IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Criminal Action No. 10-CR-00567-MSK

UNITED STATES OF AMERICA,

Plaintiff,

vs.

1. COSME MOISES GOMEZ-PAZ,
2. SERGIO ABRAHAM BELTRAN,
3. RAFAEL PELAYO-ESCARDA,
4. ESEQUIEL MEZA-TORRES, and
5. LOUIS ARMANDO CELAYA,

Defendants.

REPORTER'S TRANSCRIPT
(Continued Rule 702 Hearing)

Proceedings before the HONORABLE MARCIA S. KRIEGER, Judge, United States District Court for the District of Colorado, commencing at 9:14 a.m., on the 18th day of August, 2011, in Courtroom A901, United States Courthouse, Denver, Colorado.

Proceeding Recorded by Mechanical Stenography, Transcription Produced via Computer by Paul Zuckerman, 901 19th Street, Room A259, Denver, Colorado, 80294, (303) 629-9285

APPEARANCES

JAMES BOMA, Assistant U.S. Attorney, 1225 17th Street, Suite 700, Denver, Colorado, 80202, appearing for the plaintiff.

SOLETTE MAGNELLI, Special Assistant U.S. Attorney, U.S. Drug Enforcement Administration, Office of Chief Counsel, 8701 Morrissette Drive, Springfield, Virginia, 22152, appearing for the plaintiff.

MITCHELL BAKER, Attorney at Law, Mitchell Baker & Associates, 1543 Champa Street, Suite 400, Denver, Colorado, 80202, appearing for Defendant Gomez Paz.

JEFFREY EDELMAN, Attorney at Law, 19201 East Mainstreet, Suite 203, Parker, Colorado, 80134, appearing for Defendant Beltran.

ROBERT DRISCOLL, Attorney at Law, 455 Sherman Street, Suite 310, Denver, Colorado, 80203, appearing for Defendant Pelayo Escarda.

MATTHEW GOLLA, Assistant Federal Public Defender , 633 17th Street, 10th Floor, Denver, Colorado, 80202, appearing for Defendant Meza Torres.

BRUCE BROWN, Attorney at Law, 1630 Miner Street, Idaho Springs, Colorado, 80452, appearing for Defendant Celaya.

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PROCEEDINGS

(In open court at 9:14 a.m.)

THE COURT: Please be seated.

The Court is convened today in Case No. 10-cr-5667, which is encaptioned the United States of America vs. a number of defendants. This is a continuation of a Rule 702 hearing. And I'll have everyone enter their appearances as I read the names off the caption.

For the United States of America?

MR. BOMA: Good morning. Jim Boma appearing on behalf of the United States. And with me at counsel table are Solette Magnelli and Mr. Scott Oulton of the DEA.

THE COURT: Good morning and welcome.

MR. BOMA: Good morning.

THE COURT: For Cosme Moises Gomez Paz.

MR. BAKER: Good morning, your Honor. Mitchell Baker. I'm here with Mr. Gomez Paz, who is seated in front of me.

THE COURT: Good morning and welcome.

For Sergio Abraham Beltran.

MR. EDELMAN: Good morning. Jeffrey Edelman for Mr. Beltran. And with your permission, I'd like Ms. Arvizu to sit at counsel table as court-appointed quality control consultant and expert.

THE COURT: Any objection?

MR. BOMA: None, your Honor.

THE COURT: All right. Good morning and welcome.

For Rafael Pelayo Escarda.

MR. DRISCOLL: Good morning, your Honor. Bob Driscoll present with Mr. Pelayo, who is seated at my side.

THE COURT: Good morning and welcome.

Esequiel Meza Torres.

MR. GOLLA: Good morning, your Honor. Matthew Golla appearing on behalf of Mr. Meza Torres, who is seated to my right at counsel table.

THE COURT: Good morning and welcome.

Luis Armando Celaya.

MR. BROWN: Bruce Brown present for Mr. Celaya, who is present in custody and using the services of a Spanish interpreter.

THE COURT: Good morning and welcome.

And could I have our interpreters enter their appearances, too, please.

INTERPRETER CAHILL: Good morning, your Honor. Susan Cahill and Ruth Warner, for the record.

THE COURT: Good morning and welcome.

Does anyone object to the qualifications of Ms. Warner and Ms. Cahill to serve in this capacity?

MR. BOMA: No, your Honor.

THE COURT: From the defense, I'm seeing shaking heads.

MR. EDELMAN: No, your Honor.

THE COURT: All right. Would you please administer

the oath.

(Interpreters sworn.)

THE COURT: Thank you.

Before we begin, we have several motions.

MR. BROWN: Can we just have one second to change out a headset, your Honor?

THE COURT: Sure.

MR. BROWN: Thank you.

Thank you, your Honor.

THE COURT: Thank you.

We have several motions that were filed after the prior hearing that was continued to today. We have Docket No. 205, the Government's motion *in limine* in preclude anticipated testimony of the defense expert, and I think a response has been filed. Yes.

Is there any further argument you want to make?

MS. MAGNELLI: Your Honor, there has also been a reply filed. And unless the Court wants additional information, I'm willing to rest on that.

THE COURT: No, I don't need any more information. Thank you.

MR. EDELMAN: Your Honor, Mr. Beltran has no further argument to make.

THE COURT: Thank you.

I deny the motion. I deny the motion on several

grounds. First of all, Ms. Arvizu's report is not the limit of her testimony in this hearing. Her report delineates the testimony she may offer at trial. It does not effect her testimony in this hearing.

Secondly, the Government's argument that she will not be able to present evidence that is relevant to the 702 determination is something I'm not willing to decide at this point. We'll hear the testimony from Ms. Arvizu. If it's relevant, I'll consider it; if it's not relevant, the Government will have an opportunity to object.

Any need for clarification or further explanation?

MR. EDELMAN: None from the defendant, your Honor.

MS. MAGNELLI: No, your Honor.

THE COURT: Okay. Then we have Docket No. 207, the Government's motion to quash Defendant Celaya's *subpoena duces tecum* with regard to Ralph Keaton. The Government denies that -- the Government asks for quashing of thea *subpoena duces tecum* dated July 6, 2011. I deny that motion because the Government doesn't have standing to bring the motion.

However, there is a motion by the party who was subpoenaed, Docket No. 214, and that is the American Society of Crime Laboratory Directors and Laboratory Accreditation Board; and I've had an opportunity to look at that motion and the response.

Is there any further argument that needs to be made?

MR. BROWN: I will note, your Honor, Mr. Eid is here for the subpoenaed witness.

THE COURT: Thank you.

MR. BROWN: No. I have no further argument. I will submit on the request for subpoena to be issued and the responsive pleadings.

THE COURT: Mr. Eid, is there anything further you want to say?

MR. EID: May it please the Court, Troy Eid for ASCLD/LAB.

THE COURT: Would you come to the microphone. I can't hear you back there.

MR. EID: Absolutely.

Thank you, your Honor. For the record, may it please the Court, Troy Eid, Counsel for ASCLD/LAB and Mr. Ralph Keaton, Executive Director.

I think the grounds were set forth, your Honor, in our motion to quash. Just a couple points I'd like to make.

What I really want to emphasize is that this is totally unprecedented. This organization has been around since 1982. It's the first time it's ever been served with a federal subpoena since 1982 anywhere in the United States.

And it is our position that this is essentially a substitute, an improper substitute for discovery; that it's an abuse of the process in terms of Rule 17(c). We think that

the -- it's very clear that the defendant has the burden here. They've got to establish the *Nixon* standards for relevance. It's not relevant. The accreditation process is not going to help the defendant in terms of demonstrating whether the substance was meth.

The accreditation that was actually done, your Honor, was completed on -- DEA was notified on October 15 of 2010 that the accreditation was going to issue from ASCLD/LABs; but the testing was done, as you know, November 8 and 10. That was the Chan testimony on April 26, the Irby testimony. So it didn't -- the protocol was not involved in these documents being sought by the subpoena. The testing agent was certified on the day in question, which we think falls within the context of the precedent of *Gonzales Acosta*.

And in terms of the 702 issue, we'd just simply say that Irby testified that the testing was pursuant to the protocols of the DEA and the SWGASD, not related at all to the accreditation process.

So given the lack of relevance, the fact that it's not admissible at this point in time, they can't just get it for impeachment purposes, and that it's not specific, it seems to fall within the fishing expedition concept. We would respectfully suggest that both in terms of precedents and the public policy that this motion to quash be granted. Thank you, your Honor.

THE COURT: Thank you.

Any reply?

MR. BROWN: Thank you, your Honor.

Your Honor, this material is sought for two proceedings, obviously for this proceeding, which is why the Court is taking it up at this time; and also ultimately if a trial occurs in this case, we think it will be helpful at trial.

As far as the relevance of the subject matter, it is relevant in both proceedings for the following reasons:

Obviously, as a threshold, the People [*sic*] would have to prove at trial that the substance is in fact methamphetamine, similar to the analysis that is occurring in this hearing.

The Government sought to introduce at the inception of this hearing on the direct of Ms. Irby and shield themselves in terms of reliability and quality of analysis by citing ASCLD/LAB as a body which monitored the Western Regional Lab for compliance with the SWGDRUG standards, so the Government was the one who put forth the evidence. We seek -- or I seek on behalf of Mr. Celaya to investigate and produce evidence as to whether or not the Western Regional Lab was, as they assert, in compliance with the SWGDRUG standards by going to the source material that they have cited in order to bolster their credentials.

The timing involved is important because the reason it was put forth by the Government was to establish that on the day of the analysis that this lab had been accredited. Almost like the character of a witness, the lab's character is being put forth as establishing reliability, credibility, and methodology.

So I think that it is very important despite the fact that the on-site investigation of ASCLD/LAB took place prior to the testing -- it is important, in giving this court information for the purposes of this hearing, to determine whether or not, in fact, they are in accord -- that acted and tested in accordance with the standards of SWGDRUG as monitored by ASCLD/LAB on the date of testing.

Thank you.

THE COURT: Thank you.

The legal standard with regard to subpoenas issued by a criminal defendant on a third party is set forth in *United States vs. Nixon*, 418 U.S. 683, a 1974 Supreme Court decision. The burden of establishing these elements is on the party seeking enforcement of the subpoena in accordance with *United States vs. Morris*, 287 F.3d 985, a Tenth Circuit, 2002 decision.

The factors that the Court considers are whether the materials are evidentiary and relevant, whether the materials are not otherwise procurable reasonably in advance of trial by

the exercise of due diligence, and whether the requesting party cannot properly prepare for trial without such production and the failure to obtain such inspection may tend unreasonably to delay the trial and whether the requesting party's application is made in good faith and is not intended as a general fishing expedition.

It's sometimes difficult to distinguish between what transpires and the purposes of a Rule 702 hearing and what transpires and the purposes of a trial.

This hearing is not for the purpose of determining whether the evidence that the Government wants to present as to the testing of the substance it concludes is methamphetamine is a good opinion. It is not to determine whether or not the lab was accredited. It is not to determine whether or not the lab followed particular protocols that attach to accreditation. It is instead to determine whether Ms. Irby's process was a reliable methodology for determining whether the substance was methamphetamine or not.

I therefore find that what has been requested here, documents and documentation pertaining to the Western Regional Lab between the dates of February 1, 2010, and July 1, 2011, is not relevant to this proceeding. It may be relevant at the time of trial because it may go to the weight of admissible evidence if, indeed, the determination is made. It may go to the credibility of Ms. Irby in her opinion; but it does not

pertain to the reliability of the methodology that she used.

In evaluating that methodology at our last hearing, I defined the scope of what we were going to look at in light of what had been produced by the Government. We are assuming that Ms. Irby is a chemist who performed the chemical analyses that she did and described in her testimony at a lab that was not a government lab. The question is whether her methodology is a reliably methodology for determining the existence of methamphetamine.

I am not assuming that certification or compliance with protocols in place at a DEA lab bear on this issue at all.

As a consequence I grant the motion to quash but acknowledge that the fact that this information may be relevant at the time of trial and the defense may in the course of time between now and the time of trial, if the foundational showing is made for Ms. Irby's opinion -- may seek the same information for that purpose.

Any need for clarification or further explanation?

MR. BROWN: No, your Honor. Thank you.

MR. BAKER: Your Honor, I do have one question, if I could ask the Court for clarification.

THE COURT: Yes.

MR. BAKER: In the Court's earlier ruling concerning the fact that the Court was not going to consider the DEA standards -- and I'm looking at page 132 and 133 of the

transcript.

THE COURT: Right.

MR. BAKER: The Court indicated that the Court will regard that testimony, referring to Ms. Irby's, as being a description based upon her experience and her testimony that this comports with industry or discipline standards. And maybe I missed the import of the ASCLD testimony, but I thought that the ASCLD testimony actually was testimony about what those industry standards consist of and was part of that whole --

THE COURT: Mr. Baker --

MR. BAKER: Yes.

THE COURT: -- what that refers to is her testimony that she complied with standards.

MR. BAKER: Right. But the difficulty we're left with is that as with the DEA protocols where the Court said, I'm not going to consider whether you -- your testimony that you complied with DEA protocols, if those protocols aren't produced, because I have no way -- speaking in your voice -- that you had no way and the defense had no way of knowing what those protocols were. My confusion comes from the fact that it seems that we're in the same boat with the ASCLD standards, which, while she may say she's complying with those, we don't have any way of knowing what they are.

THE COURT: I think that's correct.

MR. BAKER: We would ask the Court to totally

disregard any statements that her -- and maybe that's what you said earlier: that any statements or any testimony by Ms. Irby that her testimony complied with ASCLD standards that nobody is willing to produce for us should also be disregarded.

THE COURT: My understanding is ASCLD certifies, certifies labs, accredits labs, and tests, does sample testing to make sure that labs are meeting the standards for accreditation. That's why there is a difference between her stating that I did this for an accredited lab, which I'm disregarding -- that's the whole point of saying I'm ignoring that this was done by a DEA lab. I did not understand her to say in reviewing the testimony that her testing was done in accordance with standards that were applied by ASCLD, because I don't understand ASCLD to apply standards, only accreditation.

MR. BAKER: May I have just one moment, your Honor? Because I'm confused.

THE COURT: Or maybe I'm confused.

MR. BAKER: No, no. That's less likely.

MR. EID: Your Honor, may I respond to that?

THE COURT: Sure.

MR. EID: Your Honor, just for the record, your summary is correct. And it's important to understand that the standards that are used in accreditation by ASCLD/LABS are ISO, International Standards Organization, standards; they're not the standards that were talked about with respect to SWGASD and

so on. That's just a misunderstanding.

So for the record, your summary is spot on. Thank you.

THE COURT: Thank you. Maybe I'm not as confused as I thought.

MR. BAKER: Your Honor, could I ask for about a five-minute recess to try to find what I'm looking for? Specifically what I'm looking for -- and before I say something that's completely wrong, I thought Ms. Irby testified about specific documents that were ASCLD documents that set out -- and I think one of them was 17-something or other; that the testing had to be consistent with --

THE COURT: I don't think we need to take a recess in order to deal with this. You're perfectly free to look through the record as we proceed with the cross-examination.

MR. BAKER: Perfect.

THE COURT: -- of this witness. And I understand that you may want to renew your request or clarify your request sometime later in the hearing.

MR. BAKER: Thank you, your Honor.

THE COURT: Thank you.

All right. Mr. Eid, I think that takes care of your issue. And you're welcome to remain and observe, if you'd like. Otherwise, if you have other business to attend to, I certainly understand.

MR. EID: I'll excuse myself, your Honor. Thank you very much.

THE COURT: Thank you.

MR. EID: Thank you.

THE COURT: When we recessed last time, it appears that we were in the middle of Mr. Driscoll's cross-examination of Mr. Oulton. Is that correct?

MR. DRISCOLL: That's my recollection as well, your Honor. If I might assume the podium.

THE COURT: You may.

And I'll ask the witness to resume his position in the witness stand and remind him he remains under oath.

(Scott Oulton was recalled to the stand.)

CROSS-EXAMINATION CONTINUED

BY MR. DRISCOLL:

Q. Good morning, sir.

A. Good morning.

Q. Are you comfortable and ready?

A. I am. Thank you.

Q. Okay. Mr. Oulton, as we recessed, you and I were discussing -- I was examining you regarding the microcrystalline test visual examination of the suspected substance and the standards relative to the use or nonuse of that examination process. Do you recall?

A. That's the way I recall that, color testing. And yes.

Q. And --

THE REPORTER: Sir, could you pull that microphone toward you.

THE COURT: You can just pull the microphone, if you want.

There you go.

BY MR. DRISCOLL:

Q. And have you had a chance to review the testimony since we recessed?

A. I have.

Q. I'm going to refer -- I'm going to try to pick up just before we recessed. And so if you need to refresh regarding those topics please, I invite you to stop me so that you can have a chance to review.

In your testimony, Mr. Oulton, you had -- you had referred to different labels or categories of tests. And I'm going to review those very briefly for the record so that we can then go forward.

First of all, as I recall, I had asked you about the Marquis reagent test; and there was testimony to the effect that that was a presumptive test. Do you recall?

A. Yes. Color test is a presumptive test.

Q. And can you describe for the Court what is a presumptive test as opposed to something like a confirmatory test?

A. Well, in the point of a color test example, when we add the

sample or this reagent to the sample, it changes the color. And there is many different compounds that turn that color, a certain color; so that's why it's considered presumptive. Its not highly discriminatory. It can give us a class of the compounds that exist. So, for example, in this case orange/brown would be indicative of an amphetamine-type compound.

Q. But it would not be an adequate test for you to -- you or a qualified examiner to render an opinion to a reasonable degree of scientific certainty concerning the identity of the substance tested.

A. By itself, no; but that's why we do additional testing, because the aggregate of all the testing show that the substance is what it is.

Q. And my question to you was: The Marquis reagent test by itself does not give you adequate data to render an opinion to a scientific degree -- a to a reasonable degree of scientific certainty. Can you answer that yes or no?

A. No. We can render an opinion as to the class of compound but not to the substance itself.

Q. So you can't identify the substance?

A. Not on the color test alone, no.

Q. Thank you. And then you also referred in your testimony to a qualitative test. Can you tell us or tell the Court what a qualitative test is, please?

A. Essentially, actually, of all these are qualitative tests; but, for example, in SWGDRUG, we have categories of testing. Category A would be the most discriminatory type test. That would be such things as mass spectrometry, infrared spectrometry, NMR, nuclear magnetic resonance, and X-ray diffractometry. Those are the types of tests that have the most highly discriminatory power.

Next we would have Category B.

Q. Excuse me.

A. Yes.

Q. Before you proceed to the categorization of Category B, can you tell us these categories, these Category A and Category B of your examination techniques, these are categories of types of examination techniques?

A. We have classified them into such categories as methods and techniques used, yes.

Q. And when you use the term "we," are you referring to SWGDRUG?

A. That's correct.

Q. So the governing body, SWGDRUG, has sorted tests and categorized them as to preference methodologies?

A. You said "governing bodies." SWGDRUG is really a scientific working group. And we're made up of scientists that get together to recommend minimum standards for the identification of drugs.

Q. And now if you could please proceed the Category B tests.
A. Yes. Category Bs would be something a little less discriminatory. Some of those things would be things like HPLC, as in the prior testimony; GC; microscopic crystalline tests would fall into Category B, and things such like that.
Q. And the microcrystalline test specifically is the test that I had asked you in reviewing, I believe it was Exhibit 1, and the freestanding results as to whether or not that test had been performed by Ms. Irby?
A. According to her notes and -- it was not performed.
Q. And are you aware of any directive by the Drug Enforcement Administration Laboratory supervising hierarchy that had instructed laboratory examiners not to physically look at a microcrystalline -- look at the crystals to identify them and compare them with a known?

MS. MAGNELLI: Your Honor, I'm going to object just because anything DEA isn't relevant per the Court's order.

THE COURT: Response?

MR. DRISCOLL: Your Honor, I believe that the testimony, the earlier testimony, was that -- that the microcrystalline test had fallen into disfavor and that it was no longer in use. And I'm trying to find out why it's not in use.

THE COURT: All right. Well, I'm going to sustain the objection.

MR. DRISCOLL: All right.

THE COURT: We're assuming for purposes of determination of the reliability of the methodology used by Ms. Irby that she was testing at some location other than a DEA lab, she was not complying with DEA protocols, or there were no protocols; and therefore, what the DEA's perspective is with regard to this isn't relevant.

MR. DRISCOLL: Your Honor, I -- I -- may I exchange with the Court?

THE COURT: Sure.

MR. DRISCOLL: Your Honor, if the basic issue is the reliability of the tests -- and I believe that prior testimony has established that it is a method of comparison of known to unknown when you actually look at the substance itself. The testimony is that -- we have in the exhibits and in the testimony scientific tests that were performed by machines. I believe it's also been established that there has been no actual examination, confirmatory tests performed by a scientist on the substance except -- but for the scientist reading the results of the mass spectroscopy, etc. and there has been no hands-on examination of the tests other than the reagent test, which is a nonspecific test. It's a presumptive test.

THE COURT: Right.

MR. DRISCOLL: And so I'm trying to find out with regard to the -- with regard to the microcrystalline test and

the relevance of that and the industry standards concerning the microcrystalline test as to -- as to whether or not the instrumental examination of the substance creates that reliability, for the test to go forward, for the Court to make a ruling.

THE COURT: Well, you can ask that. But it doesn't have anything to do with DEA policy. And that's how your question was phrased.

MR. DRISCOLL: Thank you, your Honor. I'll reframe.

MR. EDELMAN: Your Honor, I'd going to join in the Government's objection and ask that this -- my client be allowed to withdraw from any further exchange between this counsel and this witness, if we're allowed to do such a thing.

THE COURT: I have no idea what you're asking, Mr. Edelman. I'm confused.

MR. EDELMAN: I don't want any further evidence that comes out of this witness to be held against my client with this exchange.

THE COURT: I'm not sure you can do that.

MR. EDELMAN: Me, either.

THE COURT: You allowed these defendants to join in your hearing, a new 702 hearing; and you had no opposition to that.

MR. EDELMAN: I understand.

THE COURT: And now we're at the hearing.

MR. EDELMAN: I understand.

THE COURT: And I think you waived any right to separate the interests of your client from the interests of the other defendants for purposes of this hearing.

MR. EDELMAN: I understand. I still don't -- I do still join with the Government's objection to that last question.

THE COURT: All right. Thank you.

BY MR. DRISCOLL:

Q. Mr. Oulton, are you aware of any directives that were in place at the time that these samples are tested by Ms. --

MS. MAGNELLI: Your Honor, again I'm going to have to object. "Directives" is basically asking the same question without saying the word "DEA." If she's -- if the Court is not going to consider whether she was following any protocol, then directives don't matter.

If the defense wants to ask the witness about microcrystalline tests in general, it's one thing.

I would also suggest it's irrelevant because that wasn't done here and Ms. Irby is not on the stand and she did the testing, and she would be the appropriate witness to testify as to why she didn't use it.

THE COURT: Thank you. Response?

MR. DRISCOLL: Your Honor, I objected to this witness. I objected to this witness' testimony completely. If the Court

would refer to page 143 of the prior transcript on the very grounds that it seems we're here today: that the Court is saying that the industry standards aren't relevant; that the American Society of Crime Lab Directors standards aren't significant; it's whether or not the testing procedure was reliable. And yet when I attempt to examine the witness regarding -- concerning reliability, it seems that I'm in a Catch-22 situation there.

THE COURT: Any reply?

MS. MAGNELLI: No, your Honor. I mean it is true that he objected to this witness; but it was always clear that he didn't perform the tests. He is looking at the data as another competent chemist and testifying about that. He doesn't know why Ms. Irby did or did not do the tests. He is talking about the tests that were done. He can also talk about SWGDRUG as the chair. So these have been what the defense has asked about. They asked about the microcrystalline test in the past. But at this point, I don't understand how it's relevant to this hearing. It wasn't done. He's answered questions about it. It's less discriminating. I would ask the Court to uphold the objection.

THE COURT: All right. We can have a series of objections with regard to relevance, and that can proceed throughout this hearing. Technically, the Rules of Evidence do not apply in this hearing. Technically, the Court sorts

through the evidence that's presented and only considers that is which is relevant. I have tried to share with you that which I believe is relevant to this determination; but from this point forward, I'm not going for entertain any more motions or objections for determination of relevance. I will simply determine that in my ruling.

Please proceed.

MR. DRISCOLL: Thank you.

BY MR. DRISCOLL:

Q. In your earlier testimony, you testified that the microcrystalline test -- you didn't say "test" -- the microcrystalline is considered a Category B examination I assume. It is corroborative information, but it's no longer considered a qualitative Category A technique?

A. I think I can clarify --

Q. Do you remember the testimony? That was the question.

A. It was similar to that. Not exactly that.

Q. I'll read and see if you remember it, then.

"The microcrystalline is considered a Category B. It is corroborating information, but it is not no longer considered a qualitative Category A technique."

Do you remember that answer?

A. It is considered a Category B; and yes, I do -- I remember that answer, yes.

Q. All right. By whom is it not -- no longer considered a

qualitative Category A technique?

A. By SWGDRUG. The members 20-plus members voted and voted that it falls under the Category B because it is less discriminatory.

Q. I beg your pardon?

A. Because it is less discriminatory.

Q. And when was that vote?

A. That was actually before I even became on the board of SWGDRUG; so it's been probably, I'm going to say, in the early 2000's.

Q. Was that opinion communicated to your subscribing members?

A. Absolutely. In all forensic science meetings that we attended, that they attended at the time, it was communicated. The voices of the all the microcrystalline test analysts were able to be heard and considered. And ultimately we determined it fell under Category B.

And just to clarify, you don't actually look at the molecule itself under the microscope. You're doing something very similar to a color test. You add a substance to a chemical that produces a reaction. And you actually are looking at a certain formation of a crystal, so if it's a cross, if it's a pyramid, if it's this. That's what gives you the indication. But you're not looking at the molecule itself. You're looking at the formation of a crystal, which could be in some cases subjective. That's why it falls under Category B.

MR. DRISCOLL: Thank you. No further questions, your Honor.

THE COURT: Is there anyone else who would like to cross-examine this witness?

MR. BAKER: If I may, your Honor.

THE COURT: You may.

CROSS-EXAMINATION

BY MR. BAKER:

Q. Does ASCLD set forth any industry or discipline standards for the testing of methamphetamine?

A. Just for clarification, you said "ASCLD." There is actually two organizations. There is ASCLD, which is the American Society of Crime Laboratory Directors; and then there is the American Society of Crime Laboratory Directors Laboratory Accreditation Board, and that's ASCLD/LAB.

So if you're asking about ASCLD, the answer is they set standards for promotion of forensic sciences. I mean they don't set standards. Excuse me. They promote training and education for crime laboratory directors.

Q. How about ASCLD/LAB?

A. Could you repeat the question? I'm sorry.

Q. Do they set forth any standards -- do they set forth any industry or discipline standards for the testing of methamphetamine?

A. Industry or discipline --

Q. Yes.

A. -- is that the question?

They use several items. They consider ISO 17025 in their accreditation program. They've actually drafted supplemental requirements that supplement the 17025.

And they also have a -- as far as discipline, I wouldn't say necessarily discipline; but there is a code of ethics that they promote. They would hold laboratories accountable to their accreditations. So if, for example, they didn't meet certain requirements, they would revoke accreditation. So there would be some forms of revoking accreditation when they're not meeting what they say they're supposed to meet.

Q. So I take it that the answer to your [*sic*] question, is that the supplement to ISO 17025 does set forth industry or discipline standards for the testing of methamphetamine.

A. They are additional requirements that ASCLD uses to accredit laboratories.

Q. And when someone testifies that they're in compliance or that their laboratory has an ASCLD certification, implicitly they're saying that their testing meets those standards set forth in the supplement to 17025. Is that correct?

A. The process of ASCLD/LAB is once they've accredited a laboratory, that is what that means: that they're meeting those set of standards. That laboratory is meeting those set of

standards.

Q. So the accreditation process incorporates the industry standards or the discipline standards that ASCLD has set forth in those documents. Is that correct?

A. I'm not sure about the way you phrased it, but ASCLD/LAB uses those documents to accredit laboratories.

Q. And those documents contain standards for which the lab has to conduct its testing; is that correct?

A. Yes, and it's a voluntary process to be accredited by ASCLD/LAB, and it is those standards that they choose to accredit to.

MR. BAKER: I don't have any further questions. Thank you.

THE COURT: Thank you.

Anyone else?

MR. EDELMAN: Nothing further from Mr. Beltran, your Honor.

THE COURT: Redirect?

REDIRECT EXAMINATION

BY MS. MAGNELLI:

Q. Mr. Oulton, I want to clarify a few things right off the bat, and then I'm going just to ask you a few questions about some of the questions you were asked on cross.

Just to clarify, we use the word "standard" a lot in this hearing. Can you clarify the difference between an ISO

standard, a standard that's used during active analysis, and a reference standard?

A. Yes. We do interchange those words quite a bit.

When I use the word -- when we've used the word "standard" an in accreditation standpoint, we call those lines, those items as standards. We actually call them clauses or the ISO 17025 requirements. So that's what we meant when we refer to those.

When we refer to reference materials, for example, using known verified methamphetamine hydrochloride, we commonly refer to those as standards. They're better referred to as a reference material, something that's been verified, authenticated, proven to be, and then used in further testing.

Did I cover them all?

Q. The last one is a standard one might use during actual testing.

A. I'll not sure I follow.

Q. I just want to make sure that we now have all the definitions of "standard" that you've been using.

A. Yes. I think -- well, those are ones I can think off the top of my head.

Q. When you say "reference materials," these are the types of things you talked about you can find in a science journal?

A. "Reference materials," I was referring to actually purchasing them from known vendors that sell methamphetamine,

for example, that we can use to compare to. And those would even be used in reference materials or reference journals. So we would go to scientific journals and see that they've used standards or reference materials to make their conclusions.

Q. Okay. I want to clarify the difference between ASCLD/LAB, International Organization of Standardization, and SWGDRUG. Can you clarify those three entities succinctly?

A. I will try.

Starting with the Scientific Working Group for the Analysis of Drugs, they are an independent organization that is devised of several, 20-plus, forensic scientists from across the world. And their mission is to draft international standards for the identification of drugs. Their also mission is to promote them and go to meetings and discuss and talk to the community and ask for opinions, and we can weigh all of that when we make our recommendations.

ASCLD/LAB is an accrediting body that is a voluntary process that most labs in the U.S. are reaching out to accrediting bodies, asking them to come in to look at their operation, assess the quality of the laboratory, to show that we're following set recommendations or set standards, ISO 17025 and supplemental requirements, those types of things.

In ISO, ISO clauses, ISO standards, as we call them, they would be done by another body that's an international body that drafts -- For example, ISO 17025 is for testing and

calibration laboratories. So a body has got together, devised those clauses, and wrote a standard. And it gets updated roughly every five years, to be incorporated. And ASCLD/LAB is -- just chooses that particular standard to accredit to.

For example, you've heard of ISO 9000 and 9001, and people even promote that I'm ISO certified or 9001 compliant. There are all sorts of accreditation standards out there, and accrediting bodies go in to assess their accreditation towards those standards.

Q. Again, just for clarification, a lab can use the SWGDRUG recommendations, but they're not accredited to SWGDRUG recommendations; is that right?

A. That's correct. ASCLD/LAB really only uses the two standards that they accredit to, the supplemental and the 17025, not necessarily the Scientific Working Group, because they're recommendations, they're not necessarily standards.

However, they do -- When they go into the laboratories, they do verify that they are following was internationally accepted for the identification of drugs. So, for example, if they went in and found that a laboratory was only testing using a Category C test, that would not be sufficient. And I would expect the laboratory to obtain -- to receive a CAR, corrective action, because it's not sufficient alone to identify a drug.

Q. I want to get away a little bit from ASCLD/LAB and clarify.

SWGDRUG makes recommendations?

A. That's correct.

Q. And they're updated fairly regularly, maybe twice a year?

A. Twice a year we're updating, yes.

Q. Are they published on line?

A. They're publicly available.

Q. And any lab can take them and run their lab according to those SWGDRUG recommendations; is that right?

A. In fact, we're finding most labs actually copy and paste the recommendations and put the recommendations into their policies.

Q. And that doesn't mean that a third body like an accrediting body will come in and say you are accredited to SWGDRUG. That just means that lab chooses to use SWGDRUG recommendations, and that's an apart from any type of accreditation; is that right?

A. That's correct.

Q. Okay, sir. Do you have the exhibits at the stand?

A. I believe so.

Q. Would you look at Exhibit 2.

A. I have that in front of me.

Q. Can you turn to page 6 as it's identified by romanette?

A. I'm sorry. You said page 6?

Q. As identified by romanette. By Roman numerals.

A. Yes.

Q. Is there an electronic signature on that page?

A. There is.
Q. Do you recognize that?
A. I do.
Q. Whose is that?
A. That is my signature.
Q. And what position do you hold with SWGDRUG?
A. I'm the chair of SWGDRUG.
Q. And these recommendations that are you looking at: When were they issued?
A. This particular version was issued January 27, 2011.
Q. And were they good through April of 2011?
A. Yes, they were.
Q. And these are the actual recommendations that were posted on line; is that correct?
A. That's correct.
Q. And did you have any role in creating these recommendations?
A. I am one vote of 20-plus members, yes.
Q. And do you know whether or not Ms. Irby's lab testing was in compliance with these recommendations?
A. Yes. I've actually reviewed her packet that contained data and analysis and records and observations. And certainly in my opinion she has absolutely met the recommendations and then some. Three times what's required.
Q. Where a you do you mean by "three times what's required"?

A. Well, for example, to identify a drug, SWGDRUG recommends that you have to do at least a minimum of two tests. And in Ms. Irby's testimony, and as I was here listening, she had done in essence six independent tests that concluded the presence of methamphetamine.

Q. Now, you were talking about categories A vs. B vs. C; is that right?

A. That's correct.

Q. Now, why is it, based on your experience with SWGDRUG and creating these recommendations -- why are there so many in each category?

A. Why are there so many in each category? Well, we look --

Q. Why divide it the way it's been divided?

A. It was divided in discriminatory power. For example, an infrared spectrum is very, very unique to a molecule, so it gives us information about the molecule itself, it gives us a fingerprint, in essence, that can be compared to known reference material. So it's very, very definitive, unlike a color test, which would be the Category C, which gives us a color that turns a color that may, you know, five, ten, twenty other compounds might turn the same color, so it's not as discriminatory, for example, as an infrared.

Q. And can you compare the word, when you say "discriminatory" to "confirmatory"?

A. "Confirmatory" is another word that's probably interchanged

quite a bit. So confirmatory in some aspects, I think in this testimony, Ms. Irby testified was more referring to Category A tests as a confirmatory test to conclusively identify based on the highest discriminating power.

Other people might actually define "confirmatory" as actually all the tests because all of them technically confirm the presence of methamphetamine. Even it turned orange/brown with a color test, that's confirming that it's an amphetamine molecule.

The GC retention time that Ms. Irby testified to: That is confirming that again it is coming out at the same time; therefore, it is giving the same indication.

So it is an interchange of words. And to clarify, for most of what I read in the transcript, it was being used to describe Category A tests.

Q. And when you say they are all in a sense confirmatory, is that because -- Well, can you explain to me whether or not these tests can actually be taken out of context without looking at all the other tests?

A. Yes. Absolutely all tests -- that's the reason we do several tests and one of the reasons we came up with two independent tests, as opposed to just one discriminatory test, is a quality assurance measure. So if you've got one that shows that it's methamphetamine and another one shows that it's methamphetamine, you've got a very high assurance that it is

methamphetamine. If any one of those tests in aggregate show negative, that causes the analyst to stop and say, We've got to figure out what happened. Why did this particular test -- let's say one of out of the six -- came out negative? We can't make the call until we've determined was it an instrument problem, was a reagent problem, what would have caused this negative test to not be?

So actually, all the tests are extremely important. For example, even with the mass spectrometer. We can't just look at a color test alone and make an identification. It has to be coupled with all the other tests. So the mass spectrometer gives us indication as to the molecule, as to the type of molecule it is, as to the fragmentation. That's coupled with the retention time that's associated with the gas chromatograph.

All of that is what actually makes the conclusion, not just any one of those tests. We need them all.

Q. All right. And again, for purposes of clarification, we talk about a lot about ISO 17025. You are a board member of ASCLD/LAB?

A. For approximately one more month.

Q. But you are currently; is that right?

A. I am, yes.

Q. Did ASCLD/LAB write ISO 17025?

A. They did not.

Q. Okay. And ISO has a supplemental requirement?
A. ISO does not. ASCLD/LAB has chosen to do supplemental requirements.
Q. Okay. And so those two combined are what they choose to accredit to?
A. Correct.
MS. MAGNELLI: Okay. Your Honor, I'd move into evidence or for consideration Exhibit 2.
THE COURT: Thank you.
BY MS. MAGNELLI:
Q. While I'm at it, let's look at Exhibit 3 real quick.
Are you familiar with Exhibit 3?
A. Yes, I am.
Q. How are you familiar with Exhibit 3?
A. I have read the document, and I actually know several of the authors.
Q. Okay. And have you looked at Ms. Irby's lab testing, the data packet as we are calling it, as compared to Exhibit 3?
A. I did do that prior to the May hearing, yes.
Q. You had done that.
A. Yes.
Q. You have done that. Yes?
A. Yes.
Q. And this document: It's available publicly on line?
A. Yes, it is. Yes.

Q. And do you know based on your knowledge, training, experience your knowledge of authors, in fact -- Well, let me ask you this: Do you know whether or not labs utilize this?
A. Of course, yes. UNODC does publish many recommendations on their web site. UNODC is actually one of the members on SWGDRUG. So we have a member that participates, and we work sort of hand in hand.

Their mission is quite different from ours in the aspect that they actually are really tailoring towards third world countries or laboratories with minimal, not state-of-the-art instrumentation. So they're -- their recommendations are really more for that.
Q. And do you know based on your review and your knowledge whether or not Ms. Irby's testing packet complies with the publicly available recommendations?
A. Yes. As I've read through this, I felt that she did without doubt follow all the recommendations that they had.
Q. Do you recall what her conclusion was?
A. She concluded methamphetamine.
Q. Do you recall the more specific conclusion?
A. She concluded that it was approximately 11 1/2 pounds of a mixture of D and L isomers of methamphetamine hydrochloride.
Q. Do you recall purity?
A. She reported 99 percent and -- I think it was close to 99. 98.9 percent in the two exhibits that she analyzed.

Q. And again, for purposes of clarification, can you give us, I don't know, an example of an inanimate object that might be equal to size-wise?
A. I would say 11 1/2 pounds would be close to a basketball, roughly a basketball size of methamphetamine.
Q. All right. Do you recall Mr. Brown asking you about ASCLD/LAB reviewing five tests during the accreditation process?
A. Yes.
Q. I just want to clarify that really quickly.

When you testified that there were five reports, can you clarify whether you meant per chemist or per lab?
A. Yes. I actually meant five chemists -- or laboratory reports per chemist in the laboratories. So if there are 30 chemists, they're going to pull 150 of all of them, and they're going to evaluate all of those results.
Q. And do you recall Mr. Driscoll questioning about whether Attachment 2 to Document 162, which was Exhibit 1, Ms. Irby's declaration, the actual lab testing packet attached to that -- do you recall him asking you whether or not that was a freestanding document?
A. I do, yes.
Q. All right. Is that a standalone packet with regard to other DEA documents?
A. Yes, it is.

Q. Can you explain, please, to the Court what you mean by that?

A. What I mean by that, for example, even taking SWGDRUG's recommendations, is when they write a report or a case record, it is to include all of the information that another peer or competent examiner could review it and reconstruct what happened and to form a basis of conclusion.

In this case, it was extremely well-detailed as -- in the description of the evidence as it was received, the weight of it, how many independent bags that there were, how she proceeded with her testing. She did color testing, proceeded with GC mass spec. She did that. She went on and completed and made a composite. She did confirmatory testing. The method parameters are listed inside of her document.

Everything -- everything is there that another competent examiner or peer could actually evaluate to show that without question the substance contained methamphetamine.

Q. Would you agree with me that it would be similar to showing your work in a math problem so the teacher could see if you did all the calculations correctly rather than just putting the answer down?

A. I would absolutely agree. All the work is there that another person could evaluate.

Q. Do you recall both in May and today Mr. Driscoll asking you about sort of a -- the superiority of a microcrystalline test?

A. Yes.
Q. Okay. You testified that what you can see in the test are actually crystallized patterns of sort; is that right?
A. Yes. The methamphetamine forms a crystal with the reagent that turns a certain shape.
Q. Okay. Now, with the microcrystalline test in mind, how does that compare to the GCMS Ms. Irby used?
A. In this particular case, it's not as discriminatory as a mass spectrometry.
Q. What is not as discriminatory?
A. The microcrystalline test. That's why we concluded that it falls under -- That's not to say it's not a good test. It is a good test. It does have some specificity. But it's becoming a little bit less used in the field because it is not as -- because it's almost an art. You have to recognize those crystals, the shape of them. And a lot of forensic scientists are not using that technique anymore because it -- in other words, it is not as specific or as discriminatory.
Q. It's reliable but outdated. Is that fair?
A. Yes. I would say it is reliable but outdated.
Q. And the GCMS: That produces a mass spectrum?
A. That's correct.
Q. And I want to clarify this term for the record again. Would you agree that the mass spectrum is actually a graphical representation -- is that right -- of ions that sort of

separated during this testing?
A. That's correct.
Q. A picture almost?
A. It bursts the molecule into pieces, and each of those pieces are measured and represented in what the spectra results in.
Q. And why is a spectra so discriminating?
A. Because it actually gives us information about the molecule itself. It gives us a structural information, molecular ion information, all different types of pieces that a chemist can look at and evaluate.
Q. Based on your knowledge, training, and experience, do you know whether analysts in your field forensic chemistry -- do they get specialized training to look for patterns and find problems in mass spectra?
A. Yes, they do.
Q. Are they trained to look for spectral variabilities?
A. Yes, they are.
Q. Do chemists become familiar with the idiosyncrasies of their machines?
A. They absolutely do.
Q. And why are these things important?
A. They're important for several factors. One because we do perform a service for the court to prove what the substance is and we want to be 100 percent accurate without any question.

So this is why we provide them with a tremendous amount of training, so that they can develop these skills and experience to be able to make these conclusions.

Q. And are there some spectra that are somewhat similar and that training helps you identify the difference?

A. Yes.

Q. Can you give me an example?

A. Yes. For example, even in mass spectrometry, there are several other what we call radio isomers, molecules that are very similar in structure, in some cases same exact molecular weight that do give similar mass spectrum patterns. They absolutely do.

This is why we talked earlier about the aggregate of tests. The combination of that mass spectrometer with the gas chromatograph portion gives us a retention time that is -- that combination is unique. There is research that's being conducted as we speak; that's been conducted. There is research that even shows that the mass spectrum is actually different from some of the other ones.

For example, phentermine is a good example. Phentermine and methamphetamine have the same amount of carbons and hydrogens and nitrogens, same molecular weight; but they do produce similar mass spectrometer results; however, they completely separate on the gas chromatograph part. So that combination of those two tests makes it extremely unique and

very discriminatory.

Q. Now, as compared to the microcrystalline test, can you compare the IRATR that Ms. Irby did?

A. Yes.

Q. Can you compare the discriminatory power?

A. Yes. In an IR, that's one of the strengths about infrared, is that the pattern that it produces is extremely unique. So phentermine and methamphetamine, for example, are nothing alike, as were the mass spectrometers.

I won't speculate, but that could be why Ms. Irby --

Q. That's okay.

This technique, the attenuated total reflectance, the ATR: Is that a fairly recent technique?

A. It actually came around after I got off the bench. So I never got experience with it. So when I was doing testing, I left doing the testing in 1999, and that's when it was coming out in the DEA laboratories.

Q. Okay. But you've done the infrared?

A. Yes.

I actually have done the ATR since, because I do force myself to be proficiency-tested every year; so I have since experienced it. And I got to tell you, it's fantastic.

Q. So you could still go back and take the bench and do an analysis; is that right?

A. I do it every year, yes.

Q. All right. And do you know based on your knowledge, training, and experience whether analysts receive special training to analyze spectra that have a number of closely related compounds, get a feel for that discriminating feature?
A. We absolutely do. We provide this training.
Q. Have you ever seen another infrared spectrum based on your knowledge, training, and experience of a substance that gives an identical spectrum to methamphetamine?
A. I have not.
Q. All right. And finally, we'll do two more quickly. Can you compare the HPLC to the microcrystalline test, please.
A. HPLC would fall under the Category B, so it would fall under the same category as a microcrystalline test. HPLC is used to separate multicomponents; for example, if there were several things in this mixture. In this case, there was really only methamphetamine and one other trace component; but if there was three or four different compounds, it would actually separate them all.

And the point of that is for -- As Ms. Irby testified, she used the HPLC to do a quantitative analysis to determine the purity. So she wanted to make sure that she could isolate the methamphetamine by itself from all the other compounds. That's why she chose to use the HPLC. It separates the compounds. She compared it to a positive control at the same time, a known reference material of methamphetamine. She

compared it at the same time and determined it at 99 percent.
Q. All right. And I think I missed something. Is there something the IR can tell about methamphetamine that none of these other machines can?
A. Yes, there is.
Q. What is that?
A. The IR actually can help us identify the salt form. So, for example, it determines -- we can determine that it's actually methamphetamine hydrochloride.
Q. Isn't it true that the GCMS cannot do that?
A. That is correct.
Q. And why is that?
A. What happens in the injection port on the gas chromatograph is the hydrochloride part essentially breaks off, and it races for the finish line. So it's only the methamphetamine that's left at the end.
Q. All right. And finally, the GCFID, the flame ionization detector: Can you compare that to the microcrystalline test that you've been asked about?
A. Yeah. It's similar to the HPLC, except in the gas chromatograph it's done in a gas phase. It separates multicomponents.

In the flame ionization detector, it's actually what its name suggests: It's a flame that the compound goes into, it burns, it produces some electrical signals that the

instrument measures, so it can tell when something is coming out. So it can determine if there is multicomponents, and it gives us specific times. You hit "Start," and let's say it takes three minutes to come out, which makes it somewhat specific, because cocaine comes out completely different from methamphetamine, completely different from heroin; so we use these categories of testing to help us conclude that it is methamphetamine without question.

Q. All right. Does the microcrystalline test have an uncertainty associated with it?

A. Yes. Microcrystalline does. That's why it's more in the Category B, because it is in some ways an art. For example, I did microcrystalline tests when I first started; but there is a certain experience that you have to have, and it's being lost over time. And it's only because the instrumentation is getting so much more specific and so much better. Category A techniques give us molecular information. The microcrystalline gives us a formation of a crystal, so it doesn't give us the actual carbons and hydrogens. It doesn't tell us molecularly what it is. It identifies what it is based on the formation of a crystal.

Q. Okay. And are there some uncertainties with the results of some of the tests that Ms. Irby did?

A. She did. She reported several uncertainties.

Q. And why is that important?

A. Essentially, uncertainty actually provides an assurance that the results are within a tolerance or a range that we've identified. So she did it for the period of determination. She concluded that it's 99 percent plus or minus, because any time we take a measurement, as she described in her testimony about measuring cups of flour, there is always a little bit of granules that might have fell out, any time we take a measurement. She also reported uncertainty for weighing because there is also an uncertainty associated with weighing. For example, and I've done this myself: You get to a scale at home and you weigh yourself and let's say it's 180 pounds, and you weigh it and you get back on and it's 179.5. And that's the answer I go with.

Q. So is an uncertainty number akin to an error rate?

A. Not necessarily. Error rates are -- I think in my mind are being misapplied across the forensic sciences. Error rates -- What they're really trying to refer to is, for example, like DNA. DNA would say that I've identified the DNA pattern with a certain percentage, one out of one million a chance that it's not that person. Uncertainty more so is referring to measurements that we are conducting. There is an uncertainty associated with every measurement that we do; and by reporting it, it gives us a better understanding as to where does the true value lie.

Q. So it adds to the accuracy of the results?

A. Yes.

Q. Now, when we talk about error rates, is there an error rate with regard, based on your knowledge, training, and experience, with regard to identification of a controlled substance?

A. SWGDRUG has come up with language that addresses this particular compound. There can be uncertainty associated with qualitative identification. For example, there are limitations with some of the methods. If you had a mixture of, let's say ephedrine or pseudoephedrine and you went to a mass spectrometer, the molecules are exactly the same. They're just isomers. So they would produce the exact same spectrum. So if you relied only on that test and the laboratory chose to report I've identified pseudoephedrine or ephedrine, there is an uncertainty because they didn't determine which one it was.

Now, the laboratory could then go and do additional testing to identify which one it was. So there is some uncertainty associated with it as long, as it is reported and accurately transferred. But what SWGDRUG says is as long as you apply appropriate method and, for unforeseen circumstances or human error -- and you do the right number of tests and you do the right tests and you understand those limitations, there is effectively no uncertainty in reported identifications.

Q. And based on your knowledge, training, and experience, did Ms. Irby apply appropriate methods?

A. She absolutely did. In fact, again, as I've said, three

times what's required.

Q. Okay. And do you see in your -- in the lab testing data based on knowledge, training, and experience any evidence that this substance was anything other than methamphetamine?

A. Absolutely not. All tests indicate the same thing.

Q. So you can accurately identify methamphetamine without using a microcrystalline test?

A. Absolutely, yes.

MS. MAGNELLI: Your Honor, I'd move for consideration Exhibit 3. I think I failed to do that earlier.

THE COURT: Thank you.

MS. MAGNELLI: Nothing further.

THE COURT: Thank you. Can this witness step down?

MS. MAGNELLI: Yes.

THE COURT: Thank you, sir. You may step down.

Further witnesses by the Government?

MR. BOMA: No, your Honor.

THE COURT: Are there going to be witnesses called by the defense?

MR. EDELMAN: Your Honor, if I may, it depends upon what the Court does next.

I believe at this point the Government has failed to meet its burden. Based upon the Court's prior statements and rulings and the requirements of the Government, they've asked the Court to allow them to present evidence of an opinion that

the substances that were -- may I go forward on this request, your Honor?

THE COURT: Well, you can if you'd like; but technically in a Rule 702 hearing, there is no opportunity to seek a judgment as a matter of law at the end of the presentation of the Government's case. And as a consequence, even if there were, I would defer in considering that argument until I had heard all of the evidence.

MR. EDELMAN: I expected you to say that, your Honor, and I tried to see if I could find any authority to conform with your statement, and I don't think I could find any. But as usual, I wasn't sure I was correct, but thought I would at least try.

So would you like me to stop, or continue trying?

THE COURT: You can make whatever record you want to make, but I will be deferring any determination as to whether the evidence is adequate until after I have heard all of the evidence that is presented.

MR. EDELMAN: Well, just to play it safe and to continue requesting, if I may continue and be brief, if the Court doesn't mind.

I think all of the evidence, or at least most of it, was a waste of time, based upon what the Court has commented on. There are no methods. The Court has indicated that -- The Court has indicated that it would not consider any methods of

the -- that the Government has presented or that the witness has considered, Ms. Irby, applying. And she stated that the only methods that she had considered pursuant to Rule 702 were methods that she memorized from her work at the DEA.

The Court also just indicated that she did not perform these tests that she formulated her opinion from -- was not from a DEA lab. There is no other lab. So consequently, there are no tests.

I don't know if it was from another facility or no facility at all; but regardless, if there is no methods, there is no -- they failed completely in sustaining their burden and we don't need to go further. All this testimony about accreditation and about Mr. Oulton sustaining that Ms. Irby performed this test and that test and all these other scientific tests and that some of them have been around for a hundred years are not relevant.

ASCLD/LAB accreditation is not relevant.

The recommendations of the UN 17025, of ISO, of any of these other accreditation or recommending facilities doesn't matter.

What matters is the methods that were utilized. There were no methods. It would be akin to baking a cake. You have a cake. How did you get to that cake? You mixed the ingredients. How did you mix the ingredients to get to the result? We have not been provided with any of that testimony.

And therefore, they have not met that burden. And I think it's only reasonable and common sense for this court now to -- to disallow that evidence.

THE COURT: Thank you.

We'll take a morning recess. When we resume, the Government can either respond to the motion that has been made by Mr. Edelman, or you can reserve your right to respond to that until the remainder of the evidence is presented.

We'll stand in recess for ten minutes, reconvene at 10:40.

(Recess at 10:29 a.m.)

(Reconvened at 10:47 a.m.)

THE COURT: Please be seated.

Does the Government care to respond to Mr. Edelman's motion at this time, or would you rather address did in closing argument?

MR. BOMA: Your Honor, we will reserve argument.

THE COURT: Okay. Evidence, then, for the objectors to the opinion.

MR. BROWN: Your Honor, at this time I'd like to call Ms. Janine Arvizu.

THE COURT: Please step up and be sworn.

(**Janine Arvizu** was sworn.)

THE COURTROOM DEPUTY: Please be seated.

Please state your name and spell your first and last

name for the record.

THE WITNESS: Janine Arvizu. J-A-N-I-N-E, A-R-V-I-Z-U.

MR. BROWN: May I proceed, your Honor?

THE COURT: You may.

DIRECT EXAMINATION

BY MR. BROWN:

Q. Good morning, Ms. Arvizu. How are you today?

A. Just fine.

Q. I'd like to ask you a little bit -- first of all, where do you live?

A. In Albuquerque.

Q. And were you asked to attend this hearing as part of expert services that have been -- that have been requested by Mr. Beltran represented by Mr. Edelman?

A. Yes.

Q. And can you tell me what is your profession?

A. I'm a laboratory quality auditor and consultant.

Q. And do you have a resumé that you either brought with you or had previously provided in this proceeding?

A. I have previously provided one.

Q. And have you seen that as referenced at Defense D, as in David, No. 5?

A. Yes.

MR. BROWN: Your Honor, that's the first three pages

of D5 -- are Ms. Arvizu's resumé.

BY MR. BROWN:

Q. Have you had a chance to review that document before you testified today?

A. Sometime ago, but yes.

Q. And does it accurately reflect your qualifications at the time it was earlier submitted, early in 2011?

A. Yes.

MR. BROWN: And, your Honor, I'd ask that the D5, the first three pages, be moved in as an exhibit for the Court's consideration.

THE COURT: Noted.

MR. BROWN: Thank you.

BY MR. BROWN:

Q. What does a laboratory quality auditor do?

A. I work for clients who use laboratory results to make important decisions. And they need to understand how scientifically valid the methods that were used are and how reliable the testing that was performed was so they understand how much confidence they can have in the results and ensure that the quality of the results is commensurate with the intended use of the data.

Q. And do you have an educational background that supports that experience and expertise?

A. I have a bachelor of science degree in biochemistry from

California Polytechnic State University at San Luis Obispo, an ABD in chemistry from the University of New Mexico, which is all but dissertation, all the coursework and examinations and proposal defense but not defense of the dissertation.

Q. And do you have any professional certifications?

A. I am certified as a quality auditor by the American Society for Quality and have been formally trained in the assessment of laboratory quality systems.

Q. Do you have an experiential background, an employment background that deals with quality analysis?

A. Yes. I established and managed a full service analytical testing laboratory for the Department of Energy and began working on interagency quality initiatives during my tenure there, subsequently had my own quality assurance consulting firm. And in that capacity, I served as program manager for a contract to provide quality assurance services to the Navy, where we evaluated and assessed and audited the performance of both government and commercial laboratories that provided analytical services to the Navy throughout the country.

Q. Have you published in this field?

A. I actually authored the quality standard that the Navy used as the basis for its determination as to whether or not to use a given laboratory.

Q. And have you provided training in the field of quality auditing and analysis?

A. A pretty broad range of training, both training technicians in a lab, training laboratory staff, training the users of lab data, to training lawyers and judges in the analytical quality issues associated with data.

Q. Have you previously testified in courts in the United States concerning this field?

A. In the United States and outside, yes.

Q. And approximately how many times?

A. I always forget to count. Dozens.

Q. And have those included both state courts as well as federal courts?

A. That's correct.

Q. In what fields of endeavor have you been accepted as an expert witness?

A. My testimony has been generally in the field of the quality assurance of analytical measurements and has ranged from sampling issues through analytical and reporting issues.

Q. Have you had an opportunity to be present during the testimony of Ms. Irby and Mr. Oulton during the pendency of this hearing?

A. Yes.

Q. And have you had an opportunity to consider the testing practices and methods employed by Ms. Irby to determine whether or not as a quality auditor they meet accepted standards?

A. Yes. Based on both the written materials provided and on

her testimony.

Q. With respect to the types of things that a quality auditor will consider, is it typical for a quality auditor to consider in analyzing results from a laboratory a particular lab's policies and procedures?

A. Absolutely.

Q. As well, is it also typical for a quality auditor to consider scientific standards as established by professional organizations?

A. Yes.

Q. In the absence of either policies and procedures or established standards that are published within the scientific community, is it -- are you still capable of doing an analysis of a particular scientific result?

A. Yes.

Q. So, for example, if there was a forensic analyst who was operating a self-standing lab, more or less a one-man show, in your evaluation as a quality auditor, could you make a determination of whether or not that freestanding forensic analyst produced an accepted scientific result?

A. Yes.

Q. Now, with respect to that and without reference to particular standards that might have been established at a laboratory or scientific organizations, are there generally accepted standards within the scientific community for the

completion of a drug test by a forensic analyst?
A. Yes.
Q. I wanted to ask you in particular with respect to the testing that was performed by Ms. Irby whether or not in your opinion as a quality auditor -- well, let me before I do that: In the absence of policies and procedures and accepted scientific organizational standards, does that place more or less import on the documentation to support a test that a forensic analyst reports?
A. It places more importance on clear and very, very complete documentation of the practices, because I don't have any written -- written approved procedures to rely on. It's kind of like when you were in school and you had to write everything down in your laboratory notebook that you did; so essentially the burden is that that analyst would have to absolutely write down everything that in most production labs is procedurallized. The requirements and the controls are all in a procedure so they don't have to write them down every time. Well, if you don't have that, then you have to write it down every time to essentially memorialize that record.
Q. So, for example, if we say that a particular forensic analyst conformed with accepted policies and procedures within a scientific community, that would be a shorthand for you so long as you were familiar with and knew those particular policies and procedures?

A. Yes.
Q. So in the absence of that, you would expect the description of the scientific process that was engaged in to be out of necessity more detailed without reference to policies and procedures and accepted methods by an established organization?
A. That's correct.
Q. With respect to the testing that was completed by Ms. Irby, have you had a chance to consider whether or not it was done in conformance with accepted scientific standards within the forensic analyst community?
A. Yes.
Q. And can you tell the Court with respect to her testing whether or not it did or did not meet the accepted standards within the forensic analyst scientific community?
A. Did not.
Q. Now, are you a forensic analyst?
A. I am not.
Q. Have you done any forensic analysis in the past?
A. No.
Q. And why, then, are you qualified or not qualified to give an opinion as to whether or not the testing conducted by a forensic analyst was done in conformance with accepted standards within the scientific community?
A. The field of quality assurance in analytical chemistry and in this discipline is essentially largely independent of the --

its field of application. For example, the principles of quality assurance apply to pharmaceutical labs and food testing labs and the labs that test production materials for manufacturing facilities and environmental labs and forensic labs.

The principles of how -- what practices you need to go through and the computational issues associated with determining accuracy, precision, specificity, representativeness -- these quality principles for data -- are independent of the field of application.

In fact, when you look at a number of seminal reference texts in the field of quality assurance, there will be hundreds of pages of discussion of quality assurance issues, like I've just described, and no reference to the specific analytical techniques from which the data are derived because the principles are applicable universally.

Intended use of the data is obviously different from application to application, and that's part of your obligation as a quality practitioner to understand the intended use of the data.

Q. And have you been called upon to do this type of analysis in the past with respect to forensic analysis of a drug sample?

A. Yes.

Q. Approximately how many times?

A. Oh, I don't -- I'll say dozens, again because I've not

tried to actually count.

Q. With respect to the testing of Ms. Irby, what, if any, practice requirements that are generally accepted within the scientific community of forensic analysis did she fail to meet?

A. First, the most sort of overarching issue was a failure to have complete documented procedures. And as we've already discussed, in the absence of that, you could write everything down; but clearly that wasn't done in this case.

So you either have to have in existence approved documented procedures that describe all the things I'm about to list, or you have to write it down each and every time.

In addition, subordinate to that, there was no documentation as to the performance characteristics of the methods, the measurement systems that she was using; that is in this case a series of analytical instruments. Typically what's included in procedures are specifications that that instrument has to meet before you use it. You don't get to just turn it on and assume that it's operating in a state of statistical control.

There are tests that have to be run, tuning that has to be performed, criteria that that instrument's performance has to meet before you run samples.

That's the first example of the kinds of information that's necessary.

Q. Let me ask you: So specifically you're talking about

technical performance requirements. You referenced tuning of an instrument. With respect to the -- one of the methods of testing that was used by Ms. Irby, the mass spectrometer, did she document and utilize technical performance requirements?

A. There were none apparent from the written record that we received and none described in her testimony. The reason tuning is so important to a mass spectrometer is because how and when you tune that mass spec. impacts the quality of the data and the quality of the tuning -- of the mass spectra that you get out of that instrument.

When you're tuning, what you're doing is essentially adjusting the voltage of the ion source. And it sounds very obtuse, but what it does is it affects the number of ions that are produced and the relative abundance of those ions that are produced. And so if you want to compare two spectra, it's important that you understand the tuning conditions under which those spectra were generated.

We have no evidence, no procedure that says we tune using this compound -- because there is a variety of different compounds available that you can tune to. We don't know what they tuned to or to what criteria, so we can't have confidence in making comparisons to other mass spectra.

Q. So, for example, if the tuning was not documented, that is -- is or is not an essential step in mass spectrometry testing?

A. If it was not done -- That's an essential step. If it was not documented -- that's part of insuring reliability.

So I'm not sure I'm answering your question directly enough; but if that it was done but not documented, then an independent user has no basis for assessing whether or not it was reliably done, because tunes can fail. Tunes do fail, in fact, with some frequency; and then you have to go back and retune the instrument.

We don't know whether that happened in this case because it was neither testified to nor documented as to whether there were even any requirements for a tune.

Q. From the vantage point of a quality auditor, if it's not documented, do you assume that it was done, it was not done, or neither?

A. In the absence of any evidence to the contrary, we assume it was not done.

Q. Just staying on the tuning aspect for a moment, is voltage important as a facet of a properly working mass spectrometer?

A. Yes, because it affects the mass spectrum that is produced.

Q. Does tuning an instrument like a mass spectrometer detect whether the voltage is at proper levels?

A. Yes. Essentially it sets conditions. For example, if you tune using PFTBA, which is just a specific compound that's frequently used as a tuning, and you check various ions and you achieve the stated criteria for those ions, then another user

can know that that mass spectrum that you generated was generated against an acceptable PFTBA tune that morning. So when you do an acceptable PFTBA tune that morning, you can have more confidence; that is, it's more reliable that that's a valid comparison.

Does that make sense?

Q. Within the scientific community, is there an acceptable frequency of testing for something specific as voltage through tuning of an instrument?

A. Yes. That's generally made on a program-by-program basis, depending on the importance of the data. Typically you'll see numbers on the order of every 12 hours or daily -- are commonly applied. In the instrument manufacturer's website, for example, it impresses upon in the training materials the importance of doing a tune if you're going to be identifying unknowns with the instrument in that operating condition.

Q. So in the absence of proof, from the quality assurance standpoint, that the mass spectrometer was tuned in conformance with the established time frames accepted within the scientific community, do you have an acceptable result, one that you can rely on in terms of the ultimate positive for methamphetamine chloride [*sic*], or do you not, from a scientific standpoint, have an acceptable, reliable result?

A. The absence of any either requirements for a tune or evidence of a tune renders any associated results unreliable.

Q. Now, I want to move on to ask you about another type of standard accepted within the scientific community with respect to stabilization period. What does stabilization period refer to?

A. A stabilization period is the fact that at night -- typically at night in a lot of laboratories, they'll turn instruments off. And in order to get things running the next day in a production lab, you'll go in and turn the instrument, you'll turn on the vacuum pump. It takes a period of time for the -- in the case of a mass spec. for the vacuum pump to do its work and bring it to an acceptable operating pressure; so it's something that's typically addressed procedurally in terms of ensuring that everything that is calmed down and in a state of statistical control and ready to start running samples.

Q. Which of the type of testing instruments that Ms. Irby employed -- and I believe there were six of them -- which of them is required to have an appropriate stabilization period before it should be utilized?

A. Well, I've already mentioned mass spectrometry.

It's not so much an issue for some of the other instruments. I really wouldn't call it a stabilization period, for example, for an HPLC. It's just achieving a stable analytical system.

So that's written in terms of what we just mentioned, technical performance requirements for the instrument.

Q. And from evaluating the data supplied by Ms. Irby and listening to her testimony, can you determine whether or not stabilization could -- or was an issue with respect to any or all of her testing?

A. Again, no information as to whether there were any requirements or what the actual conditions were for any of the instruments.

Q. So with respect to, then, whether or not the -- That should or should not have been included in the data or information provided?

A. That's the kind of thing that either as a requirement is either addressed procedurally or in a case-by-case basis in detail in the record.

Q. And from the standpoint of a quality auditor, would you assume that the results generated in the absence of such documentation that no interference occurred because of an inadequate addressing the stabilization period -- Do you have a reliable result, or an unreliable result?

A. It renders them on the unreliable side.

Q. With respect to the specific testing conducted by Ms. Irby, do you have an opinion whether or not she actually did or properly documented that the equipment was in proper working order and where required was calibrated and adjusted properly?

A. I do have an opinion based on both the record and her testimony, and that is that she was relying on known reference

standards, which, as we heard a little bit earlier this morning, means the analysis of standards that were run some period of time previously but not on the same day that you were turning it on and running it that day; and she relied on those rather than using known positive controls at the time the testing of these samples was performed.

Q. For any of her testing, did she use non-positive controls?

A. She did for the color tests and she did for the -- let's see. HPLC, it was calibration standards, not controls. Those are two different things. You cannot use a calibrator as control sample.

And she used -- let's see -- known controls for the GC in which she made an isotopic determination, when she was looking at D and L isomers.

Q. With respect to the infrared spectrometer, did she?

A. She did not.

Q. With respect to the GCIRD, did she?

A. No.

Q. And with respect to the GCFID, did she?

A. That's the one that she did. That's the D/L isomer determination.

Q. So with respect to the infrared spectrometry and the gas chromatograph, is there a standard in the scientific community for use of a known reference standard?

A. Yes: that each time you run unknown samples on the

instrument -- it's referred to in the discipline as a "batch" -- that each time you run unknown samples, you also include a known sample, a known reference sample, what we've been calling a "standard," to verify the performance of the instrument. It is not acceptable practice to verify that your instrument is working properly by running an unknown sample and getting the expected result. That -- that's really counterintuitive scientifically that you could verify that things are working okay because I got the result I expected when I ran an unknown sample.

If you get the results you expect when you run a known sample, that's scientifically verification that the instrument is working properly.

Q. Ms. Irby, though, did testify didn't she, with regard to the infrared spectrometer, that she used a library reference standard; correct?

A. That's correct.

Q. So within the scientific community, is that an acceptable substitute for using a known reference standard to use a library reference standard?

A. She used library reference standards, I believe, for the IR spectra. The problem with that is that I have no performance data to understand the resolution of the instrument at the time she was running it.

In the -- some of the other instruments, GC mass spec.

and others, she did not include a -- not use library searches but relied on a reference standard that had been run many weeks or months previously. That is specifically a practice that is contraindicated by the generally accepted scientific community, if you're testing unknowns.

Now, if you've got an analytical lab that supports a production operation, say a hops laboratory, for example, since that was one discussed earlier in this hearing, you have a known, essentially, product in stream -- it's a very defined stream of samples that are coming in -- it's not that you're looking for any possible compound that may be at issue. So you have a different quality assurance expectation in that kind of a circumstance.

In this circumstance, when you have essentially what is a complete unknown sample, the burden of proof on the scientists is to treat that like an unknown sample and to verify the -- any identifications through contemporaneously analyzed standards. That's required in published standards.

It's certainly my observation in practice at analytical laboratories all over the world. I think the FBI lab had that as a requirement as early as 1997, is the first time -- first that I'm aware that it was published specifically for controlled substance analysis; that you contemporaneously must analyze the reference standard at the same time as the samples.

Q. So would the library reference standard under these circumstances, given the level of documentation that you reviewed, be an acceptable substitute for using a known reference standard with the infrared spectrometer?
A. No.
Q. With respect to the known standards that, for example, you said were used on the gas chromatograph by Ms. Irby, why is the source of a known reference standard important?
A. Reference standards, because scientifically they're the basis for drawing a conclusion -- so how much confidence you can have in the origin and purity of that material drives essentially your confidence in the conclusions that you draw based against it. So that's why reference standards need to be traceable, as has already been discussed here. And that means that essentially there is a paper trail or pedigree that demonstrates that that material is of known and documented purity.
Q. So with respect to that which was described by Ms. Irby either in her testimony or in the written materials that were produced, did she utilize a reliable, in terms of the accepted scientific community -- a reliable known reference standard?
A. You can't draw that conclusion based on either the materials provided or on the testimony that was given in this case.
Q. Have you investigated whether or not there are reference

standards commercially available for methamphetamine chloride [*sic*]?

A. Oh, sure. Easily available. You can look it up on the record.

Q. Are there manufacturers that supply that?

A. Yes.

Q. And have you done so?

A. Yes.

Q. Have you investigated it?

A. Yes.

Q. And do these known reference standards, to kind of use a shorthand -- do they have a shelf life to them?

A. Absolutely.

Q. And what is it? What are we talking about when we talk about a shelf life?

A. The shelf life that everybody's familiar with on the carton of milk that you have at home. It doesn't mean that the milk spoils the day after, but it might, depending on your storage conditions, because if you didn't store that milk in the refrigerator, it's shelf life is going to be dramatically shorter than what was specified on the container.

So shelf life is a manufacturer's -- and this is an accredited manufacturer of certified reference materials; for example, Cerilliant in the case of meth: They will certify or essentially attest to the quantity of meth in a standard and to

the identification of the material -- that is, in fact it's really meth -- for a period -- their shelf life is three years if it's appropriately stored. And that means it's stored unopened at temperature of 20 degrees centigrade or less and in the dark. So those are the conditions under which that manufacturer can essentially certify that this is going to be what we tell you it is for that period of time.

Q. So if it's first used on August 18, 2011, does that mean in August 18, 2014, that it should no longer be used?

A. Yes.

Q. And so would testing a known reference positive standard like that -- would testing it every three years to see whether or not it was -- still had the characteristics of methamphetamine hydrochloride -- would that be an adequate substitute or override for the shelf -- the manufacturer's shelf life?

A. It may be. And there is conditions that have to be placed on that for that to be acceptable, because the problem is you're using it during that period; right? So there are periods of use during that three-year period where it's not sealed, where it's exposed to the light, where it's exposed to the atmosphere. Poor lab practices can introduce contaminants to the materials, so it may or may not be. And there can be within a lab's quality systems a means of essentially requalifying a standard, but it's a fairly rigorous process

against another NIST certified material.
Q. Than an I apologize if I asked you this: Did Ms. Irby adequately document or provide information in this proceeding that would lead you to believe that the reference standard that she employed in the GCFID testing -- I'm sorry -- in the gas chromatograph testing was acceptable and reliable from the standpoint of a quality auditor?
A. No. It was not possible to verify the traceability of any of these materials. And by her testimony, she did not remember whether or not the materials were purchased as certified reference materials from a commercial accredited supplier or prepared in-house by one of the DEA laboratories.
Q. I want to ask you with respect to the analysis of Ms. Irby whether or not she submitted or provided information adequate for the criteria and/or requirements for approval or rejection?
A. She did not.
Q. What are we talking about there?
A. Okay. That's essentially in very specific terms the criteria that laboratory analysts use to draw conclusions about results. In the case of qualitative identification, for example, using mass spectrometry, typically that is very explicit direction as to, in order to draw the conclusion that an unknown sample is methamphetamine, these ions must be present at a specified relative abundance; and if they're not then you can't call it meth.

It's not a question of just looking at the spectrum and saying, Yeah, it looks like meth to me. There are actually quantitative, very specific criteria that must be met; and those are set in advance. You don't get to sort of change the criteria as you go along. And those criteria typically include identification of the base peak, identification of other qualifying ions that were specifically chosen because of their specificity to the compound in question.

Q. And in terms of the data provided, for example, with mass spectrometries, did she provide the base peak that was evident in the methamphetamine hydrochloride -- that she determined was methamphetamine hydrochloride?

A. I'm not sure I understand your question. Can you try me again?

Q. Was the data that she provided adequate to confirm her analysis with regard to criteria and requirements to determine what the substance was?

A. No. There was simply the conclusion, but the empirical basis for that conclusion was not documented and again not procedurally specified; so she didn't either note on the data that she confirmed meth based on these specific ions being present at the expected M over Z ratio, which is just value, and at expected relative abundance. She just said, It's meth.

Q. Now, with respect to how you determine what an appropriate standard is within the scientific community, is your testimony

consistent with the accepted standards within the scientific community at large?

A. Yes.

Q. And how -- what resources did you use or how did you kind of research or investigate or form those opinions so that you can say to this court, Hey, I am able to articulate what is the accepted standard within the scientific community?

A. Because these standards have been adopted by, dare we say it, the standard organizations. It sets very specific expectations for what constitutes a reference material, what constitutes the kinds of quality control necessary to verify results.

I'm not sure I'm answering your question.

Q. Have you discussed with other -- with scientists these types of standards and requirements for valid forensic testing?

A. Sure. Valid analytical testing in the more general sense as well as in specifically to the forensic community. And it's actually -- it's actually written down on -- the sort of an introduction to Mass Spec. 101 on the website for the instrument manufacturer; that it explains to you why these -- You don't have to dig deep to find these kinds of requirements and these kinds of guidelines.

Q. We talked about positive controls and actually the manufacture of positive controls. The type of testing that Ms. Irby employed in some aspects did require the use of

positive controls?

A. The use of positive controls is always required.

Q. And she did not; correct?

A. Did not, with the exceptions that I've already mentioned.

Q. Thank you.

I want to ask you about mass spectrometry as a confirmatory technique for methamphetamine. Is this a difficult determination with respect to methamphetamine hydrochloride as a unique substance, or is it one that's relatively simple?

A. It's seriously complicated by some facts that are specific to that class of compounds. Mass spectra -- If you look at mass spectra for organic compounds, for things we encounter routinely, caffeine and a variety of other compounds, it's what I'll call a "data rich spectrum." There are a lot of ions, lots of little lines on the spectrum; and that gives you more information to assess how specific and how unique that test result is.

The problem with mass spec. on methamphetamine is that if you look at that spectrum, its got this one big peak -- and I could pull it out of one of the exhibits that has -- I think already been introduced. Ms. Irby's declaration has it attached. But it has one large peak at a specific and very low mass-to-charge ratio. Its on the left side of the spectrum. Well, that's where smaller fragments are found.

There is not a lot of information at the right end of the spectrum, which is where the higher molecular weight fragments, the more information-rich fragments are found, the ones that are more specific for purposes of identifying an unknown.

The problem with meth is you simply don't have enough information to draw a conclusion about whether or not it's meth unambiguously if all you're doing is direct injection of a straight unadulterated meth molecule, because that is a peak representing dimethylamine that can come from all different kinds of compounds, not just meth.

And in the scientific literature it's -- and in practice in forensic labs all over the country and as guidelines from a lot of standards organizations explain to you, when you don't get an information-rich mass spectra, you have to do something. You have to behave like an analyst and you have to do something to the molecule to make it more amenable to analysis.

In the case of meth, an example of what you could do is can derivatize it, basically put some other -- chemically bond some other things to that molecule so that when you break that apart, instead of just giving that one peak, you get a lot of peaks with higher mass so it's more descriptive, more useful for distinguishing meth from something else.

That's what's done in practice widely. That's off --

that's what's -- If you're going to do direct, just straightforward with no derivatization, you've got to understand that that's only a tentative indication. It does not confirm the presence of meth because you simply don't have enough information.

Q. And in Ms. Irby's testimony, does she describe confirming it under circumstances where she hadn't done the heightened examination that you described?

A. That's correct. In addition, you can't confirm it the way she did GC mass spec. because she didn't run a contemporaneous standard; so she had no retention time information to use as the basis for saying the GC is consistent with meth and the mass spec. is consistent with meth.

So she not only had issues with the mass spec. part, but the GC part, chromatographic retention times change over time as the conditions of the column change in accordance with conditions, so you can't use a chromatographic retention time from months ago as the basis for identifying something as meth today.

Q. So --

A. So she didn't have enough information to conclude conclusively that it was meth after her GCMS analysis.

Q. So she had peaks in data to tentatively indicate that it was methamphetamine hydrochloride; correct?

A. That's correct.

Q. And there is a --
A. Not hydrochloride. Just methamphetamine. Sorry.
Q. And that there is a technique that can be used in order to amplify the molecule so that you get a more definitive result?
A. That's correct.
Q. She did not employ that technique?
A. She did not.
Q. So from the standpoint of -- and are these statements that you're making with regard to testing methods -- are they generally -- the testing methods that you've just described: Are they generally accepted within the scientific community regarding forensic analysis of methamphetamine?
A. Yes.
Q. Did she conform or not conform, then, in her conclusions about what the substance was with the mass spec. testing with generally accepted notions within the scientific community?
A. For tentative identification, possibly, but not for confirmation.
Q. As a general proposition, did the quality standards -- is the quality of Ms. Irby's testimony sufficient to meet the standards within the generally accepted scientific community?
A. No.
Q. And with respect to the production of data, meaning providing to an independent examiner an amount of data and a quality of data, is that -- that which was produced by

Ms. Irby -- is that consistent with generally accepted standards within the scientific community?

A. No.

Q. And based upon that, do you have an opinion as to whether or not the quality of examination in terms of the results meet either generally accepted scientific standards of Ms. Irby's testing -- within Ms. Irby's testing?

A. I believe they do not.

Q. Now, you heard Mr. Oulton testify, for example, today that the number of tests employed by Ms. Irby exceeded the standards as established by policy recommendations of specific organizations.

A. Yes.

Q. And would you agree that in light of the fact that you do not believe that specific tests met the quality standards generally accepted because of the number of tests that were done that within the general scientific community that we can say that we have a reliable opinion that the substance tested was in fact methamphetamine?

A. That was a long question. Let me see if I understood it.

Q. So if you have --

A. Doing essentially an unreliable -- a whole series of unreliable tests taken as a group makes them more reliable?

Q. So you've heard the statement "The whole is only as good as the sum of its parts"; correct?

A. Yes.
Q. And in your testimony today, you have in particular discussed parts; correct?
A. Yes.
Q. Are there enough -- and some of those parts, for example, what we just discussed as far as reaching tentative conclusions on one test and saying tentatively it looks like methamphetamine, that's probably acceptable but conclusively it's not; but if we kind of look at the whole, what we're left with from a posture of a quality auditor, do we have enough within the those six tests to say within the standards of the generally accepted community that what we have here is reliable testing methods and standards?
A. Yeah, you're trying to -- The problem is we, as analytical chemists, have to draw a conclusion based on each discrete test. And if there is a degree of unreliability associated with those discrete tests but I have no way of quantifying that, I don't really have a way of assessing quantitatively the effect -- the overall impact of doing a lot of unreliable tests in series.

However, I will state that I don't believe that a conclusion that I'm a hundred percent accurate in qualitative identification without exception by virtue of doing more is scientifically supportable.

MR. BROWN: Thank you. I have no further questions,

your Honor.

THE COURT: Thank you.

Any further examination, direct examination of this witness?

MR. EDELMAN: Yes. I have a few, your Honor.

THE COURT: Would you please go to the lectern.

MR. EDELMAN: Yes.

DIRECT EXAMINATION

BY MR. EDELMAN:

Q. Good morning, Ms. Arvizu.

A. Good morning.

Q. I don't think you testified today that you also testified on April 19 here in the same case. Do you remember that?

A. I do.

Q. And you testified with regards to the same sample of methamphetamine. Do you remember that?

A. Well, I wouldn't call it the same sample but a sample from the same case.

Q. And same batch, let's say, of methamphetamine. Do you remember that?

A. A sample of methamphetamine from the same case.

Q. Okay. Methamphetamine was seized in this case. I think it was 12 separate packages.

A. That's correct.

Q. And you remember that those 12 separate packages were then

made into one composite. Remember that at some point?
A. There was a series of discrete sampling and composite preparations over the course of the two testing events.
Q. And it was never segregated for the sample or broken up into the same 12 samples for the testing -- for the tests now?
A. That's correct. In this case, that's not possible given what was previously done to the samples.
Q. And you criticized -- and that was done by Ms. Chan, a chemist out of DEA lab; is that correct?
A. That's correct.
Q. And you criticized those -- that tests -- those tests; is that correct?
A. I did a data quality assessment. I wouldn't call it criticize, but --
Q. Okay. And do you remember the Court disallowed or suppressed the results of the opinion of Ms. Chan?
A. That's my understanding.
Q. You were here when the Court issued a ruling. Do you remember?
A. Yes.
Q. And do you remember -- have you compared the -- your review of the information that you examined of Ms. Chan's bench notes and the scientific results of devices with the bench notes and scientific devices utilized by Ms. Irby?
A. Yeah. The level of information provided from both separate

analytical circumstances is very similar. The actual practices were a little bit different, some slight differences in analytical techniques that were used, obviously differences in the materials subject to analysis; but many, if not most, of my conclusions were the same simply because they shared the common characteristic of not running positive controls.

There were some differences. There was some blank contamination in the mass spec. the first time around. There was no blank run with the quantitation that was performed in this -- in this set of testing. That's a critical deficiency that would render those results completely unacceptable. So there were some differences. But by and large, most of the practices appear to be the same; namely, relying on reference standards that were run weeks or months previously.

Q. That's what I wanted to get at. Ms. Chan's sampling or testing was done, I think, in November or December of 2010; correct?

A. That's my recollection.

Q. And the testing -- and testimony and the hearing was on April 19, 2010 [*sic*]?

A. Yes, in April.

Q. And the results of the Court's ruling on April 19, 2011? Excuse me.

A. 2011, yes.

Q. And Ms. Irby's testing was done after the Court's ruling?

A. Yeah, just a matter of days after, if I recall.
Q. And does it appear that Ms. Irby changed any of her testing based upon the Court's ruling, took any of the suggestions of the Court or corrected any of her methods for lack of a better word to satisfy the Court's --
A. I don't know what Ms. Irby's practices were before that. But certainly in the testing she performed, it did not address any of the deficiencies that were identified in court.
Q. Thank you. All right.

Now, briefly: So we still had that composite that we were dealing with that Ms. Irby tested?
A. Yes.
Q. All right. Than that made the test, regardless of what equipment we used, invalid?
A. It impacts your ability to draw conclusions about how representative the results are of what was received.
Q. And do you remember in the Chan testimony on April your -- the Chan hearing on April 19 -- Do you remember if you testified that a visit to the lab would have been helpful for you to validate the actual -- that Ms. Chan or that the laboratory actually conducted any of the methods or procedures that Ms. Chan may have testified to?
A. I don't remember if I testified about that; but certainly a visit to a lab as auditor is always helpful in understanding in a very practical sense practices in that laboratory.

Q. Were you ever invited to the DEA lab for either set of tests?
A. No.
Q. And in the Chan hearing, we talked about the ISO 17025 standards, and I don't think Mr. Brown referred to those standards. He was referring to the generally accepted scientific standards.

Are those ISO standards the same or similar to the generally accepted scientific standards that you were referring to in Mr. Brown's questions and your answers?
A. Yeah, generally accepted scientific standards. That is the mechanism through which those standards were promulgated and distributed internationally, is through publication of standards such as that.
Q. The ISO?
A. Correct.
Q. Okay. And was there sufficient documentation in Ms. Irby's paperwork to reconstruct her practices and protocols, etc.?
A. No, there was -- there were no procedures. And as I already testified, the level of detail necessary to understand completely the actual practices performed in the laboratory were not documented or available by reference in a procedure.
Q. And do you remember assisting me in preparing my requests for discovery in this case?
A. Yes.

Q. And did we request that information?
A. Yes.
Q. And did we receive it?
A. Only in part.
Q. And had you received that information, might you be able to have been better able to reconstruct the testing methods and procedures to be able to satisfy the criteria set forth in the Rule 702?
A. Well, sure. If there are procedures that establish criteria, performance criteria that must be met prior to analysis and those kinds of things, then that would certainly improve the reliability of the results reported; but in the absence of those procedures, I can't just assume that those practices were all acceptable.
Q. Do the ISO standards allow laboratories and the chemist to memorize methods or to use some sort of a document to rely upon when performing the tests?
A. Quality standards don't prevent anybody from memorizing their procedures, but they do require that procedures be documented and approved and they do explicitly list the kinds of things which must be included in those procedures, many of which we've talked about today.
Q. And is there any reason why they have to be secret?
A. I can't imagine why in a forensic arena. There are certainly disciplines where the proprietary nature of a testing

method is a business advantage. For example, if they're developing new instrumentation or developing methods that they're trying to patent. So there are circumstances where I, as an auditor, have had -- where an audited entity has had a proprietary interest in keeping their procedures secret from competitors. And that's readily addressed through some sort of agreement to do that. So, you know, they still share them with me as an auditor.

Q. Is there a reason that you can think of for a forensic -- a public entity forensic lab to keep something like their procedures and methods secret?

A. If there is, I can't think of what it might be.

MR. EDELMAN: Thank you. I have nothing further.

THE COURT: Thank you.

Any further direct examination? I'm not seeing anyone stand up, so probably this is a good time for us to take our noon hour recess. When we reconvene this afternoon -- and we'll reconvene at 1:30 -- we will begin with cross-examination of Ms. Arvizu.

We'll stand in recess until then.

(Recess at 11:45 a.m.)

(Reconvened at 1:34 p.m.)

THE COURT: Please be seated.

When we recessed, we were getting ready for cross-examination of Ms. Arvizu. Are you ready to proceed?

MS. MAGNELLI: Yes, your Honor.

MR. DRISCOLL: If I may, your Honor, I would like to ask the Court's permission to pursue one short line of questioning on direct.

THE COURT: Any objection?

MS. MAGNELLI: No objection.

THE COURT: You may proceed.

MR. DRISCOLL: Robert Driscoll on behalf of Mr. Pelayo.

DIRECT EXAMINATION

BY MR. DRISCOLL:

Q. Good afternoon, ma'am.

A. Good afternoon.

Q. I would invite your attention to Government's Exhibit 1, which is before you, or the Government's exhibit package, and then please invite you to the Exhibit 1 portion, page 19, 20, and 21, and ask you what you find there, please.

A. 19, 20, and 21 of 76? Are those the correct pages?

Q. Yes.

A. It's a forensic chemist's worksheet, three pages of essentially continuation of the same form.

Q. Do you see an author and a date?

A. Let's see. I'm not sure how you pronounce her name. Shana Irby, reported on April 26, 2011.

Q. And what does that appear to be to you?

A. This appears to be the contemporaneous record of the testing performed by Ms. Irby on the work in this case.

Q. And are you familiar with a term, maybe a term of art, with reference to scientific reports; and that term of art is a self-supporting document or a self-sustaining document?

A. Familiar with it.

Q. And what is your understanding of the use of that term?

A. A document that essentially stands of its own weight or a set of documents that essentially presents a complete picture of the analyses in question.

Q. And you have been present throughout these proceedings and specifically present when Mr -- predecessor witness Mr. Oulton testified?

A. Yes.

Q. And do you recall Mr. Oulton testifying concerning the exact documents that I've invited you to review and his testimony being that that -- those three pages, 19, 20, and 21, are self-supporting documents?

A. I don't know if his specific reference was to the three pages or to Ms. Irby's entire declaration. I didn't hear carefully enough to know how they qualified that exhibit.

But this exhibit in its entirety does not constitute a complete auditable record of the work that was done in this case.

Q. And what if you combine the three pages, page 19, 20, and

21 of Exhibit 1, with the declaration? Then do we have a document or a body of work that you consider consistent with your understanding of the term self-supporting document, a self-supporting document?

A. No.

Q. And why don't we have a self-supporting document, contrary to the testimony of Mr. Oulton, please.

A. From the information presented, you don't have the level of detail necessary that would typically be provided in a procedure. There is not traceability documentation demonstrating the traceabilities or the scientific acceptance of the standards that were used. Those are examples.

Q. And so when you were present and recall, if you recall, my questions of Mr. Oulton regarding the source of what was -- what is alleged to be a known sample, what's lacking is the condition of that source, that source reference material; the age of the material; the conditions of, for instance, whether it was in the light or dark or whether it had been accessed before, those sorts of things, are absent in the exhibit and in the declaration?

A. That's correct.

Q. And these insufficiencies render the documents not self-sustaining or self-supporting; am I correct?

A. That's correct.

THE COURT: Is there anyone else who wants to engage

in direct examination?

All right. We're moving to cross-examination now.

MS. MAGNELLI: Thank you, your Honor.

CROSS-EXAMINATION

BY MS. MAGNELLI:

Q. Ms. Arvizu, picking up on that point briefly, you just testified that that document is not self-supporting, it does not have an auditable record; is that right?

A. Correct. It does not establish a complete audit trail.

Q. Okay. And that's how you're looking at it, as an auditor; correct?

A. That's correct.

Q. Not at a chemist; is that correct?

A. Oh, I'm a chemist auditor.

Q. I understand that. But you're not looking at it a chemist. You testified that you're working as an auditor; is that right?

A. In conducting an assessment of laboratory work product, my training s an auditor is specifically to the assessment of laboratory work. For example, as an auditor, I would not be in a position to go audit bridge construction because that's not my area of expertise. My area of expertise is specifically related to analytical measurements.

Q. It's actually related to energy and environmental type of analysis, isn't it?

A. That can be one of them, yes.

Q. But you have no training in forensic chemistry whatsoever?
A. I have training in the underlying disciplines. As I understand forensic chemistry, it is the practice of chemistry intended for introduction in courts of law, the practice of toxicology in introduction of courts of law, the practice of a variety of scientific disciplines as applied to the legal system. And that's not a legal answer, but that's my very practical answer.
Q. Well, you've testified before that you've never analyzed a controlled substance; correct?
A. I have not.
Q. And you've testified before that you have never audited for accreditation a forensic lab; isn't that correct?
A. I have audited the work product of innumerable forensic labs. I have not conducted an on-site audit for accreditation purposes.
I thought I heard you say "accreditation" in there.
Q. You did. Yes, ma'am.
A. Okay.
Q. So is it safe to say that when you've audited data from forensic labs, it's been for defense; is that right?
A. Yes, ma'am.
Q. Okay. So you've never actually walked in, independent of either the defense or the government, and audited a lab for accreditation for a third party?

A. A forensic lab?
Q. Yes.
A. No.
Q. Okay. So again today you're testifying as an auditor -- is that right -- and not a forensic chemist?
A. That's correct.
Q. So when you talk about these documents not being self-supporting, you're not actually reviewing them as another competent chemist might review them. You're reviewing them for auditing purposes; isn't that right?
A. No. As an auditor, what I'm doing essentially is conducting what's called a data audit and making a determination as to whether the final result reported by a laboratory stands of its own weight; if that complete audit trail exists to support exactly what happened to that lab, that sample from the time it was originally collected to the time the result was reported; is there a complete and consistent audit trail to understand who did what to it when and in accordance with which criteria.
Q. So you're looking at the final result to see if that's reliable?
A. Yes.
Q. Okay. Do you understand that that is not at issue here today?
A. I don't make any claim to understand the legal issues. I

simply am trying to testify to the scientific reliability of the results that were reported in this case.

Q. Now, auditors don't actually make scientific conclusions; isn't that right? They look at a standard and see whether or not a lab follows that or not?

A. In the case of auditing for, for example, if you're auditing on behalf of an accrediting agency, that's exactly what you do. But you can't divorce yourself from the underlying science, because that's the difference between -- You've heard testimony earlier about ISO 9000 and ISO 17025. The big difference between those two standards is the technical performance part of 17025. You need to demonstrate technically and prove technically that you're capable of making those conclusions.

Q. Okay. So you just mentioned ISO 17025, and we've heard testimony that there is a supplemental requirement; is that right?

A. Yes.

Q. And you don't have that supplemental requirement?

A. I do not.

Q. Okay. So you actually don't have all the standards that ASCLD/LAB accredits to; is that right?

A. I do not.

Q. And you would not qualify as a technical assessor for ASCLD/LAB; isn't that correct?

A. That is correct.
Q. Because you don't have any experience in a crime lab or in the forensic chemistry discipline?
A. That's correct, as applied by ASCLD/LAB.
Q. Correct. As ASCLD/LAB?
A. Yes.
Q. Okay. So I want to talk about ASQ for a moment. You, I think, indicated you were still certified by ASQ?
A. Yes.
Q. Is that right?
A. That's correct.
Q. And you are a member of their energy and environmental division; is that correct?
A. No.
Q. You are listed on their web assignment as member of the energy and environmental division. Is that an error?
A. It must be, because I just renewed a matter of a couple of weeks ago, and I am not; so I don't know if there was a problem on their end.
Q. Okay.
A. But I'm a senior member of ASQ. I'm not affiliated with a particular section.
Q. Okay. And ASQ does not audit for accreditation forensic labs; is that right?
A. That's correct.

Q. Were you at some point --
A. They're not an accrediting agency.
Q. Correct. They don't audit forensic labs.
A. No.
Q. All right. And were you a member of their energy and environmental division at some point?
A. I was in years past, yes.
Q. Okay. I'm going to have to apologize. I'm going a little bit out of order, and this might not make a lot of sense; but I'm trying to encompass everything that was asked of you as well as my own questions, so bear with me, please.

I want to talk a little bit about your education. You were asked several questions about the educational background that you have to support -- or in your CV. Do you remember that?
A. I'm sorry. I missed part of your question.
Q. Your educational background: You were asked about that --
A. Yes.
Q. -- in terms of your CV, and you were asked about your CV?
A. Yes.
Q. Now, it's my understanding that you have an undergraduate degree in biochemistry?
A. That's correct.
Q. From 1976?
A. Yes, that's correct.

Q. And biochemistry: That deals with the chemical processes of a living organism?
A. Yes.
Q. Okay. Now, you talked about an ABD in chemistry from the University of New Mexico; is that right?
A. Yes.
Q. And you've actually testified about that in numerous cases; is that right?
A. Testified about what? I'm sorry.
Q. Having an ABD in chemistry.
A. Yes.
Q. Okay. Now, you've testified that's an all but dissertation, and I just want to understand a little bit. From your CV, it's not clear what years you attended the University of New Mexico. Could you tell us, please.
A. Oh, dear. Let's see. I think I started -- I didn't start in '76. There was a year delay, so I would have started in '77, I guess. I'm really, really bad with dates, unless there is some big event I can tie it to. And I think I was there -- well, I just -- until I went to Idaho.
Q. Okay. And your CV lists EG&G in Idaho starting in 1982?
A. Okay. Yeah. EG&G was the operating contractor for the Department of Energy's laboratory there.
Q. And that's in Idaho. Is that correct?
A. Yes. I left straight from graduate school to go there.

Q. So you were at UNM for about five years?
A. Yes.
Q. And you testified about the dissertation. How many semesters did you actually completely of the coursework?
A. I don't know. I don't remember specifically how long I took courses. I'm guessing it was probably about two years' worth of coursework --
Q. Okay.
A. -- on a full-time basis.
Q. Okay. And correct me if I'm wrong, but for the graduate chemistry department at UNM, after you finish the coursework, you take a series of examinations; is that right?
A. That's correct.
Q. And after the examinations, you write a research proposal, and that can either be accepted or declined?
A. That's correct.
Q. Did you write a research proposal?
A. Yes.
Q. What was the topic?
A. It dealt with fluoro -- amino fluorene compounds and their similarities to some other compounds near them on the periodic chart. It basically was a further application of some of the work that I had done.
Q. Okay. And was that accepted?
A. Yes.

Q. And was it accepted the first time?
A. Yes.
Q. And who was your research advisor?
A. Robert Paine, P-A-I-N-E.
THE COURT: Counsel, is this for discovery purposes?
MS. MAGNELLI: Not at all, your Honor. These are for qualifications.
THE COURT: Well, please move along.
BY MS. MAGNELLI:
Q. And you said you had an ABD, and in the first hearing you testified that you are a candidate for the Ph.D. program; is that right?
A. It's -- what it is is it's admitted to candidacy once you've completed all the exams, course work and exams and qualifiers.
Q. Okay.
A. ABD is just an indication that I didn't defend a dissertation.
Q. Isn't it true that UNM doesn't actually offer or bestow a certificate, title, designation, or degree called ABD?
A. That's correct. That's correct.
Q. And isn't it true that UNM requires Ph.D. candidates to get their Ph.D. within five years?
A. I believe it's ten, but there is a time limit.
Q. Okay. So would it be correct to say your ABD status has

expired?
A. It's not -- it's not a degree, so I don't know how that -- what I'm trying to convey is that I completed the academic coursework through admission to candidacy but did not defend. If that -- may be a term of art. That may not be the best way to do it, but --
Q. Well, let me ask it this way: Isn't it sort of a loose term that's used between research advisors to talk about their current Ph.D. candidates, someone that has an all but dissertation but is an active candidate for Ph.D.?
A. I've not heard it used in that way. I was actually advised to do it this way.
Q. Would it surprise you to know that the UNM graduate chemistry department considers that a loose term that's only used on campus?
A. Only on UNM campus? That would surprise me a lot.
Q. All right.
A. Because I see it used in throughout the country.
Q. You see it used on people's CVs?
A. Oh, yeah.
Q. Would it surprise you to know that your status has expired?
A. Oh, not at all. My status of being eligible for a Ph.D., you mean?
Q. Yes?
A. Yes, that's correct.

Q. Okay. And just to be clear, you've never worked in a forensic lab in any capacity as quality manager or anything?
A. That's correct.
Q. You've never managed a forensic lab?
A. No.
Q. And as you testified, you're not familiar with the law, you're not an attorney?
A. Not at all.
Q. You're not a member of the law enforcement community?
A. No.
Q. And when was the last time you actually did an analysis?
A. Oh, it's been many years. It would have been when I was in Idaho.
Q. And you were in Idaho from approximately 1982 to 1992; is that right?
A. Yes.
Q. And you were part of the environmental chemistry unit there?
A. That's correct.
Q. And the Department of Energy's Idaho national laboratory is one of 17 DOE labs across the country; is that right?
A. I actually don't know how many there are, but there are a number of them.
Q. Okay. Within DOE, it's a 900 square mile facility, isn't it?

A. It's very, very large.
Q. It's huge?
A. Yes.
Q. Okay. So they really don't have -- When you say that you managed -- established and managed an analytical lab, DOE would consider that a unit because the whole thing is a lab; isn't that right?
A. Oh, I see your question. Yes, because we call them national labs. I certainly would never mean to suggest that I managed INL. My management was directed specifically to the analytical testing laboratory, which was 40-some people.
Q. Okay. When it began, it was 1985. You had about four people; is that right?
A. Yeah. I don't remember the specific dates, but it started with about four people.
Q. Okay. And the machines that you had -- the only ones that would mimic the ones here were the GC and GCMS; is that correct?
A. We also had FTIR, is my recollection.

Let's see. We did not have LC -- HPLC. And we did not have are a GC interface to the IR. We just had them as separate instruments.

Q. So the other tests that Ms. Irby ran, you've never actually run them before; is that right?
A. I've never run a color test. I've run liquid

chromatography, I've run GC and IR and mass spec. but not their instruments.

Q. But you've never run the hyphenated techniques?

A. GC mass spec, yes.

Q. Just the GCMS?

A. Just the GCMS. Not the GCIR. I said they were separate.

Q. The IRATR: The ATR is actually something that was developed after you left actual analysis; is that right?

A. Yeah. The ATR component of the IR, it's really just like a component. It's not a separate instrument like the GC.

Q. And that came about after you left analysis?

A. Yes.

Q. Okay.

A. Actually, I believe it was in the literature and out there. It's just we didn't have one.

Q. And when you were doing analysis, you were doing things like environmental contaminants, waste, things of that nature?

A. Yes.

Q. Again pardon me for skipping around a little bit.

You talked a little bit about data quality assessments. Is that your term?

A. No.

Q. Okay. The data quality assessment: This is really just looking at paperwork; correct?

A. That's correct. It's based on simply the written record.

Q. And you've talked about you were not able to reconstruct practices, protocols, things of that nature. What you mean is the documentary record. You couldn't, in other words reverse-engineer and figure out the protocols based on the documents.
A. That's correct.
Q. So you're not talking about the actual testing that was done. You didn't try to recreate the actual testing.
A. Did I physically try to re-create?
Q. Yes?
A. No, ma'am.
Q. And in the world of auditing, you're familiar with the ISO 17025 requirements. Each clause is mandatory; is that correct?
A. Yes.
Q. None of it is optional whatsoever?
A. That's correct.
Q. And if you don't, if a lab does not comply with the clause or fix it, if they're not complying, they don't get accredited; is that correct?
A. That should be the case. That's correct.
Q. So it has to be perfect execution of the protocols to get accredited.
A. Well, as has been discussed -- and I don't -- I think it was in the previous hearing -- it does not guarantee that everything a laboratory does is perfect, certainly. An assessment for purposes of an accreditation is simply an

assessment to see whether the systems are in place and whether they have the theoretical capability of meeting the requirements on an ongoing basis. Doesn't mean that that actually happens, and it's certainly not intended to be some guarantee that it happens all the time.

Q. Okay. Just to be clear, quality assurance is actually itself no guarantee of reliability; isn't that right?

A. Oh, certainly.

Q. Okay. And, in fact, the identification of drugs, controlled substances: That predates quality assurance or accrediting bodies; isn't that right?

A. I don't -- it certainly predates the recognition in the forensic community that quality assurance is an important issue. But quality assurance has actually been around for a very long time.

Q. More than a hundred years?

A. I would imagine so.

Q. But you don't actually know?

A. I don't know the exact start date, no.

Q. So it's possible that the identification of controlled substances completely predates quality assurance principles?

A. The principles -- I guess I've never tried to study the history of quality assurance that far. But the principles are so foundational to the analytical measurement process that I would expect that the principles have been around for a very,

very long time packaged --

Q. Differently?

A. Perhaps not.

Q. You talk about -- you just talked about that the assessments. The accrediting is just sort of a checkmark, the theoretical capability that a lab has of providing reliable results; correct?

A. Yeah, because you're looking as an auditor, as an assessor -- you're looking at whether or not they have procedures and whether they follow the procedures. It doesn't mean you check their entire body of work to make that determination. It's very much a spotcheck exercise to see whether or not the required procedures exist.

And I should mention it's not generally a hundred percent check against whether every required procedure exists but whether the required procedures exist and whether there is empirical evidence, actually documentary evidence, that that procedure has been followed.

Q. And that is an assessment. You go in you make the assessment and you accredit for the future. You don't accredit retroactively.

A. That's correct.

Q. So if you actually go into a DEA lab today would have no bearing on whether or not -- on the results at all from either testing in this case; is that right?

A. If I was going in on behalf of an accrediting agency, no, it certainly would not.
Q. Well, even auditors -- they're not going to -- there is not going to be necessarily all the documents you need from that particular date; isn't that right?
A. Well, that's actually what auditors frequently are asked to do, to go back and assess what systems and practices were in effect at the time a given peace of work was performed.
Q. And with regard to this lab Ms. Irby worked at, you happen to know that they do use the ISO 17025 standards; right?
A. That is the standards that is the basis for their accreditation, yes.
Q. And you also heard testimony about SWGDRUG; is that right?
A. Yes.
Q. And you've heard testimony that what Ms. Irby did was in compliance with SWGDRUG?
A. I've heard that testimony, yes.
Q. Correct. Now, you testified in very general terms that her testing in fact did not meet accepted standards in the forensic community do you recall that?
A. Yes.
Q. Where in SWGDRUG Exhibit 2 did she fail?
A. Sorry. Mine has little Post It notes, but this one doesn't, so it may take me a little bit to find the specific examples.

Q. Sure.

A. Okay. Here's one. This is at the top of the page. It's page 25 of 63. At the bottom of the page, it says page 14.

Q. Okay. I'm with you.

A. Okay. Are you there?

Q. Yes.

A. We've heard a lot of testimony about Category A and Category B, and I certainly don't take any exception to that. That's a reasonable means of segregating these techniques by their specificity in general. But just like the rest of life, science is not always about absolutes. And even though mass spectrometry appears in Category A as the most highly discriminatory type of technique, there is some qualifying information in the section that's titled "Title 2, Characterizing Analytical Techniques."

Q. Yes, ma'am.

A. May I read?

Q. Please.

A. Okay. It says, "however, the classification of a technique may be lowered if the sample analyte or mode of operation diminishes its discriminating power."

Q. Okay.

A. And then they give as an example of diminished discriminating power "includes a mass spec. technique which only produces molecular weight information." That's a very

generic description that doesn't exactly say what I testified to earlier in terms of methamphetamine. As the analysis was performed in this case, it is not a very discriminating technique because you don't get the information.

Q. I'm sorry. Let me stop you so I can understand. What information, what specific ions are you looking for in a mass spec. to identify meth?

A. That's exactly the question that the laboratory has never answered.

Q. No, ma'am. I'm asking you.

A. The problem is that in order to make a mas spectral determination, you need a base peak that you can identify and confirm between the sample and the standard and you need qualifying ions, fragments that comport with that reference standard's breakdown products.

Q. Okay. Let me ask it another way because I don't want to waste the Court's time.

A. Okay.

Q. What are the specific mass-to-charge ions that a chemist looks for on a methamphetamine spectrum?

A. A direct injection? I don't know other labs that are actually qualitatively identifying meth on the basis of this kind of direct injection because of the problems that I've described. Typically they derivatize the molecules first, and then they get more information, and then they can identify

specific ions.

Q. So you don't know.

A. I don't know --

MR. BAKER: Objection, your Honor. That's totally a misstatement of what she said.

MS. MAGNELLI: It's not a misstatement.

THE COURT: Counsel, the record says what the record says. What you hear it to say and what it says may be two different things. It says what it says.

MS. MAGNELLI: Let me ask a different way.

BY MS. MAGNELLI:

Q. What are the specific numbers on the bottom of the mass spectrum chart that a chemist looks for? Whether or not you can use it to identify meth, what are the actual numbers they're looking for?

A. Well, the base peak, if you do a direct injection of methamphetamine, is at an ion charge ratio of 58, which conforms to a specific fragment of -- I believe it's dimethylamine. I'd have to sit down with a periodic chart and look up to the weights to be sure of that. But that's really -- that's really the problem. Dimethylamine fragments are not unique or other fragments with that particular ion are not unique to methamphetamine.

Q. Okay. And you're not familiar with any literature that would say otherwise?

A. I'm familiar with the UNODC guidance document that the state introduced earlier that specifically address this issue and says that that's the problem: It lacks sensitivity, so they recommend doing derivatization so you get more information.

Q. Are you familiar with the Sachs and Woo paper?

A. Which Sachs and Woo paper?

Q. That says you can in fact identify methamphetamine from mass spectra only with certain conditions?

A. If this is the same paper that I heard testimony about in the earlier trial, I'm not sure that that's the case. That was not working from an unknown but working backwards from a known, essentially trying to identify what they did see. That's a very different circumstance than starting with an unknown. They're essentially working from the other direction.

Q. Well, let me ask it this way: When combined with the GC, which is what we have here, the hyphenated technique, that retention time on the GC -- that makes it unique, doesn't it?

A. No, ma'am, it doesn't. And the reason for that is because they didn't run a known standard to see what the retention time was for methamphetamine on the day they ran these unknowns. And retention times are notoriously subject to change over time. I don't remember, without looking back, how far ago the reference standard was run; but literally over a period of days or even hours, if the instrument has been shut off, retention

times are known to change. And you can't identify a compound based on a retention time unless you have a contemporaneously analyzed standard.

Q. Are you aware of the fact that instruments in this case don't get turned off?

A. That may be the case.

Q. Would that change your testimony?

A. No. No.

Well, I should -- they may not be turned off as a part of routine operation. A lot of labs run shift work and run 24-hour-a-day operation, but they still get turned off for maintenance and changing out columns and that sort of thing.

Q. Are you aware of fact that they ran a standard over time in this case and it didn't change?

MR. DRISCOLL: That's not evidence in, your Honor.

MR. BAKER: I may have missed it; but I don't think there has been any testimony of that, your Honor.

THE COURT: Thank you.

MS. MAGNELLI: Court's indulgence.

Sorry, your Honor. I got distracted.

BY MS. MAGNELLI:

Q. All right. Let's talk about contemporaneous standards for a second. You've testified actually quite a bit about running positive controls contemporaneously; is that right?

A. Yes.

Q. Now, you've testified -- you testified in April that it was the best practice, and you testified today that it was an absolute requirement. So which is it?

A. If the expected work product, the results, need to be reliable in terms of the qualitative identifications of the species in the unknown, then it's a requirement.

Q. And where is that requirement?

A. There is not a law. It's scientific practice. It's scientific practice as I described earlier today in the training materials for the instrument's use in this case. It's addressed in the standards that you just asked me to look in, in SWGDRUG. In SWGDRUG, it says -- let's see. It's in a couple of places. This isn't the only one. Let's see.

6.1.4 on page 32 of 63: "Laboratories shall monitor the analytical processes using appropriate controls and traceable standards."

Now --

MR. EDELMAN: I'm sorry. What page was that again?

THE WITNESS: I'm sorry. Page 32 of 63 on the top, page 21 on the bottom. This is still Exhibit 2.

BY MS. MAGNELLI:

Q. Where does it say "contemporaneously"?

A. It doesn't say that contemporaneously. It says you have to monitor it. And again, depending on the intended use of the data, you may have to monitor it with more or less frequency.

The UN document specifically requires analysis at the same time using the same standards and the same instrument.

Q. Can you show me where that reference is?

A. Yes.

Okay. It's on -- this is Exhibit 3.

Q. Yes, ma'am.

A. And on page 46 at the top of the page.

Q. Is that 46 of the total or 46 --

A. It's the header information. 37 is the document page number, but 46 is the one in the header.

Q. Thank you, ma'am. Please continue. Where does it say contemporaneous?

A. About two-thirds of the way down under "Results," it says -- this is in reference to using GCMS as an analytical technique for meth. "Identification is accomplished by comparing the retention time and mass spectrum of the analyte with that of a reference standard." And it continues: "All compounds identified by GCMS and reported by the analyst must be compared to a current mass spectrum of the appropriate reference standard preferably obtained from the same instrument operated under the same conditions." And it goes to reference that there are libraries, but those should be for reference purposes only.

Q. It never says "contemporaneous," does it?

A. It calls them "current."

Q. It says "current." But current doesn't have to say at the same time; it just means it's still good, doesn't it?
A. Well, "current," when you're talking about "obtained from the same instrument under the same conditions," we can't exactly reproduce instrumental conditions. We, as analysts -- we can't -- we can reproduce settings, but we can't reproduce the actual performance characteristics, the actual characteristics of that instrument. The only way that can be done is by doing it contemporaneously. That's what "current" means.
Q. It doesn't say "same time," does it? Same instrument, same conditions. Does not say "same time," does it?
A. It does not say same time.
Q. Now, I had asked you earlier -- and we really didn't get anywhere -- what exactly -- what clauses exactly did Ms. Irby clearly fail to follow in SWGDRUG?
A. 6.1.1. "Laboratory shall have and follow documented analytical procedures," for example.
Q. Let me ask you this: You don't have those procedures; correct?
A. I do not.
Q. But you know ISO 17025 exists; correct?
A. I do.
Q. And you know that this particular lab is accredited to that standard?

A. I do.
Q. And they require analytical procedures; is that right?
A. They do.
Q. Okay. So it's not that they don't exist. It's just that you don't know what they are; is that right?
A. I will tell you as an auditor auditing accredited laboratories, it would not be the first time that I did not see labs that did not have procedures during a period when they had active accreditation. Again, accreditation doesn't guarantee that it's all done in accordance with the standards. It simple is an acknowledgement that the systems exist.
Q. I understand that. But let me ask you more specifically: You don't know whether or not she violated this clause because you don't have the procedures; is that right?
A. That's correct.
Q. Thank you. Can you point me to another clause that she violated in the SWGDRUG protocols?
A. It's going to be the same kind of an issue where it talks about -- 6.1.4 on that same page.
Q. Yes, ma'am.
A. "Laboratory shall monitor the analytical processes using appropriate controls and traceable standards."

If it was Ms. Irby's contention that her infrequent use of standards was sufficient, then there are should have been a data set provided along with this to demonstrate that

her measurement system was in a state of statistical control at the time this work was done.

That was not provided, so there is no basis for saying that this was acceptable.

Q. Let me ask you this, then, as a follow-up: That is assuming an auditing function. That has nothing to do with a court of law and what the Government might be required to provide; is that right?

A. I'm sorry. I don't understand the question.

MR. DRISCOLL: Objection. It requires a legal conclusion on the part of the witness.

MS. MAGNELLI: Your Honor, I'm trying to make the distinction that this is just about auditing.

THE COURT: She's already testified to that.

BY MS. MAGNELLI:

Q. Let me ask this question, then: I understand that it is your opinion that Ms. Irby should have produced this document in association with the lab data packet; correct?

A. Yes.

Q. That doesn't actually mean -- or you don't know whether or not that doesn't exist. You just know you don't have it; is that right?

A. That's correct.

Q. Okay. Can you point to me another clause that she violated, she actually violated?

A. Section 7.1, Instrument Performance. "Instrument shall be routinely monitored to ensure that proper performance is maintained."

And subsection 7.1.1: "Monitoring should include the use of reference materials, test mixtures, calibration standards, blanks, etc."

Q. And how did she violate that?

A. Again, by her testimony, she did not perform routine monitoring. In some cases, it was monitoring results from, if I recall correctly, months previous.

Q. Okay. She did reference certain logs and other materials; is that correct? You recall that?

A. She made reference in a couple of cases to the existence of logs, yes.

Q. Okay. So again, it's not that you know she violated this clause; it's that you don't have the materials with regard to this clause?

A. It's possible that it's -- it's certainly within the realm of possibility that those logs exist; that they're very complete; that they demonstrate a state of statistical control. It's possible.

It's possible that the DEA's standard, how high you have to go over the bar in order to draw a conclusion, is low enough that it doesn't require the use of a positive control.

Q. The fact is you just don't know. You don't have the

documents. You don't know?
A. I don't know. And from her testimony, I couldn't tell that any such standards existed.
Q. But it would be inaccurate to say that they don't exist. What is accurate to say is, is that you don't know one way or another if these things you're pointing out exist.
A. That's correct. It's possible that they exist.
Q. And whether or not those documents are required for an audit really has nothing to do with the science of the testing.
A. It has a great deal to do with the reliability of the testing.

The underlying scientific principles of GCMS or any of these other techniques are not affected by this, but the reliability of the application of that technique is absolutely driven by these things.
Q. Let me ask you another way: When you were taking all your chemistry courses, did they teach you quality assurance principles at the same time?
A. You know, very little quality assurance makes its way into a conventional undergraduate curriculum in chemistry.
Q. So really my point is, is the quality assurance principles are separate and apart from the science behind the identification of a controlled substance. Wouldn't you agree with that?
A. That's true. If by "science" you mean the underlying

physical chemistry principles that essentially make valid -- because I have no -- absolutely do not take any exception to the fact that GCMS, for example, is a robust and effective analytical technique. No question. It's well proven, it's well-understood. Scientists have been using it for years very successfully. And I've seen tremendously both valid and reliable results produced from that kind of instrument. But simply because you run it on a GCMS doesn't make it good science, doesn't make it reliable.

Q. I understand. I'm trying to establish that there is -- there are two worlds at play here. There is the world of quality assurance, which is what you're talking about; and then there is the world of science. Is that right?

A. I hope they're not completely separate, because it's quality assurance as applied to science.

Q. I understand. Quality assurance, as you say, though, can be applied to numerous different types of disciplines.

A. And it is.

Q. Correct. But there is a real distinction: When you're learning science, you're not learning these quality assurance principles at the same time. There is a difference.

A. That is true. That's very true.

Q. Now, you talk about -- we talk about the GCMS a lot; but really, there are six tests here; right?

A. Yes.

Q. And it's not your opinion, is it, that these six tests don't identify methamphetamine? That's not your opinion, if I'm understanding you correctly.

A. They're capable of so doing to differing degrees of confidence.

Q. Now, is there any indication in the testing packet that this substance was anything but methamphetamine?

A. No. That's not the nature of my assessment.

Q. I noticed in your submissions to Mr. Edelman, your February and May letters, which were submitted for the Court's consideration, you talk about how -- how methamphetamine hydrochloride was identified by the GCMS. But today you acknowledge that you can't actually identify the hydrochloride with the GCMS. So which is it?

A. You can't identify the hydrochloride in the mass spec. even if you do derivatize it.

My concern about the confidence with meth identification and using the GCMS is the fact that it does not produce a specific data-rich spectrum. Its not got anything to do with the hydrochloride.

Q. I understand. I think my question goes more to the fact that after Mr. Oulton testified, your opinion seemed to change. Is it now -- do you now agree that you cannot identify the hydrochloride by GCMS?

A. Oh, no, you cannot identify the hydrochloride. You can

identify methamphetamine, if you derivatize it; and then there is not a problem.

Q. And we talked about the color test a little bit. We've talked about the GCMS extensively.

The infrared: That is a highly discriminating, unique test, isn't it?

A. If the substance in question is very pure, it has the ability to be -- and if the instrument is operating in a high resolution mode, then it absolutely has the ability to be a highly discriminating technique.

Q. And the substance here you've heard is 99 percent pure?

A. Well, we'll have to talk about the quantitation that was done.

Q. Well, you've heard that result; correct?

A. I've heard that result, yes.

Q. So that's the kind of purity you would be talking about in your last sentence?

A. Yes.

Q. And just to skip forward, all the other techniques that Ms. Irby used: Those are all capable of combining to identify methamphetamine; is that right?

A. Oh, yes.

Q. So there is really nothing wrong with the methods; isn't that correct?

A. That's correct. Not the methods. What -- there is not a

problem with is the instrumental techniques that were applied in this case; however, the method as practiced in the laboratory is what's the problem.

Q. So you would agree that methods were used here in this case; correct? Ms. Irby used methods?

A. She did use methods. We just don't know what they were because we don't have their procedures.

Q. Well, let me clarify what I mean by "method." Even when you look at the United Nations documents, it talks about method parameters, and those would be the settings for the instrumental techniques for the machines?

A. That's correct.

Q. So methods can be the actual tests she performed. That can be a method?

A. That's my point. The -- we don't have that level of procedural detail associated with her performance or her use of the GCMS.

Q. Okay. Let me ask one different time, because you're not actually answering my question.

A. I think I am.

Q. No, you're not.

Regardless of how the machine was operating, how GCMS was operating, GCMS all by itself is a method?

A. No.

Q. Whether or not it was operated correctly, it's a method.

It's considered a method under the United Nations documents, because they have method parameters.

A. There are method parameters, but it's specific to the application of that instrumental technique to a specific analyte and specific conditions. It's a narrower world. GCMS is huge. It can be done -- used to analyze innumerable compounds and innumerable species. But when I come in and ask you in the laboratory, "What's your method for determining meth using GCMS," that implies not just the fact that it's a GCMS; it's how the measurement is performed in your laboratory.

Q. Okay. Now, I understand your answer. You are answering from an auditing position and not a science position; is that right?

A. No. That's science.

Q. Well, the method, how it's operated and the protocols and procedures: That's a quality assurance principle, isn't it?

A. The policies -- we haven't talked about policies much, but policies are higher order lab-level goals than an objectives, essentially. The procedures are how things happen in practice, the recipe if you will for how things happen in a laboratory.

Method is a very generic kind of term; but generally asking me "What's your GCMS method," going to a lab and asking "What's your GCMS method," is not specific enough. It doesn't give enough information for the analyst even to answer the question, because GCMS as an analytical technique can be

applied to so many different applications.

So I guess I'm having a hard time understanding your question.

Q. I understand. My point -- I'll ask one more time and then move on. Walking into a lab and asking, "What's your GCMS method," is not my question. I'm using "method" as you noted earlier you were here during Mr. Oulton's testimony. Terms are used interchangeably a lot in this realm, aren't they?

A. Yes.

Q. Isn't it true that in the forensic community, the term "method" can simply be applied to the fact that this method -- an analyst used this method and that method could mean simply a reference to the instrumental technique. That is in the literature in the forensic community. That term is used in numerous ways, isn't it?

A. That's certainly possible that it is that broad or that generic.

Q. Okay.

A. I'm not suggesting that that doesn't ever happen.

Q. Okay. Thank you.

You've talked -- I'm almost done. I swear.

You've talked about things that have been done widely in practice in forensic labs. You talked about standards in the forensic community. Isn't it true you're not actually part of that forensic community?

A. No, I'm not.
Q. And one more point on the forensic lab, just so I can make my record: You talk about in your CV that you did some work for the Navy; correct?
A. Yes.
Q. Okay. And you actually never audited any of the naval criminal investigative services labs; correct?
A. That's correct.
Q. And those were the labs that did all the forensics for the Navy?
A. That's correct.
Q. Okay. Essentially in -- throughout your testimony, what I'm understanding -- and please correct me if I'm wrong -- is that from an auditing perspective, you don't have sufficient information to say whether or not the test results were reliable or not; is that correct?
A. In general, yes; but my degree of discomfort in terms of the reliability results -- of the results is further diminished- or I guess my degree of discomfort is increased by the fact that I'm aware that they do not run contemporaneous positive controls and that they quantified meth in this case without including a blank in that batch, which if there had been a problem with contamination, they would never have detected it. And that's arguably probably the most important place to include a blank, in analysis such as this.

Q. I just want to make sure I understand that question because it seemed two-pronged -- or answer. It seemed two-pronged to me.

A. It was.

Q. You're not giving an opinion, then. You're talking about your level of discomfort. Is it true that you don't have an actual opinion as to whether or not the test results are reliable or unreliable?

A. No, I definitely have an opinion. And my opinion is that the lack of contemporaneous positive and negative controls for the measurements reported in this case and the lack of procedures to verify the validity of the scientific method together or even separately render the results unreliable.

If a client asked me, "Are these reliable," I have to tell them no. There is no objective scientific basis for concluding that they're reliable when there are no positive and negative controls and no written procedures.

Q. You just said scientific conclusion, but you're not giving a scientific conclusion today; correct? You are testifying as an auditor, not a chemist; correct?

A. The practice of data quality assessment, the practice of conducting a data audit on analytical measurements, relies on scientific principles and is, I believe, a scientific conclusion.

Q. And that's your opinion it's a scientific conclusion?

A. That's correct.
Q. And your opinion that the standards need to be contemporaneous is also your opinion; is that right?
A. I'm sorry?
Q. The contemporaneous standards you just testified goes to your level of comfort. The fact that -- the testimony that they should be run contemporaneously is your opinion; is that correct?
A. It is my opinion. It is shared by innumerable scientists practicing in the field. It's stated explicitly in the UN documents. It's stated explicitly in the Society of Forensic Toxicology documents. There are a lot of places where it is stated explicitly as a requirement.
Q. But not in SWGDRUG.
A. Not in SWGDRUG, no.
Q. And you have cited SWGDRUG as one of the -- as one of the well-accepted principles or one of the well-accepted bodies and recommendations in the forensic communities.
A. It's widely utilized in the field.
Q. I'm sorry?
A. It's widely utilized in the field.
Q. Okay. Two last questions: You talked about no positive or negative controls that -- about Ms. Irby's testing. But you were here when she testified; correct?
A. I was.

Q. And you recall her testifying that she did a negative control on the IRATR; correct?
A. She did negative controls for all the tests except the quantitation, the test where she determined how much meth was present.
Q. And the quantitation is the HPLC. Am I right?
A. That's correct.
Q. Wasn't it her testimony that no blank was required because blanks are used to show contamination and the HPLC is used to show purity?
A. No. I'm sorry. The HPLC is being used in this case to determine or to quantify how much meth is present. And the problem with not including a blank when you're doing a quantitation is that if there is a contaminant present, the blank -- you don't have a blank, so you won't be able to detect it, so your results will be biased. Your results will indicate the presence of methamphetamine at a higher level than maybe was originally present, or even present when it really wasn't.
Q. But you do recall her testifying about that?
A. Oh, I certainly recall her testimony, yeah.
Q. So you just disagree with it?
A. She simply stated, as I recall, that a blank was not required in this instance.
Q. If I may, what she said on page 51 of that transcript was "The blank is normally there for -- the blank is there to show

contamination. This is qualitative vs. quantitative. I'm only doing it to show what the purity is, and it's not a requirement to run a blank in this instance."

Do you recall that testimony?

A. I do.

Q. So you just disagree with her?

A. I absolutely disagree with her. That represents a complete misunderstanding of the purpose of a blank.

Q. And yet you're not a forensic chemist.

A. No, I'm not a forensic chemist.

Q. And with regard to the contamination, did you hear the testimony that this amount of meth is about the size of a basketball?

A. Yes, I heard that testimony.

Q. So really, can you contaminate 99 percent pure meth?

A. Absolutely you can, because that conclusion that it was 99 percent pure was based on an HPLC test where she never ran a blank. So quantitatively, that is not a scientifically supportable conclusion, because when you run a method, ever, by virtually any technique, you run the technique with a blank to see what response or signal the method gives you for a blank. And then you run it with known standards, so you can compare the two and develop a calibration curve and quantify an unknown. But if you don't bother to run that blank, you have no basis for assigning -- just assuming on the basis of no

empirical evidence that there was no contamination present in that batch.

Q. Isn't that why the chemist ran a known positive control test first?

A. I'm not sure I understand your question. Isn't that why they run?

Q. Didn't she run a positive control test before the HPLC?

A. She ran calibration standards.

Q. She ran positive controls on several of the tests, didn't she?

A. Are you still talking about HPLC?

Q. No. HPLC was the last test she did.

A. Okay. Yes, I'm sorry. She ran positive controls months earlier. Are you suggesting that that would tell her whether she had contamination?

Q. What I'm asking is: Did she run positive controls before she got to the HPLC?

MR. DRISCOLL: Objection. I think the form of the question. The form of the question is whether -- what the witness' recollection is rather than what the testimony is. If the question is what is the testimony, I think it should be offered to the witness so the witness can review it and recite it to counsel.

MS. MAGNELLI: I'll withdraw it.

Court's indulgence.

Nothing further at this time.

THE COURT: Thank you.

I think this might be a good time for us to take a midafternoon recess.

The court clock is showing 2:35, and we'll try and reconvene at 2:45, standing in recess for 10 minutes.

(Recess at 2:35 p.m.)

(Reconvened at 2:50 p.m.)

THE COURT: Please be seated.

Redirect?

MR. BROWN: Thank you, your Honor.

REDIRECT EXAMINATION

BY MR. BROWN:

Q. Ms. Arvizu, I'm going to be asking you questions regarding Ms. Magnelli's questions of you, and hopefully we'll be responsive to that subject matter.

She asked you, do you recall, about whether or not you had the -- had visited a forensic lab?

A. It wasn't that generally phrased, as I recall. Because I certainly visited a number of them, have witnessed testing at a number of them.

But my recollection is it was something along the lines of having done an accreditation audit of a forensic lab.

Q. Do you recall being asked whether or not you had actually gone to the Western Regional Lab or a forensic lab of that

type?

A. I -- I frankly don't remember if she asked me if I had been to the Western Regional Lab or a lab of that type specifically.

I have not been to the Western Regional Lab. I've certainly been to a number of laboratories that test controlled substances.

Q. And if given the opportunity to visit the Western Regional Lab for the purpose of either -- preparing an examination along the lines of quality control, would you accept that invitation?

A. Certainly.

Q. And with respect to such a request, are you aware that in this case that that was a request made on your behalf for you to go and visit the lab?

A. I believe I've heard that, yes.

MR. BROWN: Okay. And just for the reference, I'll direct the Court and Counsel to the hearing of April 1, 2011, at page 9, the bottom of the page. There is an indication that the Government would not allow such a visit.

BY MR. BROWN:

Q. I want to ask you about the supplemental requirements of SWGDRUG 17025?

A. Yes.

Q. Those are promulgated by ASCLD/LAB; correct?

A. That's correct.

Q. You were asked questions --

A. Well, no, not SWGDRUG. The supplemental requirements to ISO 17025. If there was a "SWGDRUG" in there, that's not appropriate.

Q. When they refer to supplemental -- okay -- those are supplemental to what?

A. They are supplemental to 17025.

Q. Thank you. And the origination of 17025 is at SWGDRUG; correct?

A. No. 17025 is the international standard promulgated by the International Standardization Organization.

Q. Those supplemental requests you were asked about, you were asked in particular -- you haven't seen them; correct?

A. That's correct.

Q. Are they available to the general public?

A. They are not.

Q. Are they published on line?

A. No.

Q. Are there -- is there a method by which you could request those and receive them?

A. It's been attempted but so far not successfully.

Q. You've tried to get those?

A. I've actually tried to get the ASCLD/LAB standards in the past. Many, many years ago, I was successful; but subsequently, they stopped answering my e-mails.

Q. These are substantive standards of scientific examination

for the particular purpose of forensic analysis, and you're not allowed access to them?

A. I don't know if they're substantive or not because I've never seen them. I've heard them described as clarifying or providing examples of how ISO 17025 applies in the forensic field. Until this case and until the testimony in this case, I've never heard them described as adding additional or more stringent requirements to 17025.

Q. If you were given the opportunity today by Ms. Magnelli or Mr. Oulton to review those, would you like that opportunity?

A. Sure.

Q. In your capacity as an auditor, do you as a matter of practice attempt to physically recreate a test?

A. No.

Q. You were asked a question regarding the history of quality assurance testing, examination within the forensic community. Do you recall that question?

A. Yes.

Q. Are you familiar with in general, because I think you said you're not a historian about quality assurance -- but are you in general familiar with the historical record of quality assurance in different disciplines of scientific analysis?

A. Yes.

Q. As compared to forensic analysis, have other disciplines been more willing to accept quality assurance examination, or

less willing?

A. Oh, other disciplines have adopted generations before the forensic field essentially attempted to start to address quality assurance principles within the forensic laboratory community. It was well-established conventional practice, inculcated into the culture, if you will, of pharmaceutical, food, environmental laboratories for many, many years before the forensic laboratory community essentially got on board. That's pretty much happened within about the last -- just about the last decade or so.

Q. You were asked about auditing protocols in general and the standards related to auditing protocols and indicated that the stringency or the type of standards might depend upon the intended use of the data.

A. It is a fundamental precept of quality assurance that when you're essentially setting the bar and how rigorous a measurement needs to be and how much quality control needs to be associated with a given measurement that you cannot make that determination without knowing the intended use of the data.

It's the same premise as method validity. Method validity is determining through empirical testing that a method is appropriate for its intended use. Results that may be perfectly acceptable in one application may be deficient or unreliable in another application.

So it's really important that you understand the intended use of the data before you set the bar for how much quality control is necessary to ensure reliability.

Q. So just to kind of take us away from the forensic analysis for a second; but to demonstrate what I think you're talking about, would you expect the rigorousness of auditing protocols and standards to be different if we were examining a manufacturing process such as applying paint on the handle of a screwdriver vs. the coloring involved in maybe an infant pacifier?

A. Absolutely.

Q. And why?

A. Because the intended use is so very different. An infant pacifier is going into the infant's mouth, and so it's absolutely important that there could be nothing that could present a health hazard to that child associated with the materials of construction.

So that puts boundaries and sets expectations for the quality control necessary to be very, very confident to use very proven, valid, and reliable methods and to do them reliably in the laboratory, as opposed to the fact that if the paint chips off of a screwdriver, it's not probably an issue of significant health or physical impact, for example.

Q. In this proceeding, have you tried to apply that type of principle in your quality control analysis?

A. Absolutely.

Q. And how have you analyzed this type of proceeding along the pendulum of seriousness, as low, medium, high being, I guess, subject to the most stringent standards of quality control analysis?

A. My understanding of forensic data, having testified in a variety of cases, is that the consequences of the outcome of the hearing, the intended use of the data is so important that the court needs to know whether or not results are reliable before they'll allow them to be introduced n court.

That's a standard of reliability that exceeds paint on a screwdriver or "can I dump this down the drain or not." That's a higher threshold, if you will, with more stringent expectations.

And I typically, especially in the last decade, see that more and more frequently in the protocols that I review from forensic labs. They are starting to step up to the bar and set the bar a little bit higher to ensure that they meet that threshold.

Q. There was discussion about the use of a positive control standards and whether "current" as was reflected in those UN standards, was synonymous with "contemporaneous." Do you recall that discussion?

A. Yes.

Q. And I think it was your understanding, applying principles

that are generally accepted within the scientific community, that this type of forensic testing would be contemporaneous.
A. Yes. It's a little clearer that the point is that you're trying to ensure that the measurement system applied to unknowns can be used as indicator of the method's performance. You can use the performance on knowns to -- as a reliable indicator for the performance on unknowns. The only way that makes sense scientifically to interpret "current" is that it's the same instrument, the same time, using the same conditions. They said it a little differently than that.
Q. I believe in quoting the standards -- I believe you said, "same instrument under the same conditions"; correct?
A. Yes.
Q. Again, you construed that as being contemporaneous?
A. Yes.
Q. And do you recall that Ms. Irby had authored an affidavit, I believe, or declaration that was admitted in this proceeding, Exhibit 1, could be 8H; and it was referenced in the prior hearing, in particular, for the Court and Counsel, the May 27 hearing at page 106. And I'll just quote from that at line 6.
A. Can you quote? Because I'm not finding it.
Q. That's okay. You can listen to me -- where she testified, quote, in reference to her declaration -- I'll just read it. It says, quote, "There are some other instrumental techniques, including chromatographic methods where the data is not

necessarily invariant between different instruments and at different times. In these instances, it is prudent to include a positive control when the data is collected for an unknown sample for the alleged purposes of comparison," unquote.

Do you recall her authoring that and also stating that?

A. I do.

Q. And that referred to a positive control sample being used appropriately on the same machine where it had been previously tested; correct?

A. Correct.

Q. And do you recall her also testifying -- and I can refer the Court and Counsel to the following page, line 11, following page 107, quote: "So when I ran that standard 618, it had already been verified to be what it was on another instrument that is able to confirm that; so now that standard is able to be used in the laboratory," end of quote.

Is that different from what she stated?

A. Yeah. She's talking about two completely different things. In one case she's talking about verifying the composition of a standard that's received by the lab, which is a required practice. You don't just use them. You verify them before you use them.

In the other, she's talking about analysis of unknowns. And her statement that chromatography changes over

time so it's prudent to include a positive control is very true. Unfortunately, she didn't so in her GCMS spec or in her -- well, she did -- she didn't do a control, she only did a calibrator in her HPLC and in her CGIR.

Q. So the standards that were used here had not necessarily been used on the same machine, the same instrument?

A. They were not necessarily used on the same machine and, they were certainly not used at the same time under the same conditions.

Q. And I believe that Ms. Magnelli was asking you and saying that in the absence of logs of such reference standards being tested, you can't say that this testing methods are unreliable? Do you recall that, in the absence of seeing the logs?

A. Yes.

Q. Now, in discovery, with respect -- and I'll refer the Court and Counsel to Mr. Edelman's motion for additional discovery, Document D1, as previously marked, paragraph 9B, at page 6, did Mr. -- do you recall Mr. Edelman requesting copies of bench notes, log books, communication logs, and any other records pertaining to the case samples or instruments and records describing the condition of the evidence?

A. Yes.

Q. Would that type of a request have encompassed seeing logs identifying the standards that were used?

A. Yes.

Q. So they were requested. Did you know they were requested?
A. Yes.
Q. Did you want to see them?
A. Yes.
Q. Would they have helped answer Ms. Magnelli's question about whether or not these results and the methods were reliable, if you had seen those logs?
A. Yes.
Q. But she asked you, and you said, I can't say they're unreliable but -- because I haven't seen the logs; right?
A. Right.
Q. But you asked for the logs and didn't get them?
A. Correct.
Q. And so this questioning where you were asked kind of to distinguish answers where "I don't know" vs. "they don't exist": How does a quality control analyst address this dilemma where you've asked for data, it's not provided? From a quality control analyst's standpoint, does that mean that the data should be accepted, it's unreliable, or how do you otherwise go about analyzing that?
A. It means that its reliability has not been demonstrated because there is no -- It's like you said: I don't know if they didn't exist or they simply weren't provided. But in any case, the reliability has not been demonstrated; and I have to advise my client that the results are unreliable.

Q. You were asked about the HPLC test at the end of your examination by Ms. Magnelli and the fact that that was done for a quantitative analysis and determined to be 99 percent pure.
A. That's correct.
Q. And in this -- I think you testified to the fact that no blank was used, no negative --
A. That's correct.
Q. -- control was used.

And there was some discussion, I guess, of whether it was needed or not. And is it your opinion it was needed?
A. Absolutely.
Q. Is there a danger of a false positive in the event where it is not utilized?
A. The danger is either a false positive or high bias in the results.
Q. And do you recall --

MR. BROWN: And I'm referring, Counsel -- I evening Ms. Magnelli actually referred you to this portion on the May 27 transcript on page 51, and I'll refer to the specific line of 10 through 16. And I'm not sure. I apologize, your Honor. I'm not sure who the questioner was at that point.
BY MR. BROWN:
Q. But the question was: "All right. And did you use a blank before you started the procedure?"

And the answer of Ms. Irby was, quote, "I did not on

this instrumentation. The blank is normally there for -- the blank is there to show contamination."

And I'm going to stop there.

Agree with that statement, or disagree?

A. That's correct. If contamination occurred, the blank is there so you'll know about it.

Q. "This is qualitative vs. quantitative. Agree or disagree?"

I'm quoting again.

A. I'm not sure what she's referring to in this, but HPLC, as she used it, was for purposes of quantitation.

Q. I'll continue. "I'm only doing it to show what the purity is, and it's not a requirement to run a blank in this instance," end of quote. Agree or disagree?

A. Disagree.

MR. BROWN: Thank you. Nothing further.

THE COURT: Any further redirect?

MR. DRISCOLL: Please, your Honor.

REDIRECT EXAMINATION

BY MR. DRISCOLL:

Q. Madam witness, in the course of examination by the United States, cross-examination by the United States, a series of questions were asked. And to summarize, these questions went to your thoughts on whether quality assurance principles are separate and apart from science. Do you recall that series of questions?

A. I certainly do.

Q. I would invite you, if you need to, to reexamine United States Exhibit 1. You and I reviewed parts of it before. And it consists of the declaration of Ms. Irby, page 1 through 76.

A. Yes.

Q. You're familiar with that exhibit in its whole?

A. Yes.

Q. You're also familiar and testified earlier this afternoon relative to pages 19, 20, and 21.

Reviewing those, would it be safe to say that the declaration, the exhibit, and the specific pages contained therein render an opinion, the opinion of a scientist, Ms. Irby; and in her opinion, she proffers there or offers it to a reasonable degree of scientific certainty that the identity of the substance was methamphetamine and that it's very, very, very pure?

A. That is her opinion, yes.

Q. And would it be safe to say the quality assurance principles that you've testified exhaustively about here today go to the reliability of the opinion?

A. Yes.

Q. And your testimony interfaces quality assurance principles with science, in that before we get to an opinion that a court can rely on, the opinion must be based on reliable methods?

A. Yes. Decades of experience in fields of metrology have

demonstrated that the only way to consistently ensure reliable results is through a rigorous quality assurance program.

Q. And so by extrapolation, quality assurance is at the very core of science, in that reliable quality assurance predicts a scientific opinion that a court or a finder of fact can rely on?

A. Reliable quality assurance enhances the reliability of results; so good quality assurance gives you a means of providing results with confidence.

Q. And conversely --

A. And the converse is true: In the absence of a robust, well-documented quality assurance system, you simply don't have that degree of reliability for the results. It doesn't mean that labs out there aren't going to get it right. The science might work. But you can't consider them reliable unless you have this objective empirical evidence that it's working at the time you're running your unknowns.

Q. And that empirical evidence is not contained in Exhibit 1, pages 1 through 87?

A. That's correct.

MR. DRISCOLL: Thank you.

No further questions. Thank you, your Honor.

THE COURT: Thank you.

MR. BAKER: Your Honor, if I may just ask just one or two questions.

THE COURT: You May.

REDIRECT EXAMINATION

BY MR. BAKER:

Q. There has been some talk about the reliability of the results. Just so I'm clear on this: Your work as a quality control analyst focuses primarily on the reliability of the methodology in use; is that correct?

A. It's probably split between how scientifically valid is this method for its intended use and then, once you have a valid method, you have the empirical data, that you know it's capable of generating acceptable results, then how reliably was it implemented in the laboratory. So both of those pieces have to be present in order to get reliable results. And I probably spend equal amounts of time on both of them.

Q. And here there is problems with the reliability of the methodology used by Ms. Irby throughout the testing process; is that correct?

A. Yes.

MR. BAKER: Thank you.

THE COURT: Any further redirect?

All right. Can this witness step down?

MR. BROWN: No objection, your Honor.

THE COURT: Okay. Thank you, ma'am. You may step down.

Further evidence by the defense?

MR. BROWN: None, your Honor. Thank you.

THE COURT: Rebuttal evidence by the proponent of the testimony?

MS. MAGNELLI: Yes, your Honor. We call Mr. Oulton back to the stand.

THE COURT: Please retake the stand. You remain under oath.

(Scott Oulton was recalled to the stand.)

MS. MAGNELLI: Your Honor, may I take water to the podium?

THE COURT: Of course.

DIRECT EXAMINATION

BY MS. MAGNELLI:

Q. Mr. Oulton, I'm going to remind you you're still under oath.

A. Yes.

Q. Now, I'm going to skip around.

You've heard testimony of Ms. Arvizu; correct?

A. That's correct.

Q. All right. So let's get to it. Do you know anything about the positive controls in the HPLC in this case?

A. I do.

Q. What can you tell us with regard to what Ms. Arvizu testified about?

A. Well, essentially overarching positive controls in the

entire case.

And I would offer that Ms. Irby's Exhibit 1, Ms. Irby's declaration and her notes, actually does include the fact that positive controls were done on virtually every instrument that she used. Now, whether they were done contemporaneously, that's a different question; but they were in fact done on every technique she used.

For example, the mass spectrometer, the GC mass spectrometer, she compared to a reference material that was run several weeks prior. And it actually shows that the retention time, the GC portion, is remaining consistent. So it's actually good evidence to show that that technique is robust, it is maintaining the retention time throughout.

Some of the tests for the GCIRD, in that particular case there was -- excuse me -- it was compared to another positive control, and that one was roughly a year before. And it shows that the retention time again was maintaining consistent throughout that period of time. So it was compared to that positive control.

As for the HPLC, same thing. Yes, in this case, the way that she -- she attacked or the way she conducted her analysis is at that particular point she had already had five tests done to show the presence of methamphetamine was confirmed. And then she wanted to do the quantitative testing, so at that point she felt or she testified that it was no

longer required to do positive controls -- or excuse me -- blanks or negative controls, because at that point she already knew what the substance was, she was no longer fearing the possible contamination. But she did actually run standards -- or excuse me -- reference materials in connection with her unknowns, and those were run before and after her runs. So it's a known amount of material that she put on the instrument, she looked at the measure, she looked at the retention time that was there, and she compared that again to those things.

So, yes, it was used as a calibrator; but it was also used as a positive control to show that the instrument was producing a result at the anticipated result over time.

Q. And you just talked about contamination, and there has been a little bit of testimony about that. Based on your knowledge, training, and experience, how would you -- how would you contaminate a basketball size of methamphetamine?

A. Quite frankly, I have no idea. This essentially was a pure methamphetamine, 11 1/2 pounds. To contaminate it would be virtually impossible that I'm aware of any other way other than replacing it with something that was there.

Q. Let me ask you this: If there was something else found, would it affect result?

A. Yes. Well, in this particular case, all of tests indicated that there really was nothing else there. There was a -- in the mass spectrometer, she found a very small component of

dimethyl sulfone but wasn't able to identify it because it was such a small level.

But in every one of her techniques, she showed the presence of nothing else present except for methamphetamine. In, for example, the infrared, the IR, she included one of the things that Ms. Arvizu testified to -- is that it's in a high purity. And that's absolutely correct. If in a high purity, it doesn't have the influence from other compounds that were there.

If you look at the sample that she ran, that spectra produced -- that particular sample that she compared it to, it is essentially pure methamphetamine. If there was anything else in there, you would see those other absorbances contributing from those other compounds that are part of that spectra. If you look at that spectra, compared to the reference materials she did, it's essentially a very, very good match.

If you look at reference materials, you're going to find that every methamphetamine hydrochloride standard matches exactly the spectra that she got from this particular sample.

MR. BROWN: Your Honor, I'm going to object at this point. It seems that the testimony of the witness is either in the nature of a summary of the evidence that has previously come before, does not state anything new, and it seems to be weighted to now a conclusion about what the results were as

opposed to the focus of the inquiry of a 702 hearing.

THE COURT: Your objection is noted for the record.

MR. BROWN: Thank you.

BY MS. MAGNELLI:

Q. Was there anything else you wanted to add before I move on?

A. Essentially just all the individual tests showed that it was essentially pure methamphetamine.

Q. All right. I want to break this down just a little bit. You heard Ms. Arvizu talk about ion 58 on the mass spectrum of the GSMC [*sic*]. Excuse me. Do you recall her identifying that ion?

A. Yes.

Q. What did she ID that as?

A. I believe she said it was a dimethylamphetamine.

Q. Is that accurate?

A. No, actually. It does not -- it would actually have three carbons and the nitrogen.

Q. Is that something a trained analyst would know?

A. Certainly a competent analyst in drug chemistry would know that.

Q. Are you familiar with the Sachs and Woo paper that talks about identifying methamphetamine from mass spectra alone?

A. I am. In fact, I've had Sachs and Woo come to our laboratory when I managed the San Diego DEA Laboratory, discuss her paper and how they can differentiate between the regional

isomers of amphetamine- and methamphetamine-type related compounds.

Q. And is the point of that is that there is literature out there that says that mass spectra alone can be used to identify meth?

A. There is literature out there that does say that, yes.

Q. There was testimony about derivatives. Do you recall that?

A. I do.

Q. And do you recall that there was testimony that the -- adding a derivative essentially would make it bigger so that the results would be more prominent essentially?

A. Yes. Essentially you're adding something to it to make it bigger, and it gives you more detail in the spectra, as was testified earlier. But nowhere is it a requirement. It is what used to be done in the past before the research was conducted to show that it actually is and can be identified. There is even ongoing research. I have several chemists before I left San Diego laboratory that are working on another research project that's doing something very similar to that.

Q. So the current state of science is that that's not necessary; is that right?

A. That's correct.

Q. There was testimony about shelf life. Do you recall that?

A. I do.

Q. And what can you tell us about shelf life with regard to

Ms. Arvizu's testimony?

A. There is actually, when we purchase or anybody purchases a reference material -- there would be a shelf life associated with that. It is our procedure -- excuse me. It is our practice to actually have that be verified every three years, as Ms. Arvizu testified to. It is verified.

In fact, for the most part, we run through it so quickly, we never make it past a year before we're buying new material to put into the -- especially for the main drugs that we analyze.

Q. And there was testimony about in various terms -- about the composite that was formed. Do you recall that?

A. Yes.

Q. And do you know or do you have an opinion based on your knowledge, training, and experience as to whether or not a composite, the kind that was formed here, is a good thing forensically?

A. Yes, I do. In this particular case, the first analyst actually combined all of the units. Once she had identified that it contained methamphetamine in each one, you combine them all. And the purpose of that was to determine the purity. And the best way to get the purity is actually to combine all the units, mix it, homogenize it, run through all of the testing that we have to do. And it gives us the most accurate result based on the whole. So that is a viable technique in the

science community.

Q. And there was testimony about method validation. Do you recall that?

A. Yes.

Q. I want to talk generally about the science. These six tests, these methods: Have they been validated as methods that can identify controlled substances?

A. Yes, they have.

Q. And there was some testimony about the color test and how it simply is presumptive. Do you recall that?

A. Yes.

Q. The color test is essentially a field test; is that right?

A. It's a field test much like a police officer would use in the field.

Q. And do you know any of lab that would use that solely to identify for purposes of a court hearing the drug?

A. No, I do not.

Q. Now, you heard -- you have some experience with quality assurance; is that correct?

A. Yes, I do.

Q. In fact, are you a certified auditor for ASCLD/LAB?

A. Yes, I am.

Q. And when you leave your four-year position in a month, will you be qualified to audit again?

A. Yes, I will.

Q. And you maintain proficiency as a quality auditor as well?
A. Yes, I do.
Q. What kind of auditor are you?
A. I'm a technical assessor.
Q. What does that mean?
A. It means I have relative experience and competency in the field that I participate in, and I would be invited into a laboratory for evaluate, to assess another laboratory's controlled substances section.
Q. And are the requirements that you have four years' minimum experience in a crime lab?
A. That is correct.
Q. In a specific discipline in forensic chemistry?
A. Yes. That is correct.
Q. Give me an example of something you cannot do.
A. For example, toxicology is very similar, same type of chemistry. They use the mass spectrometer. But I've never done any toxicology work, so I would not qualify as an assessor in that particular because I have no experience, nor would I offer any testimony -- or any assessing in that particular field.
Q. You also have significant background in science; is that right?
A. That's correct.
Q. And you've already testified about that, so I don't want to

go through it. So you have experience in both science and quality assurance?

A. That's correct.

Q. Are those two worlds separate and apart?

A. In my opinion, yes.

Q. Why?

A. Well, for example, before we -- before even laboratories got into the quality assurance aspects, we were conducting testing using the science that's been reliably applied over the years and years and years to show that we can identify a drug based on the science that existed. So now to now say that that is all excluded is a little bit ridiculous, in my opinion.

The quality assurance aspect is very important. We chose -- at least the laboratory systems -- we have chosen to become accredited in these standards because we do believe in the quality assurance aspects. But in no way can it nullify the fact that what we did before that existed was not correct [*sic*].

Q. So for purposes of reliability, the methods that were used -- they are reliable in terms of identifying controlled substances in the scientific community; correct?

A. That's correct.

Q. And based on your testimony, based on your knowledge, your training, experience, the lab testing done, Ms. Irby's results: Can you tell whether they were reliably applied to the facts of

this case?

A. Yes, I can.

Q. And were they?

A. Yes, they were.

Q. And that's from a scientific perspective; is that right?

A. That's correct.

Q. And scientifically, are there sufficient facts and data upon which to draw an opinion?

A. Yes.

MS. MAGNELLI: Court's indulgence.

Nothing further.

THE COURT: Any further cross-examination of this witness?

MR. BROWN: May I?

MR. EDELMAN: Yes, your Honor, I have a few questions.

CROSS-EXAMINATION

BY MR. EDELMAN:

Q. Mr. Oulton, did I understand that you said that in a few weeks or months, you're going to be a quality control auditor?

A. Essentially, I'm on the board of the ASCLD/LAB and I serve a four-year term. During that term, I was not allowed to do assessments because I was on the board. But I come off the board, my four-year term expires in September, in which case I will be then put back into the quality assessing, ability to do so.

Q. So that's a yes?
A. Yes.
Q. And when you do that quality control assessment, you will then go into a particular laboratory; is that correct?
A. Correct.
Q. You'll actually enter it, go into it, look at the lab?
A. First they would have provided us with the information; and then, yes, we go into the laboratory to assess how they meet the standards that they're being assessed to.
Q. Again, that's a yes?
A. Yes.
Q. And you will watch the people, the chemists there performing some of the chemical tests and using the devices and the equipment that we've talked about today; correct?
A. For a quality audit assessment of a laboratory, yes.
Q. You will look at their paperwork, their log books; correct?
A. Yes.
Q. You will examine their manuals; correct?
A. That's correct.
Q. And you will examine their manuals that set forth their methods; correct?
A. That's correct.

MR. EDELMAN: Thank you.

THE COURT: Anyone else?

MR. BROWN: Just briefly, your Honor.

CROSS-EXAMINATION

BY MR. BROWN:

Q. Mr. Oulton, the quality control responsibilities of the Western Regional Lab rest with Ms. Irby?

A. She is one component. The quality manager was actually Bryan Henderson.

Q. And so she's supervised by Bryan Henderson, did you say?

A. That's correct.

Q. So in the chain of command, what's her title?

A. Her title is the quality assurance specialist. She reports to the manager, which is Bryan. And she essentially assists with the quality assurance program.

Q. And in that capacity, should she have familiarity with the source of positive controls that are shipped to the lab?

A. She would know where the records are located to be able to identify where they were sourced.

Q. But should she know where the samples actually came from?

A. Off the top of her head?

Q. Right.

A. Off the top of her head, I think she would have to go back to the laboratory, look at the source documents, and to figure out this one came from Sigma-Aldrich, or this one came from Special Testing. Unless she knew off the top of her head. I don't know.

Q. Does the positive control samples utilized within the DEA

labs -- are those all commercially generated, or are those are all created at the DEA -- by the DEA?

A. It's a combination of both. We actually purchase them from companies, and we have some that are manufactured and verified by our special testing research laboratory.

Q. Do you know how much the DEA pays to ASCLD/LAB to conduct the audits --

MS. MAGNELLI: I'm going to object.

BY MR. BROWN:

Q. -- on an annual basis?

MS. MAGNELLI: This goes way beyond the scope of direct.

THE COURT: Sustained.

MR. BROWN: I have nothing further. Thank you.

THE COURT: Thank you.

Thank you, sir. You may step down.

MS. MAGNELLI: Your Honor, if I may, one question on redirect.

THE COURT: Why?

MS. MAGNELLI: Because I want to clarify something Mr. Edelman asked.

THE COURT: Ordinarily, we do not have re-redirect here.

MS. MAGNELLI: I directed him on rebuttal, your Honor. I just had one question.

THE COURT: Oh, following cross-examination.

MS. MAGNELLI: Correct.

THE COURT: Okay. I got lost. I apologize. Please proceed.

REDIRECT EXAMINATION

BY MS. MAGNELLI:

Q. Sir, you were asked a series of questions by Mr, Edelman if you recall them, about what you need as a quality auditor; is that right?

A. Correct.

Q. And that would be quality auditor for ASCLD/LAB?

A. Yes, for ASCLD/LAB.

Q. And that would be where a lab hired ASCLD/LAB to audit them; correct?

A. That is correct.

Q. And that's the only time you would walk into a forensic lab to audit them; isn't that right?

A. That's correct.

Q. And unless the lab hired you to assess them, you would not be invited; isn't that right?

A. That's correct.

MS. MAGNELLI: Thank you.

THE COURT: Now can this witness step down?

MS. MAGNELLI: Yes.

THE COURT: Thank you, sir. You may step down.

THE WITNESS: Thank you.

THE COURT: Any further rebuttal evidence by the Government?

MR. BOMA: No, your Honor.

THE COURT: Thank you. This completes the evidence that has been presented.

Counsel, do you prefer to make a brief oral argument at this time, or to make written arguments?

MS. MAGNELLI: Your Honor, I'd like to make a brief oral argument.

THE COURT: And for the defense?

MR. EDELMAN: Orally, your Honor.

MR. BROWN: That's fine.

THE COURT: Anyone in disagreement with that?

I'm not seeing anybody who prefers to write a brief.

All right. Then we'll hear from the Government.

MS. MAGNELLI: Just one minute, your Honor.

CLOSING ARGUMENT

MS. MAGNELLI: Your Honor, we have given some written submissions. There has been extensive testimony, so I'm going to try to keep this brief.

I want to talk about the guiding factors that have been set out under *Daubert*. I don't think those have been addressed --

THE COURT: I'm familiar with them.

MS. MAGNELLI: I just want to address how the evidence fits of those, for the record.

Whether the particular theory can be and has been tested. Your Honor, I would submit that these theories, all six of them -- they have been tested, they can be tested, they are repeatedly tested in the world of science. They're tested in courtrooms all over the world. And the science, as you heard, has been around for more than a hundred years. And actually, DEA, or the lab Ms. Irby is at, tests them on a daily basis. She herself has tested them hundreds and hundreds of times. She's used them.

Whether the theory has been subjected to peer review and publication. The Government has previously provided a bibliography which is just a sampling of literature on the science behind the drug and on the ability of these particular instrumental techniques to identify drugs. Every individual lab report such as Ms. Irby's -- her lab report was subjected to a technical and administrative review. It was reviewed internally.

The known or potential rate of error. Your Honor, there has been testimony about the uncertainty associated with measurement and purity. That is evident on the lab report. It's right there in front. And the testimony shows that that actually lends some accuracy to the results.

As the testimony also shows, Ms. Irby has undergone

training and proficiency tested [*sic*]; and the law is clear that what is important under *Daubert* is the reliability of the scientific methodology at issue, not the reliability of the laboratory performing the test, which was specifically at issue under *U.S. vs. Ewell* out of the Northern District of New Jersey.

Furthermore, as long as the process is generally reliable, the courts have held that any potential error in the analysis can be brought to the attention of the jury through cross-examination and testimony of qualified experts.

The existence and maintenance of standards controlling the techniques' operation. First of all, as the Court knows, the *Daubert* factors are flexible. In other words, standards are not required. Notably, there are numerous types of forensic expert testimony that are admissible, although they spring from fields without uniform standards, such as fingerprint experts in *U.S. vs. Baines* out of this Circuit. Despite argument that the method of fingerprint analysis had not been tested that there were no established error rates; that there were no uniform and objective standards, and that there was an absence of professional literature to support the admission of testimony of fingerprint examiners, the court found that the Government had still met its preponderance burden under *Daubert* because the reasoning and methodology underlying latent fingerprint evidence was scientifically valid

and properly applied.

So in other words, even in disciplines where there is a total lack of standardization, that in and of itself is not a bar to admissibility. However, the discipline at issue here, the forensic identification of controlled substances, is something with standards. There are recommendations. The Government has provided a myriad of those.

And just to note with regard to the questioning about the fact that Ms. Arvizu didn't have access to protocols and procedures, that's a Rule 16 issue. The Government is not required to provide the defense's expert with the basis of their testimony or opinions. Moreover, the fact that the Government did offer some of those protocols and procedures, they were specifically rejected by the defense. I think that's worth noting.

However, those don't even matter, because we have all the other requirements and the testimony of Mr. Oulton, where he could testify about SWGDRUG, as well as a competent chemist.

Finally, whether the technique has achieved general acceptance in the relevant scientific or expert community. There is an abundance of evidence that these techniques have achieved general acceptance. The testimony is clear that Ms. Irby went beyond even the SWGDRUG requirements, which have also been acknowledged as widely accepted. And it's clear that really the community at issue here is the forensic scientific

community, not the quality assurance community.

The validity of the tests performed in this case is not reasonably in question here. They have been described as robust, as well-documented; and regardless, *Daubert* wouldn't limit the scientific testimony to results obtained through a single or superior method of inquiry.

Finally, your Honor, there is really no allegation that the substance was anything other than methamphetamine; that these methods were not viable. In fact, Congress has specifically endorsed the use of GCMS under 18 U.S.C. 3583(d) with regard to the testing of urine for drugs under supervised release.

There has been no argument of specific testing error in this case. There has been some disagreement between the experts, but that is not a bar to admissibility.

Ms. Irby didn't just take the stand and say this is more than five keys of 99 percent pure meth hydrochloride. She testified in detail about her steps. She explained her training and her knowledge. She explained some science journals and reference materials.

And even if there was a viable argument of error, *Daubert* doesn't require perfect execution of protocols. Experts can disagree. Things can actually be done incorrectly, and none of that really matters under *Daubert*.

And that really brings me to my final point, your

Honor: The point of *Daubert* is that differing opinions -- they're okay. It's about keeping out junk science. It's not about saying one method is superior to the other or this expert's opinion is superior to the other opinion. And the fact of the matter is that there is case law that says even if you have protocols and there is imperfect execution of those protocols, it doesn't matter under *Daubert* because that's not the ultimate purpose of *Daubert*.

And as I was saying, really my final points is this mixing of apples and oranges when we talk about quality assurance and *Daubert*. Under quality assurance principles, if you fail to follow one clause of a standard, then you fail, period. You must have perfect implementation of those, and the testimony was that they are all mandatory.

Under *Daubert*, that is not true. You don't have to have that level of perfection. You have to have the same type of intellectual rigor in the courtroom that you would have back in your lab. It's a much different standard.

What -- The testimony about reliability under quality assurance does not supplant legal reliability. Evidentiary reliability is not the same as reliability under quality assurance.

The fact of the matter is the standard is preponderance of the evidence. There is an abundance of evidence that the Government has met that standard. And while

we -- while we believe that the lab -- the recommendations, the SWGDRUG recommendations are unnecessary to a determination here, those are in evidence at this point. The Government has provided those and provided the testimony of compliance with those. And there is nothing really to say that there was no compliance. Even testimony from Arvizu was general, nonspecific, and really didn't relate to the actual testing itself.

Finally, the Government would incorporate its arguments from its previous filings, the attachments to those filings, and maintains that Ms. Irby's testimony is reliable under Rule 702, the guiding principles of *Daubert*, and should be admitted at trial for the jury to weigh.

Thank you.

THE COURT: Thank you.

For the defense?

CLOSING ARGUMENT

MR. EDELMAN: Thank you, your Honor.

This quest began with my filing of my motion for additional discovery, which was quite extensive. It was not complied with, as I alleged at our hearing many months ago. And I recall the Court asking me what was complied with and what wasn't. And I couldn't answer you because it was way above my ability to respond. And quite frankly, I was taken by surprise.

And the Court, as I recall, said, Well, it was the Government's responsibility to prove at a 702 hearing that they met their obligations and criteria set forth in Rule 702. We had that hearing on April 19, 2011. And the Government failed to meet their obligations, and the evidence was suppressed.

At the end of that hearing, Mr. Boma at that time offered to in a general statement -- to give me the information I had requested without being specific. And I rejected that offer. That is the only time that the information that Ms. Magnelli said -- that it was offered. It has not been offered since. It has not been provided since. There was some discussion on May 27 to offer some information off the record subject to a -- as I recall, subject to some protective order that was never prepared, presented, or offered. And we have not seen anything. We have not seen any log books. We have not been permitted or offered to go into the lab. We have not seen any documentation to assist Ms. Arvizu to offer any more specific opinion as to whether or not the Government has or has not met any methods or followed any methods in Ms. Irby's testing of these controlled substances.

I would submit to you it is not whether or not the controlled substances are drugs, are controlled substances, are methamphetamine; it's how the Government got there; whether or not they followed methods that are reliable and their methods have been and their procedures have been reliably applied.

And of course, there are no methods. The Court has indicated that Ms. Irby has not applied any methods at a DEA lab. And the Court, as I understand it, would not consider any DEA methods.

THE COURT: Let me clarify for you, because you've repeatedly said that; and that is not what I have said. The methods that Ms. Irby used were the methods she described. You have confused methods with protocols. Protocols are what DEA laboratories require as background procedures; and those, I'm not considering because those have not been disclosed.

So the methods that we're talking about are what Ms. Irby did.

MR. EDELMAN: I apologize. It is my confusion.

Then that may be another issue. I don't believe she describes the -- described adequate methods. I don't believe they are sufficient, according to Ms. Arvizu, that are described by the -- by ISO, by SWGDRUG -- that are sufficient to meet 702 criteria.

With all due respect, I -- I can't disagree with what the Court just said; but I reviewed the Court's transcript, and I had to look up what methods -- the term "methods" are because I was confused as to the term "methods," "protocols," "procedures," "principles." And I was quite confused to what all that meant.

It's my understanding that you have tests. You're

testing these drugs. It was best described to me as the preparation of a cake. You have eggs, you have sugar, you have flower, you have chocolate, you have baking soda. You have these methods, these procedures, these protocols. You have some way in which you have to prepare all of these ingredients to come to the conclusion, to have a cake. There is different ways to do it so that you have the cake. You can have different kinds of cakes. If you don't have the cake that is intended by the sufficient reliability because of the -- as Ms. Arvizu suggested because of the importance of what we're talking about here, then it's not reliable.

And Ms. Arvizu suggested that the industry requires a higher standard than that performed by the -- the DEA laboratory. And they're hiding behind these procedures, these protocols. They're hiding these documents for some reason. And it is unclear why they're hiding behind these protocols, these methods, why Ms. Irby memorizes these procedures and these protocols or however you want to term them or call them.

And I would submit to you that the Government has not met that burden. And as a result, this evidence should be suppressed, because as the gatekeeper, you have to keep it out. It has to be suppressed. It's not -- it's not an issue of weight. It's an issue of admissibility.

Thank you.

THE COURT: Thank you.

CLOSING ARGUMENT

MR. BROWN: With respect to how this evidence should be treated, obviously I think that what we've tried to do through the testimony of Ms. Arvizu is address each individual test and give the Court information why each individual test was not properly documented and is not reviewable from a quality control analyst's standpoint in a fashion that can lead one to be confident in the results.

It seems that the Government wants to emphasize that the result that there is no other conclusion but this must be methamphetamine. And it seems that it's a basic tenet that in order to address that -- that conclusion -- that you have to understand the underlying underpinnings of each specific scientific test.

In addressing those individual tests, what is quite interesting in my listening to the testimony and Mr. Oulton's recent testimony is that in discussion with the one tells where the blank was not used, I think we all agree with the absence of a blank could cause some form of contamination.

His reasoning for giving the stamp of approval to Ms. Irby's testing methods was that she didn't need to use a blank because the four previous tests that had been conducted were all positives.

That's not what Ms. Irby testified to. She testified you never need to use a blank.

And what that is is it's telling of the way in which the protocols get interpreted individually by individual scientists. And it should be the type of confusion or disagreement amongst the DEA's own forensic analysts that lead to a lack of confidence that the result of that one individual quantitative test is in fact accurate. But that is just one example of why in other facets these other tests were not done to sufficient scientific protocol.

And I think it is a difficult question for the Court, because what does appear is that in the scientific community, you do get somewhat of a general standard. It doesn't necessarily comport with the specific individual forensic analyst's completion of a test. And so the Court is left with a situation where it must choose from the competing scientific opinions which one is entitled to perhaps more confidence.

And I think that the testimony of Ms. Arvizu -- she isn't a forensic analyst, doesn't sound like she's ever going to be a forensic chemist; but she's a quality control analyst. And the ultimate question for this court is whether the testing was done in a sufficient and adequate manner so that we can have confidence in terms of the quality. It's clear that Ms. Arvizu's opinion is that it was not. I'd ask the Court to adopt that in making its ruling.

Thank you.

THE COURT: Thank you.

MR. DRISCOLL: Nothing for Mr. Pelayo. I'll submit the case on cocounsel's argument, your Honor.

THE COURT: Thank you. Anyone else?

CLOSING ARGUMENT

MR. BAKER: Your Honor, excuse me. I just have -- I think when I started out this morning, I raised an issue about the term "standards" and the supplement to 17025. I don't know whether the Court used "standards" in its ruling back in May the same way it's been used in multiple -- I think it's been used in several different ways today; but my understanding is that the type of -- that the supplement is a standard. We have evidence that the supplement is a standard.

Everybody has refused to produce that. The Government's refused to produce it. The agency has refused to produce it. And I think we're in exactly the same boat we are with respect to the DEA standards and protocols and that the Court's ruling with respect to those standards and protocols are equally applicable to the supplement in question here.

THE COURT: Thank you.

Anyone else for the defense?

MR. GOLLA: Your Honor, Mr. Meza is relying on arguments of cocounsel.

THE COURT: All right.

REBUTTAL ARGUMENT

MR. BOMA: Your Honor, if the Government night make a

factual clarification regarding Mr. Edelman's argument from the last hearing, because there are inaccuracies in his argument as to what occurred at the May 27 hearing.

THE COURT: I have a transcript.

MR. BOMA: Your Honor, if I might make a proffer for the record.

THE COURT: Okay.

MR. BOMA: Mr. Edelman implies that the DEA procedures -- which they were relevant excerpts from the DEA laboratory manual -- were not turned over.

Well, there is a reason for that. We were prepared to turn those over to the defense under a requested protective order that they not be disclosed outside the defense camp, if you will. And the defense initially said that they would like those materials. And the Court offered a continuance of the hearing or allowed the defendants to proceed without those laboratory excerpts. And the defense elected consciously not -- to continue the hearing and not to receive those offered DEA laboratory manual excerpts.

So I think what Mr. Edelman said was factually inaccurate. Thank you.

THE COURT: Thank you. Is there anything further?

Then the matter will be deemed submitted. I will not make the mistake of confusing everyone with an oral ruling. Instead I will issue a written ruling. It will be issued

within 30 days. And at the time of the issuance of written ruling, I will advise you of the next hearing to be conducted in this case.

Thank you all. We'll stand in recess.

(Recess at 3:56 p.m.)

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Exhibit	Offered	Received	Refused	Reserved	Withdrawn
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REPORTER'S CERTIFICATE

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter. Dated at Denver, Colorado, this 24th day of August, 2011.

S/Paul A. Zuckerman
Paul A. Zuckerman