing in those scenarios. The establishment of minimum testing criteria is the heart of this document, as stated in section 5, Table 1 and sections 6.1.1 through 6.1.5.

The observation in section 4.2 that "validated methods" must be used is fine, but without a specification of what those are or what must be done within an individual laboratory, it provides no real guidance. To be sure, the section refers to a separate standard that might contain this information, but that Standard has not been approved for the repository. Would approving this one automatically effectively approve that one? If Standards are interdependent, must not both of them be considered for incorporation into the repository at the same time?

Not persuasive. Specific methods are validated and documented at the laboratory level to comply with individual accreditation and jurisdictional requirements. A separate document, E2549, addresses how validation is to be conducted and used. As mentioned above, E2329 establishes minimum requirements, including that laboratories must use validated methods. The requirements, procedures and documentation of the actual validation studies will depend on the actual test/technique being validated. All these are outside the scope of this document.

Section 4.2 also states that "It is expected that in the absence of unforeseen error, an appropriate analytical scheme effectively results in no uncertainty in reported identifications." This somewhat wordy sentence comes directly from ASTM E2764−11. Neither document defines what it takes to expect "no uncertainty" or what an "effective uncertainty" of zero really means. The dichotomy in the latter document between quantitative measurements (which "have an

associated uncertainty") and qualitative one (which somehow do not) is not easily understood and is not consistent with some court opinions from other forensic-science fields.

Editorial. The Seized Drug subcommittee intends to clarify the quoted language pertaining to uncertainty and error during the next ASTM revision of this document.

Section 6.1.2.1 states that "Laboratories shall define the acceptance criteria for these [botanical] features for each examination." On what basis? The "practice" here sounds like a recommendation to do the right thing. Section 6.1.3 does not offer much more in the way of meaningful guidance.

Not persuasive. These acceptance criteria will differ from laboratory to laboratory and should be documented in their individual laboratory procedural requirements. In most cases, it will depend on specific jurisdictional requirements. Section 6.1.3 is intended to address laboratories where botanical identifications are performed by botanists, not forensic chemists. Again, it is not the purpose of this Standard Practice to dictate what criteria are to be used, simply to establish minimum identification requirements.

Section 6.1.6 calls for quality assurance, but it only gives examples of what would suffice. It may be that other Standards on quality assurance generally cover the topic (in which case it is not clear why this Practice also tries to).

Not persuasive. Providing examples of quality assurance measures enhances the interpretation of the document and is not expected to have any inherent issues.

Section 6.1.8 states that "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)." Precluding all false positives would be wonderful, but is it possible? There is inevitably a trade-off between false positives and false negatives, and rarely is there any realistic way to preclude *all* false positives." I saw nothing in ASTM E2764 that solves this fundamental problem.

Editorial. The subcommittee intents to clarify the language in a future document revision.

Another section should address what kinds of conclusions should, can, or must be in reports and testimony. I doubt that an assurance that the method precludes all false positives, with no studies to establish this assertion of infallibility, is advisable. If this standard is not intended to offer any guidance whatsoever on how to present a determination of the nature of a compound, its limited scope should be made explicit and justified on the ground that another document will deal with the problem of incorporating statements of uncertainty into these determinations.

Not persuasive. This is to be the scope of a separate document.

2. Drafting Problems

Section 1.1 states that "This practice describes minimum criteria for the qualitative analysis (identification) of seized drugs." The term "qualitative analysis" is not normally equivalent to "identification." For example, determining the color of a solution by looking at it is a qualitative analysis. Measuring the wavelength of light reflected from the solution is quantitative. Either might help identify something.

Not persuasive. In the field of chemistry, the terms qualitative and quantitative analysis are distinctly used to refer to tests providing identification and purity/concentration of chemical component(s), respectively. They shall not be confused with the terms qualitative and quantitative result. Yes, "measuring the wavelength reflected from the solution" is a quantitative result (that is, it produces a number). However, that numeric result could be used solely as a qualifying characteristic of the compound under investigation or as a measure of its concentration/purity in the solution. The latter result would only be valid under appropriately validated experimental conditions where, among others, require comparison with a known-concentration positive control. In the chemistry discipline, a quantitative analysis cannot be performed without prior (or simultaneous) qualitative testing. In other words, analysts cannot test how much of a compound is present without first identifying which compound is present.

Section 1.4 states that "This practice does not replace knowledge, skill, ability, experience, education or training and should be used in conjunction with professional judgment." Either this goes without saying or it is overbroad. Does it mean something more than that in using an analytical scheme or technique, knowledge, skill, ability, experience, education or training is required. If so, what?

Not persuasive. Previously considered.

The disclaimer in section 1.5 does not seem to achieve any legal objective. It is hard to see how any reader would think that a "standard . . . purport[s] to address all of the safety concerns." Stylistically, the phrase "all of the safety concerns, if any" is awkward. Every other section in this part uses the word "practice" to refer to the document or its content. This one uses "standard." Why the change?

Not persuasive / not germane. This is a common disclaimer included in ASTM documents. Not sure why its inclusion is interpreted to have a legal objective. This document has been identified, per ASTM protocol, as a Standard Practice.

Section 3.1 departs from the ideal of having a set of definitions of important terms developed through the OSACs. That goal is not essential, but the definitions in question should be part of the document. They could go in an appendix.

Not persuasive. Separate on-going efforts within the OSAC are geared towards the development of a general Terminology document that would include many of the terms in this Standard Practice.

Section 6.1.4 requires "data that are reviewable" for some techniques. It seems like a documentation requirement rather than an identification criterion. These requirements, along with ones for other techniques, might belong in a new section.

Not persuasive. This is not stated as an identification requirement, but as a documentation requirement that goes along and depends on the techniques and methodologies selected to achieve identification. The documentation provides the evidence of identification.

The following members of the LRC agree with the comments made by David Kaye:

Barry Scheck and David Moran join in all of David Kaye's comments.

Ron Reinstein joins in all of David Kaye's comments except the comment regarding Section 1.4. Judge Reinstein believes the section should be clarified but not deleted. Judgment, training and experience are important but must be used in conjunction with the test method (but not in place of it).

Comments by LRC Member Barry Scheck:

Barry Scheck would like to emphasize concerns expressed in the comments by Jennifer Friedman and David Kaye that the deficiencies in the statistical explanations offered is troubling and not ready for court, whether one is in a *Frye* or *Daubert* jurisdiction. These should be rejected from the OSAC Registry and, hopefully, the OSAC subcommittee and/or ASTM will revise the proposed standards to follow the template laid out in the Technical Merit Worksheets. The requirement of general acceptance in the scientific community, particularly among statisticians, cannot be met, nor the requirements of clearly identifying limitations and weaknesses in the methodology or an explanation of how it is "fit for purpose."

Not persuasive. Not sure what is referred to as "deficiencies in the statistical explanations offered". There are no statistical explanations included in this document as they would only be applicable to a test method or procedure – which this document is not. The minimum requirements stated in this document have been nationally and internationally accepted by seized drug laboratories and courts for over 10 years as an ASTM publication and over 15 years as a SWGDRUG recommendation. Its fitness for purpose has therefore been demonstrated.

It is unrealistic to expect previously vetted and published ASTM documents to fulfill the requirements just recently established by OSAC, as they are completely separate institutions.

This comment does not offer any specific explanation as to how this document does not meet "the requirement of general acceptance in the scientific community, particularly among statisticians". And again, it appears the document has been misinterpreted as describing a particular methodology.

DISCLAIMER: ***The failure of any member of the Legal Resource committee (LRC) to provide a comment, identify a legal issue or join in another LRC comment should not be***

interpreted as a disagreement or endorsement of the comment, the standard or its legal sufficiency.