IN THE SUPERIOR COURT FOR THE STATE OF VERMONT

IN AND FOR THE COUNTY OF CALEDONIA, CRIMINAL DIVISION

STATE OF VERMONT, Plaintiff, v. DALE B. SMITH, ET AL., Defendants.	Docket No. 382-6-12 Cacr 9:08 a.m. February 7, 2013 Volume I of II Pages 1 - 194

MOTION HEARING
BEFORE THE HONORABLE MARY MILES TEACHOUT
JUDGE OF THE SUPERIOR COURT

APPEARANCES:

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(Proceedings commence at 09:08 a.m.)

THE COURT: We're here for a hearing, Defendant's motions to exclude breath test, and a number of different cases, some of them from Caledonia County, but also some from Essex County, and in addition by special assignment some from Orleans, Orange, Windsor, and Chittenden Counties.

And I think it probably makes sense to, for the record, review all of these cases to make sure that the cases and files that I have match those that you believe that you're hearing.

First the Caledonia cases: Nicholas Guyer, 12-1-12 and 68-12-11; Dale Smith, 25-6-12, 382-6-12; Steven Gaboriault, 28-7-12, 393-7-12; Brian Lavigne, 32-7-12, 444-7-12; Gregory Hovey, 36-8-12, 499-8-12, 62-12-11, 737-11-11; Jere Kendall, 37-7-11, and 433-7-11; James Tidyman, 4-1-12, 56-1-12; Andrew Schibly, 50-11-12, 746-11-12; Keenan Chenail, 549-9-11; Rose Coughlin, 55-11-12, 761-11-12; Gregory Crum, 552-8-12; Shannon Budziak, 57-11-11, and 697-11-11; Wilfred McAllister, 60-11-12, and 820-11-12; George Lyon, 61-11-12, and 837-11-12; Dale Stone, 63-12-12, 855-12-12; Dennis Bessette, 64-12-12, and 872-12-12; Dylan Bertolini, 66-12-12, and 887-12-12.

(Judge reads off Essex County, Orleans County, Orange County, Windsor County, Chittenden County cases from calendar)

THE COURT: Are any of you aware of any discrepancies?

MR. NAGURNEY: No, Your Honor.

MR. SLEIGH: No.

THE COURT: Okay.

And present for the Defendants are Attorney Sleigh, Hatt, and Christman?

MR. SLEIGH: Correct. Yes, Your Honor.

THE COURT: And for the State, Greg Nagurney?

MR. NAGURNEY: Yes, Your Honor.

THE COURT: And Glen Barnes?

MR. BARNES: Yes, Your Honor.

THE COURT: And I -- Mr. Nagurney and Mr. Barnes, you are here on behalf of all of the State's attorneys in all of these counties?

MR. NAGURNEY: That's correct, Your Honor. Yes.

THE COURT: All right.

Mr. Sleigh.

MR. SLEIGH: Thank you, Your Honor.

I don't know how the Court would like to proceed. If you want brief opening statements or explanation of how we see the issues, or if you'd like to just jump right into the testimony?

THE COURT: I think a brief introduction would be helpful.

DEFENDANT'S OPENING STATEMENT

MR. SLEIGH: Okay. The legislature required the

Department of Health to generate rules that would govern breath alcohol analysis. As of March of 2012, the responsibility for supervising and administering the breath alcohol program was shifted from the Department of Health to the Department of Public Safety. That act, Act 56 as it's referred to, that shifted the responsibility, said that the then existing rules that had governed breath testing under the Department of Health would remain in effect until such time as the Department of Public Safety generated new rules. Act 56 instructed the Department of Public Safety to issue its new rules, and by my understanding, they are now finally in the rule-making process.

So I say that only to let the Court know that the rules in effect now have been in effect for all times pertinent to all the cases that are docketed here.

The rules require that the breath testing method and instrumentation meet certain precision and accuracy requirements. The seminal case of State versus Rolfe says that if the State can prove that those somewhat foundational requirements are met, the analysis generated by the instrumentation would be admitted with the defendant free to contest its weight. However, Rolfe said that the State had the burden of establishing those foundational facts and that the defense had an opportunity to introduce evidence contrary or to rebut, if you will, the State's assertion of the foundational facts.

I've talked this case -- these cases over with Mr. Nagurney and I think we agree, at least procedurally, that in each of these cases, the State has filed an affidavit saying that the machine, the DataMaster T, meets the precision and accuracy requirements set forth in the Rule. It's our intention today to produce evidence as allowed by Rolfe to contest whether the State can actually establish those precision and accuracy criteria.

Now the heart of the argument is this, Your Honor. The Department of Health and the Department of Public Safety have undertaken certain efforts by which they say they have credibly demonstrated that the DMT meets these precision and accuracy requirements. We're going to try to show the Court that the methods by which the Department of Health and the Department of Public Safety undertook to establish the criteria did not meet minimum scientific standards.

Now, there's nothing in the Rule that says that the Department of Public Safety and the Department of Health have to abide by any standards at all in proving that the machine meets the criteria. But it's our position that there's an implicit criteria that the agencies use their expertise in a way that would meet minimum scientific standards in order to establish foundational and scientific facts. And we will call, I believe, one witness to testify about the state of the minimum standards applicable to testing laboratories, and

establish that the Department of Health and the Department of Public Safety's efforts to establish the precision and accuracy criteria did not meet any recognized minimal scientific standard, and thus their assertion that they've established this -- those facts should be discredited.

THE COURT: Thank you. That's helpful. I also would like you to address the procedural aspect of it. In other words, you filed this as a motion to exclude. What -- what exactly is the basis for that? Is that like a motion in limine where you're saying that the expert -- well, you articulate it yourself.

MR. SLEIGH: I look at it as sort of a 104 hearing, Your Honor. In other words, what I'm saying is that if the State were to offer the breath alcohol test results in these cases, they would -- should not be admitted because the State has not and cannot prove in a reasonable way the criteria that are a condition preceding to the admissibility of the test, i.e., so-called foundational facts. That is, in this instance, whether they're precise and accurate as required by the Rule.

So I think the short answer to your question is it's, in essence, a motion in limine, based on foundation -- a lack of foundation claim.

THE COURT: Okay. So this is a preliminary hearing on the admissibility --

MR. SLEIGH: Right.

THE COURT: -- of the evidence.

All right. Mr. Nagurney?

STATE'S OPENING STATEMENT

MR. NAGURNEY: Thanks, Your Honor.

And I agree with a lot of what Mr. Sleigh said. I agree this is a 104(a) hearing. I agree that the rules to control are the E ones that have been issued by the Department of Health and adopted by the Department of Public Safety. And those are available in a number of places for you, I believe, judicially noticeable.

THE COURT: Did anybody make a copy?

MR. SLEIGH: Exhibit A, Your Honor --

THE COURT: Okay.

MR. SLEIGH: -- are the rules.

THE COURT: Thanks.

MR. NAGURNEY: I believe, Your Honor, they're also set forth in State v. Rolfe, which is the controlling case here which is found at 166 Vt. 1.

But as far as Mr. Sleigh's statement, Judge, what you're being asked to do here under Rule 104(a) is to assess the foundational sufficiency for the State's evidence and as I'm sure you're aware, that's a decision that -- in which you're vested broad discretion to do. And findings regarding foundation are reversible only for clear air on appeal, I believe is the standard. So what I'm suggesting to Your Honor

is that really under 104(a), you're deciding by preponderance of the evidence whether there is an adequate foundation for the State's expert testimony.

This hearing is somewhat unique in that Mr. Sleigh and I agree. I think what you'll hear ultimately is that the State provides no measurement of uncertainty to accompany a DataMaster result.

THE COURT: Say that again?

MR. NAGURNEY: I think ultimately what you'll hear from Mr. Sleigh's expert is the State provides no, what's known as a, measurement of uncertainty or a confidence interval to accompany a DataMaster test result. So in other words, if a defendant blows a 0.1, and that's a 0.1 BAC, and that's his test -- I believe Mr. Sleigh's testimony would go to the fact that we can't rely on that because there's no confidence interval associated with that measurement. And that, you'll hear further on that from the expert.

So, Your Honor, I guess the second part of the foundational assessment you'll be asked to make is to determine by the parties whether the lack of the inclusion of an uncertainty number and whether the State's decision to report the DataMaster test absent the uncertainty associated with it, more properly affects the admissibility of that result, or more properly affects the weight the fact finder should afford to it. It's our position, as the State, that the admissibility of

the DataMaster is controlled exclusively by the plain language of the regulation promulgated by the Department of Health and adopted by the Department of Public Safety. And as Mr. Sleigh said, his argument requires you to imply and to assume that it's implicit within those regulations that an uncertainty measurement is required to be associated with the test. That of course is contrary to my understanding of the discretion Court affords to agencies, both in the agency's adoption and -- excuse me, the agency's interpretation of their enabling statute, which in this case is 1203(d). And further in the agency's interpretation of their run regulations which are the breath testing regulations we'll be discussing at some length today.

THE COURT: All right. And have either of you prepared a memo?

MR. NAGURNEY: I posted a memo on Monday of this week, Your Honor, to the Court. And there have been several filings in other associated cases by State's attorneys that largely contain the contents of the memo. So if you don't --

THE COURT: If you sent it on Monday?

MR. NAGURNEY: I mailed it Monday, yes.

THE COURT: Okay. I haven't yet received it yet.

MR. NAGURNEY: Okay. I can certainly get you a copy.

THE COURT: Okay.

Mr. Sleigh?

MR. SLEIGH: I have none. My intent was to ask to be able to submit with a findings and proposed conclusions at the close of the case.

THE COURT: Okay.

MR. SLEIGH: Your Honor, I want to -- I know opening and closing statements sort of -- you can get different views, but I really want the Court to understand the focus here. I am not saying in this motion that the reported results of any given breath analysis require an accompanying uncertainty measurement. You're going to hear a lot about traceability and uncertainty, but what that goes to, and this is why this is a raw question, my issue is with how the State went about proving that the machine met the performance and accuracy criteria. It has nothing to do with the expression of an individual test result. I mean -- so that's going to be the focus, and I think it will become clear from the testimony.

THE COURT: All right. We'll proceed with evidence.

MR. SLEIGH: Thank you. Perhaps we could just stipulate to the admission of Defendant's A which is a copy of the Rules.

MR. NAGURNEY: Sure.

THE COURT: Defendant's A is admitted.

(Defendant's Exhibit A received)

MR. SLEIGH: May I approach, Your Honor?

Your Honor, the Defense would call Janine Arvizu.

THE CLERK: Raise your right hand, please.

JANINE ARVIZU

called as a witness for the Defendant, having been duly sworn, testified as follows:

THE WITNESS: I do.

THE CLERK: Thank you.

THE WITNESS: Thank you.

DIRECT EXAMINATION

BY MR. SLEIGH:

Q Good morning. How are you?

A Good morning.

Q Could you state and spell your name for the record, please?

A Janine Arvizu, A-r-v-i-z-u.

THE COURT: And your first name, too, please?

THE WITNESS: J-a-n-i-n-e.

MR. SLEIGH: Thank you.

BY MR. SLEIGH:

Q And where do you reside?

A In Tijeras, New Mexico.

Q Where is that in relation to Albuquerque?

A It's in the mountains just outside of town.

Q And are you engaged in a profession?

A I am.

Q And what is your profession?

A I am a quality assurance consultant and a certified quality auditor.

Q And do you have a current resume or a CV?

A Yes, I do.

MR. SLEIGH: May I approach the witness, Your Honor?

THE COURT: Yes.

BY MR. SLEIGH:

Q Let me show you what I've marked as Exhibit M, and ask if you could identify that for me.

A That's a copy of my resume.

Q And that's current as of today's date?

A Yes.

MR. SLEIGH: Your Honor, we'd move the admission of Exhibit M.

MR. NAGURNEY: No objection, Your Honor.

THE COURT: Defendant's M is admitted.

(Defendant's Exhibit M received)

BY MR. SLEIGH:

Q So can you tell me a little bit about your educational background?

A I have a Bachelor of Science degree in Biochemistry from California Polytechnic State University at San Luis Obispo, and ABD in Chemistry from University of New Mexico. ABD is an indication that I've been admitted to candidacy for the Ph.D. degree in Chemistry. That is completion of the

coursework and qualifying exams and proposal defense, but I have not defended my dissertation.

Q How long have you been a laboratory quality auditor?

A Oh, gosh, many years. I guess I don't remember when I first was certified, but I have been conducting audits of testing laboratories for Federal agencies for many years.

Q So what does a laboratory quality auditor actually do? What is it you do when you test a laboratory?

A As an independent auditor, I work for clients who use analytical results from testing laboratories to make important decisions and they need to understand the scientific validity of the methods that were used and the reliability of the results. And some of those results can be used with confidence to make very important decisions.

And so I work for the users of laboratory data in assessing the work done by laboratories and assessing the results reported by labs.

Q And in that connection, do you have any professional certifications?

A I am certified by the American Society for Quality as a certified quality auditor. That's a process that you go through. ASQ is the professional organization for quality practitioners. And if you meet the minimum requirements in terms of academic education, practical experience in the field of quality, and if you sit for an examination on the body of

knowledge that ranges from how to conduct an audit to sampling theory and sampling statistics, then you sit for an exam. It's not a "gimme" exam. It's a, you know, kind of an all day affair, and has an appreciable failure rate. Then you can be certified as a quality auditor. And there are recertification requirements periodically where you submit evidence of continuing education.

Q Okay. And is your certification up to date?

A It is.

Q Can you tell the Court a little bit about your employment history in the field of laboratory quality auditing?

A After graduate school, I went to work for one of the national laboratories, Idaho National Engineering Laboratory, where I established and managed a full-service analytical laboratory. At the time I started, I think there -- we had three employees in the laboratory, and when I left about a decade later, there were about 45 employees in the laboratory. So it was everything from purchasing the equipment to validating the methods and putting in place procedures and it was a full-service lab that did both organic, inorganic, and classical testing.

Q What is a national laboratory?

A The Department of Energy manages a series of laboratories across the country that people are probably familiar with the ones, like Oakridge National Laboratory,

Argon National Laboratory, the Hanford Reservation, Los Alamos National Laboratory. Those are the laboratories that evolved out of the Manhattan Project during World War II.

Q And you said the laboratory that you worked in Idaho was an analytical laboratory?

A Idaho National Engineering Laboratory was a large facility. It had probably 10,000 employees. My section was actually the analytical laboratory, my unit. And it didn't exist when -- as a functioning entity when I joined the laboratory, but it was established during my tenure.

Q Okay. What did you analyze?

A We analyzed a wide variety of samples for -- with a variety of matrices. That is the component of the sample, the major component of the sample, for both organic and inorganic constituents. That included, for example, GC testing which will be the subject of some discussion today. It included testing with a gas chromatograph instrument for the presence of volatile organics, analogous to the testing that we'll be talking about.

Q So how long were you at the National Lab in Idaho?

A Just about a decade.

Q And when -- what was -- what period of time was that?

A Right when I left graduate school, and I'd have to actually check my resume for the specific dates.

Q Feel free.

A Let's see -- '81 to 1990.

Q All right. After you left the lab in Idaho, where'd you go?

A I started my own quality assurance consulting firm, and we did quality assurance consulting work for primarily Federal agencies, for the Department of Energy, for the US Navy, and it included things like auditing laboratories and conducting data quality assessments to evaluate the usability of results reported by testing laboratories.

Q We'll get into some greater detail later on, but when you say you do the -- you said, data reliability assessments?

A Yes.

Q Could you just explain what that means?

A Sure. That's the process that is done after the fact, after the data have already been reported. And it's essentially a reconstruction of the entire analytical process to determine whether the sample was collected and managed and processed in a manner that maintained its integrity, because if there's any ambiguity about whether it was the right sample or the -- where the sample was compromised during processing, then the results cannot be used reliably. It looks at whether the site, the method actually used to test the sample was scientifically valid. That means something very specific to count as a method validation study is an empirically -- an empirical testing scheme through which you essentially

determine the performance characteristics of a method, determine its accuracy, its precision, those kinds of things. And including its uncertainty. So you determine whether it's a scientifically valid method as appropriate for its intended use. Because a method that may work perfectly well in one environment may be completely unsuitable in another environment, because they have different intended uses.

In -- after scientific validity, the last reconstruction piece is essentially, was the method reliably performed? If you have the sample with integrity, and you used a valid method, was the laboratory's measurement system operating in a state of control of the time that particular test was performed so that you have a reliable result.

So that reconstruction of the analytical process as an auditor, it's in some respects analogous to what an IRS auditor does. You can't just say that I remember that two years ago I made this charitable donation. You actually have to produce contemporaneous records that demonstrate the amount of the donation and whether it was a legitimate 501(c)(3) that you made it to, and when you made it, and all those kinds of things. In very similar respect, in a laboratory environment as an auditor, you can't rely on somebody's memory for what they did to do testing in the past. You rely on contemporaneous records that very, in very excruciating detail sometimes, document all the components of the measurement

system necessary to understand the reliability of the result.

It's a very challenging exercise because frankly what we're expecting of these kinds of laboratories is to connect production scale science. That is science at a production line. The challenge is not a discrete individual measurement. The challenge is having in place all the components of the measurement system to contemporaneously document performance so that scientifically we can understand how reliable result it.

Q Roughly, if you can, how many labs have you audited in that fashion?

A I've conducted onsite audits, actual onsite inspections of dozens of laboratories, I've conducted data quality assessments, essentially data audits, of hundreds of laboratories all across the country and around the world.

Q Just getting back to your resume a little bit, have you published in this field?

A I have. I authored the quality standard that the US Navy used for evaluation of its testing laboratories, both government and commercial.

Q Well, I was just going to ask you, when you said you did these audits, I take it these audits are done in compliance with generally recognized standards? It's not your own opinion about whether these people are complying with rules and regulations?

A That's correct.

Q All right. And you actually authored quality standard for the Navy?

A Yes.

Q Have you ever provided training to other people in connection with lab auditing activities?

A A great deal over the years. I've trained bench chemist technicians, field sampling personnel, the engineers and the users of laboratory results, and in recent years, in the last decade or so, I've gone to CLE legal conferences and been training attorneys. I did a session for appellate judges at Duke on judging science and the issues associated with forensic quality.

Q And have you provided testimony as a laboratory quality assurance expert in court prior to today?

A Yes.

Q On how many occasions?

A Dozens, not probably hundreds, but many dozens.

Q Have you been previously qualified here in Vermont?

A I have.

Q And have you been qualified in other state courts?

A Yes, all over the country, state and, I think sometimes they're -- I don't know. I don't understand all the jurisdictions, but sometimes they're local, but often what -- state district court.

Q Okay. How about in Federal courts?

A Yes, in Philadelphia, in Denver, in El Paso, a variety of locations.

Q All right. And how about in international courts?

A Yes.

Q Where have you been qualified as an expert in international courts?

A The Supreme Court of Palau in Micronesia. And I guess, is the Virgin Islands part of the US Court system?

Q It's a good question. I don't know the answer.

A I don't know, but there.

Q Okay. And in what fields have you been accepted as an expert by these courts?

A I testify as to the analytical quality assurance issues, the laboratory quality assurance, and the reliability of the results from a quality assurance perspective.

Q Have you ever testified about quality assurance in a toxicology labs?

A Yes.

Q Have you ever testified about the scientific validity and reliability of blood alcohol test results?

A Yes.

Q How often?

A More than a dozen times, I'm not sure how many.

Q Okay. The State may be interested in knowing this, but obviously we've hired you to be an expert in this case. Is

that right?

A Yes, sir.

Q And how much are you getting paid for testifying today?

A Well, I bill my time for $150 an hour, regardless of whether I'm reviewing data or traveling or testifying.

Q Are you a forensic toxicologist?

A No, I am not.

Q Have you ever worked in a forensic laboratory?

A No. My laboratory -- analyze samples that have the potential to end up in court, and some of them very well may have, but forensic testing, that is testing for the purposes of generating data specifically for introduction in court was -- is not part of my work history.

Q Have you ever used a gas chromatograph to test for the presence of alcohol?

A I have not. I've used a gas chromatograph to test for the presence of volatile organics, but ethanol, the issue in this case, is not one of the target analytes that I have historically tested for, other alcohols, but not ethanol.

Q And have you ever used a breath alcohol testing instrument?

A No, I have not.

Q So if you are a forensic toxicologist, you haven't worked in a forensic laboratory, you haven't analyzed samples for ethanol, what makes you qualified to express the opinion

that I've asked you to look into in this case?

A The reason is because the principles of quality assurance in the field of analytical chemistry are universally applicable. And so you can actually go -- one of the seminal texts in the field is by a fellow from what is now called NES, but the old National Bureau of Standards, named John Taylor, Analytical Quality Assurance and Measurements, and you can read through that entire book and it doesn't talk about specific -- in general, doesn't talk about specific testing techniques. It talks about the general principles of how accuracy is determined, of how precision is determined. And it's a universally applicable practice that has been adapted by the field of analytical chemistry. Quality assurance is how for decades we have recognized that you can put in place systems in a testing laboratory to ensure the consistent and reliable production of acceptable quality data for its intended use.

And so I've testified to, and conducted, data quality assessments, and conducted onsite inspections and reviews of actual testing processes in DNA laboratories, for example. I've testified about gunshot residue, a variety of toxicology, both other components in body fluids and body samples as well as things like blood alcohol. The principles are the same of reconstructing and conducting a data audit after the fact.

Q You've reviewed literally thousands of pages in connection with these cases. Is that right?

A Yes.

Q And you've become familiar with how the Department of Health, the Department of Public Safety went about trying to establish whether these DataMaster DMTs met the performance criteria set forth in the Rule. Is that right?

A Yes.

Q Is there anything in your review of the lab's performance, of the Rules, of any of the results that you've looked at, that leads you to believe that assessing the quality of the Department of Health, the Department of Public Safety efforts to meet the criteria of the Rule fall outside generally accepted scientific principles? In other words, there's something unique about this lab that would cause you to assess the quality differently than any other lab?

THE COURT: I'm sorry, I got lost in the question, so I'm not going to understand the answer.

MR. SLEIGH: Here's what I'm trying to ask.

BY MR. SLEIGH:

Q I think what you said is that when you undergo quality assessment of a laboratory's work, you apply generally accepted scientific principles. Right?

A Yes.

Q What I'm saying is there anything about this case that would cause you to say it falls outside those generally accepted principles? Not that their work did, but whether your

assessment of it would have to be different than assessing a DNA lab.

A Like science doesn't count?

Q Well, that's basically what I'm asking. So can you apply your usual standards in assessing the Department of Health's performance in this case? That's the short question.

A I did.

Q Okay. All right.

A I'm not sure that answers your question.

Q Well, it's a bad question. I tried three times, now I'm giving up.

MR. SLEIGH: Your Honor, to the extent that we have to, we'd offer Mr. Arvizu as an expert in the field of laboratory quality auditing and quality assurance.

THE COURT: Mr. Nagurney?

MR. NAGURNEY: Your Honor, with that qualification to this limited area, I would have no objection.

THE COURT: She is so qualified.

MR. SLEIGH: Thank you.

BY MR. SLEIGH:

Q So, what is science?

A I try, whenever I'm in the state in April, I always try to judge our state science fair. It's a great system. We have, you know, hundreds of kids all locked in a gymnasium, and they all understand the scientific method and can all recite

it: observation, hypothesis, testing, validation, verification. It's a process that trained practitioners in the field of science and there are lots of fields of science used, to ensure that the conclusions that we draw are useable and valid and transparent and can be communicated to other scientists and be subject to their review and assessment. It's a transparent process. It's not something where we go into a black box and generate data and results and then come out with stellar conclusions that can't be reproduced by anybody else, witness cold fusion in years past. The scientific method relies on the fact that we don't rely on memory, we don't rely on anybody's best recollection of what happens, everything is documented so it can be subject to independent assessment.

And as an auditor, I rely on that practice, the fact that everything needs to be documented so that we can independently assess what was done, when, by whom, and to what standards.

Q And you may have asked -- answered this in anticipation, but what is the scientific method? What does that mean?

A It's a sequence of events that I described. Observation; you make an observation that you think is something that can be scientifically evaluated. You make a hypothesis, I think I can make this measurement in this manner. And then you test that hypothesis; is it, in fact, possible to

make the measurement in the manner that you hypothesized? Then are the two "V" steps that most frequently are forgotten in the scientific process; validation and verification.

Method validation is the process that I described earlier, that is one of the steps that I evaluate in a data quality assessment. A method validation study as applied to analytical chemistry is a study that you conduct according to a discrete plan -- these are the objectives that I'm trying to achieve. I'm trying to evaluate a method for a particular purpose. Because method validation is testing, empirical testing in the laboratory, to determine whether or not a given method is appropriate for its intended purpose.

In this case, for example, the intended purpose is to be able to comply with the Vermont Rules as published in whatever legal language that document is, that first exhibit that we just came out. That sets discrete performance standards for the method. So you have a target that you have to determine whether or not your method is capable of achieving. That's the validation step. It is testing conducted using known samples, known reference materials. It can't test a method by using unknown samples. You can only evaluate its performance by using known samples.

And then the last step in the process is verification. And that is once you're using a method that has been demonstrated to be valid, you continually need to verify

that your local performance is capable of, in fact, meeting the performance specs of the method.

Q Can you distinguish for us the difference between investigatory science and applied science?

A That's the difference between research and what goes on in a laboratory, like a forensic laboratory that does production-scale work. There are forensic labs that do investigative science. That's research. That's actually studying a new field of scientific endeavor where your -- you've made the hypoth -- you've made the observation, you've poised the hypothesis, and you're doing the testing. You're not to the point of having a validated method that you're going to apply, you're doing the testing. It's the early part of the scientific process.

When it gets to the point of routine forensic toxicology testing, the kinds of testing that goes on in terms of blood alcohol testing, breath alcohol testing, testing blood and urine for the presence of controlled substances, that kind of testing has moved past the investigative stages. It's no longer a research project. At that stage, once you're testing unknown samples, and reporting on the result of an unknown sample, that's the application of science. That's using a method that has already been validated and shown to be appropriate for its use, that you've already verified that you're capable of meeting those requirements, and that's where

you're doing science on a production line where it's necessary to have all the quality control measures in place that I talked about earlier.

So all science starts with the investigative side, it has to get through that process before you can put it into the application field.

Q And this might sound like an obvious question, but I don't think it is, can you provide the Court a working definition, what is forensic science?

A It's interesting that in the -- at the time I went to school, the science fields that we had were things like chemistry, and biology, and physics, the hard sciences, if you will. And when I first became aware of the field of forensic science, all that I understand forensic science to be is the application of traditional scientific endeavors to applications where the intended user of the data is the Court.

So it's not a completely new field of science in the way that chemistry and biology and physics are. But it's the application of material science and chemical measurement and those kinds of principles with the intended purpose being simply to generate results that are material to a given criminal or civil case. And so, the intended user of those data generated through traditional scientific methods is, in fact, the Court system.

Q Is there any reason, given that the user is going to be

the Court system as opposed to other scientists, that the scientific methods used in producing the results be less rigorous or more lax?

MR. NAGURNEY: Objection, Your Honor. At this point I think he's asking her for a legal conclusion as to -- again he's asking her not what the specific questions regarding the admissibility or the foundation for the admissibility evidence here. But whether what weight Your Honor should assign to it based upon the strength of the evidence that the fact finding might proceed.

MR. SLEIGH: All I'm just trying to ask is if there's a lesser standard for forensic test result expression than there is in other fields of science. It seems like a question that would answer itself but --

THE COURT: If you know, you may answer.

THE WITNESS: In the forensic community increasingly -- with increasing frequency in this country, forensic laboratories are moving toward adoption of what are, for purposes of accreditation, international standards for testing laboratories. Those are universally applicable. They're just -- and it recognizes being so to environmental labs, food testing labs, pharmaceutical labs, forensic laboratories, material testing laboratories.

BY MR. SLEIGH:

Q Are there agencies or institutions that have provided

guidelines and standards to the forensic scientific community in terms of their testing efforts?

A Are there agencies?

Q Well, institutions.

A Institutions. Yes. There are -- I mentioned ISO.

Q What is ISO?

A ISO is the International Standardization Organization. You may be familiar with ISO-9000 which is a management standard for -- quality management standard that's very widely applicable. The purpose of ISO is to develop consensus standards. It's an international organization and it develops them in a wide, wide variety of applications.

The ones that are germane to our discussion here today are ISO standard 17025, which is general requirements for the competence of testing in calibration laboratories. That is the international standard that the organizations that accredit forensic laboratories in this country have adopted as their applicable standard for forensic labs.

Q Have you ever heard of an organization called ILAC or Eye-LAC (phonetic), I-L-A-C?

A Yes.

Q Who are they?

A ILAC is the International Laboratory Accreditation Corporation, and it is an international organization whose members or signatories, essentially, in an attempt to

homogenize requirements internationally so that if I'm using a result from an Australian laboratory that is accredited to ISO 17025 I can be confident that they conformed to the same requirements as the laboratory here in this country that conforms to ISO 17025.

So, the accrediting agency in Australia is a signatory to ILAC. The accrediting agencies here in the United States are signatories to ILAC. It's an attempt to homogenize essentially the accreditation practices throughout the world.

Q And have you ever heard of an organization called SOFT, S-O-F-T?

A Society of Forensic Toxicology. And in cooperation with the American Academy of Forensic Sciences, they have released guidelines, I think most recently published in 2006, that are specific to the practice of forensic toxicology. That would also be considered a consensus standard. It's a guideline. It's not anything that's mandated by law. But it's something that has been developed by practitioners in the field.

Q Have you ever heard of an organization called ASCLD/LAB?

A Yes.

Q Who are they?

A American Society of Crime Laboratory Directors Laboratory Accreditation Board. It's an organization that was

spun off from the trade organization of crime laboratory directors from ASCLD for the purpose of accrediting forensic laboratories. It started several years ago. They initially prepared and used their own standard, their own guidelines, their own manual is how they described those standards and accredited laboratories to that.

At present, laboratories that were accredited under ASCLD's own self-defined standards are known as legacy laboratories. And the reason for that is that ASCLD/LAB no longer will accredit laboratories to their old legacy system. On a going forward basis, they will only accredit laboratories to the ISO 17025 standard.

Q We'll get more into it, that standard is on that, but -- and finally do you -- does the College of American Pathologists provide accreditation programs for toxicology laboratories?

A They do. They also have published their accreditation requirements.

Q Okay. I want to switch gears a little bit here and just talk about some basic concepts attendant to measurement itself. Obviously, what we have in these cases is an attempt to quantify the ethanol in a breath alcohol sample. That involves measurement, true?

A It involves two kinds of measurements. It involves the qualitative identification of ethanol and its discrimination

from other compounds that could potentially interfere with or be misinterpreted as ethanol. And it includes the quantitative analysis, that is the determination of the concentration or quantity of ethanol present in a sample.

So, those two kinds of techniques, the what is it and the how much is it, qualitative and quantitative testing are both addressed in this.

Q Okay. Let's talk sort of about quantitative testing in the abstract just for a minute. If you were to repeatedly test or measure a given unknown, a single sample, and measure or test it a hundred times would you get the same result every single time?

A Not as a general rule, no.

Q So, how would you, as a scientist, express the measurement result, let's just say you're measuring the length of a stick and you have a yardstick. What would you have to do to develop confidence in your report of the result of that measurement?

A It's an inherent principle of metrology that every measurement, whether it's measuring a stick with a yardstick or whether it's measuring the quantity of ethanol in a sample, every measurement process has a degree of what is called uncertainty associated with it. And you sort of infer that that's the case by the fact that if you test something a hundred times you don't necessarily get the same answer a

hundred times.

That doesn't mean that you've done anything wrong. Uncertainty is sometimes confused with error or described as error or confused as mistakes. It is not. It's the fact that if I'm measuring the length of something, say the length of this pen, I could use a yardstick to measure the length of this pen. But if it was a yardstick that only had three marks on it, one for each foot, it wouldn't do a very good job of being able to measure. I would have to do some estimation. And I would probably not get the same result as the next hundred people who measured that pen using that yardstick.

Whereas if I went to a high precision laboratory and got one of the measuring, a good caliber that was capable of measuring to a fraction of a millimeter, I would be able to get a very accurate measurement of this. But again, because of its -- in fact, because of its precision I wouldn't get the same measurement every time necessarily. But I would do a much better job of measuring it than I would if I used a yardstick.

So, there's different uncertainties associated with every measurement and we'll talk more about it but the complexity of this process varies as a function of how many components to the uncertainty there are. And the more components, the more parts to the process, the more inherent uncertainty there is associated with the measurements.

Here in the United States our National Metrology

Institute is the National Institute of Standards and Technologies, what used to be called the National Bureau of Standards. It's referred to as NIST, N-I-S-T. NIST is, if you look in the ISO standards it refers to using what are called SI units, which are standard units. It doesn't say in ISO standard that you have to use measurements that are traceable to NIST. It says you use measurements that are traceable to these SI units, these SI standards.

How that gets implemented in practice in the real world is through these National Metrology Institutes. Here in the United States we use NIST. They have their counterpart in other countries. And if you look at the measurements generated by NIST they have a very high degree of understanding of how uncertain their measurements are when they craft primary standards. So --

Q So, even NIST if they're crafting a primary standard would express that together with some sort of uncertainty measurement?

A Absolutely. It would, in fact, not be a measurement if it didn't have any associated uncertainty with it.

Q And let me just jump ahead because I want to clear this up. There seems to be in the general public some confusion about error rate and uncertainty measurement. In other words, that the two get conflated somehow. Could you differentiate or at least maybe explain a little further why the uncertainty

measurement is not necessarily an expression of error?

A Yes. I think that's an unfortunate sort of convocation of terms that has contributed to that and our own tendency to not use them very precisely. Error rate typically applies to falsely identifying, for example, ethanol as present in a sample when, in fact, it is not. That's referred in a term that people can understand it's falsely identified as positive.

So, there's no ethanol, for example, in the sample yet it's reported as being present. That would be a false positive. Similarly, if ethanol in fact is present in a sample and a testing laboratory determines that it is not, that would be a false negative. Those are the kinds of errors or actual erroneous conclusions that can be reported by laboratories and you can actually quantify an error rate for that kind of occurrence.

And that's contrasted with just mistakes, blunders that happen in the laboratory that may or may not result in generation of a result. None of those things are uncertainty. An uncertainty associated with a measurement represents the boundary conditions. Every single measurement that you make and I know people are accustomed to thinking this pen is six inches long. So the answer is six but it's six plus or minus a number. It's actually better expressed as a range of results. The true value is somewhere between five and seven inches, if it was six plus or minus one. I don't know if that's accurate

for this pen or not.

But that's the whole point. That scientifically we can do through a process. We can determine all the components that contribute to the uncertainty of a measurement and we can do an analysis to determine the uncertainty and the expanded uncertainty so that we can give you a scientific statistically valid conclusion on just how confident I am that the true value of this measurement of this six inch pen lies between five and seven inches. Doesn't mean it's six. It means that to a known degree of confidence I know that the true length of this pen is somewhere between five and seven inches.

What happens is labs that report results without uncertainty only tell you it's six. They aren't telling you that the real result is somewhere between five and seven and they just don't know whether it's five, five and a half, six, six and a half or seven.

The reason that's so important when I talked about quality assurance, data of different quality is used to make different quality decisions. If you have to make a measurement comparison to a threshold, if you have to compare a laboratory's result to a standard or a threshold in the case of ethanol testing that's usually .08 percent. Then it's impossible scientifically to make that comparison in a reliable manner unless you know the uncertainty of the results that you're making the comparison against. You simply can't do it.

I have a little picture here that tries to explain that. I have a figure if -- or I could put it on the board or --

Q Would you like to approach the board?

MR. SLEIGH: Is that all right?

THE COURT: She may.

MR. SLEIGH: Thank you.

THE COURT: Although it may, for the record, be better to do it on a piece of paper.

THE WITNESS: I can make this the record and put it on the board so everybody can see it. How about that?

MR. SLEIGH: That's fine with me.

THE WITNESS: Will that --

MR. SLEIGH: I'll get that marked.

THE WITNESS: Okay. This axis is concentration.

MR. SLEIGH: One second because we're having the exhibit reviewed.

THE WITNESS: Okay.

MR. SLEIGH: Now we've marked the paper version of this as Exhibit N. We'd offer that as a demonstrative exhibit.

THE COURT: Any objection?

MR. NAGURNEY: No.

THE COURT: Defendant's N is admitted.

(Defendant's Exhibit N received)

THE WITNESS: Can I look at it so I can actually make

it look like the picture?

MR. SLEIGH: Yes.

Your Honor, would this be an appropriate time for a morning recess. She's going to draw for a little bit and I could use a bit of a break.

THE COURT: All right, we'll take the morning break early. I also just want to let you know, Mr. Nagurney, your memo has -- was received today.

MR. NAGURNEY: Oh, good.

THE COURT: So, it is filed with the Court. So, you don't need to supply a different copy.

MR. NAGURNEY: Great.

THE COURT: I don't know whether Mr. Sleigh has one or not.

MR. SLEIGH: I think I actually received one on Monday via email. So --

THE COURT: All right, thank you.

THE BAILIFF: All rise.

(Recess at 10:12 a.m., recommencing at 10:32 a.m.)

THE BAILIFF: All rise.

THE COURT: Please be seated.

MR. SLEIGH: Thank you.

BY MR. SLEIGH:

Q So, you've had a chance to put your diagram on the board?

A I did.

Q So, we were talking about uncertainty and you wanted to discuss this on the board.

A This is why it's so important when you need to compare a result to a threshold. There's basically five things that can happen when you make a measurement result of ethanol concentration. One is you don't get any ethanol and if it's not detected we don't have much to talk about. But if you get a detected quantity of ethanol that you're expected to compare to the regulatory threshold which is fixed at .08 percent, these are the four things that can happen.

First, there are the four -- these four dots just represent four results. The numbers are really not important, the absolute numbers are really not important. What's important is that this result, if you include its measurement uncertainty, lies somewhere between here and here. There -- no matter -- and if I know to a known degree of confidence that my measurement result is within those bounds, I can tell you with that degree of confidence that it exceeds that threshold of .08 percent, unquestionably. I know that that result is over the limit and would be prepared to draw that scientific conclusion.

The next result right here also looks to be over .08 percent if you only look at the number. But when you look at the number with its associated uncertainty, and remember scientifically that's all I can say. All I can say is the true

value lies somewhere between here and here. I don't know if that result is over the uncertainty or not because the measurement result between here and here spans that .08 percent number.

It can be below the number or it can be above the threshold. So, my conclusion of whether or not it exceeds the threshold, scientifically, I can't tell you. Similar situation exists here. If you just look at the number, you might think oh they're under the limit, no problem. But you must look at the number with its associated uncertainty. With the uncertainty it may be over the limit.

And this last case, so again, this one is also unknown. In this last case, the number's below the limit even if you include the uncertainty it's still under the limit. So, this one very clearly would be under the limit. This one would be over the limit. But scientifically in these two cases, cannot tell you whether or not that result is over the threshold of .08 percent.

Now, there's different ways of addressing this and attacking this. It's like as a scientist one of the ways you can improve your ability to encounter this problem less often is by reducing your uncertainty. So, if I get my measurement system more and more in control and I put tighter and tighter constraints on everything and I get less uncertainty. All of a sudden, in these cases this one is over even if you include the

uncertainty. This one is under even if you include the uncertainty.

But the counterpart is also true. If you have a laboratory that has problems and has very large uncertainties associated with it then you have a problem. But you'd really -- until you quantify, actually do the testing, collect the data, do the analysis to quantify how big those error bars are, I think you can see that no matter what your number tells you, you don't know whether or not it fails or passes against the threshold until you know the uncertainty.

Q Okay. Well, I've got some questions about that. If you want to take the stand that would be great.

(Witness retakes stand)

So, your explanation obviously --

THE COURT: Can I just ask you a question before -- you just said until you quantify how big the error bars are --

THE WITNESS: I --

THE COURT: But earlier you said there was a difference between error an uncertainty.

THE WITNESS: And I apologize. That was an inelegant use of terms and that's part of the reason we scientists have confused people so badly. Because those bars that I drew on there used to colloquially be called error bars and so that was my poor use of the term. That actually is a representation of the uncertainty. I apologize. Good catch.

BY MR. SLEIGH:

Q So, this all sounds well and good but it raises obvious questions. How do you determine uncertainty? What are the components of uncertainty?

A The components of uncertainty are of two types. They are referred to as type A and type B. And type A uncertainty measurement components are those things that we can evaluate statistically. And laboratories typically make that kind of a determination by running large, large numbers of replicate analyses and evaluating the precision of the measurement process.

Statistical techniques, they're better when you have more data. So, that when you get a lot of data that gives you good results for purposes of determining the type A component of uncertainty. Type B components are those things that cannot be evaluated statistically. And in a very practical sense let me just sort of describe what some of those would be for these kinds of issues that we're dealing with.

When you purchase a calibration standard from an accredited supplier of reference materials, it's a solution that they provide a certificate of analysis and it has a concentration of ethanol in water and it has its associated uncertainty. So, that uncertainty essentially gets added in to your uncertainty for your final result.

So, every component of uncertainty in every step of

the measurement process contributes to the uncertainty of your measurement. It includes uncertainties from things like if you weigh out the ethanol to prepare your reference materials, your standard solutions, then it's the uncertainty of the balance measurement. If you use what's called a pipette to deliver volume of ethanol to make known solutions then the tolerance of that pipette for volume delivery contributes to the uncertainty.

It includes things like the thermal expansion coefficient of the glassware of the solutions that are actually used depending on the temperature at which you prepare those solutions. So, there's a very rigorous process that scientists go through to identify each contributor, each variable in the measurement process.

Q So, let me just interrupt real quick. Let's say you're doing these replicate tests to try to generate a database. Would each such test have to be documented to include the uncertainty measurement from each step of the way?

A Would each --

Q So, does there have to be contemporaneous documentation of each replicate test --

A Oh, absolutely. Yes. Yeah. You've got to know what you're doing at each step of the test. It's a process where every single component -- you make a measurement. You have to step back scientifically and evaluate all the factors that

contribute. Did I use a balance? Did I use a pipette? Does temperature affect what I'm measuring? Was -- were there uncertainty provided by the manufacturer, the accredited manufacturer?

Every one of those must be contemporaneously documented so that I can add all those components together and determine my final uncertainty on my measurement result. That's what's called traceability, to have all the documentation to support all those individual components of uncertainty in my final result.

Q So, in expressing any analytical result or measurement for that matter, you need to scientifically accompany that with an expression of uncertainty. Is that right?

A Everyone, yes.

Q And that uncertainty itself is calculated in a scientific fashion?

A Yes.

Q That incorporates the notion of traceability which is a contemporaneously generated accessible transparent documentation?

A Correct.

Q And then scientifically adequate calculations that can be expected by others?

A Yes.

Q Anything else?

A Yeah. That's -- the elements of traceability are that the procedure used must be documented. That is you can't just -- you can't -- no one else can review and assess whether or not what you did was appropriate unless it's documented. So, the procedure that was followed must be documented.

The participants must be competent. That is, if you purchase materials from a reference material supplier, one of the common ones is Cerilliant. They're accredited to the relative ISO standard for as a reference materials supplier. So, they're accredited to ISO 17025 and under guide 35 -- 34.

So, if you have contemporaneous documentation of the procedure, of the competence of the participants, if you have contemporaneous records documenting each component of the uncertainty, then you're capable of generating a final uncertainty for your measurement that is traceable. It's every link in the chain is complete.

Q All right. Let me just show you what I've marked as Defendant's B, C, D Prime, D and E Prime. If you'd just, one by one, identify those and explain what it is.

A Exhibit B is guidelines for forensic science laboratories issued in 2002 by ILAC. This is the International Organization's attempt to not essentially restate the provisions of ISO 17025 but to clarify them with respect to the practice of forensic science.

Q And --

A It has entire sections addressing specifically traceability.

Q And does it specifically reference the applicability of these guidelines to forensic science laboratories dealing with alcohol? I'd refer you to page 5.

A Yes. In page 5, which is the table describing the scope of forensic science work, it specifically identifies the determination of alcohol as one of the components in toxicology.

Q And Exhibit C?

A Exhibit C is a copy of the forensic toxicology laboratory guidelines issued in 2006 by SOFT and AAFS.

Q And do those guidelines incorporate the requirements of uncertainty measurement and traceability?

A I'm going to have to cruise through it to find it. Okay. The issue of reference materials in this document is addressed in section 9.3.

Q Thank you. And can you take a look at what's been marked as D prime and identify what that is?

A Exhibit D Prime is a document entitled 2006 supplemental requirements for the accreditation of forensic science testing laboratories. Corresponds to ISO IEC 17025 2005.

Q And because it's an ISO 1725 predicated accreditation guideline, would that include the requirements and traceability

and uncertainty measurement?

A It does. It specifically incorporates all the provisions of uncertainty of measurement from ISO under section 5.4.6 and it provides additional clarification on measurement traceability section 5.6.

Q And let me show you what's -- let me return your attention to Exhibits D and E and ask if you can identify and explain what those are?

THE COURT: E or E Prime?

MR. SLEIGH: Sorry. I'm sorry. It would be now D without the Prime and E.

THE COURT: But E without the Prime?

MR. SLEIGH: E without the Prime, yes. E Prime will be next. I'm sorry about this.

THE WITNESS: Exhibit D is ASCLD/LAB policy on measurement uncertainty. And Exhibit E is the ASCLD/LAB policy on traceability of measurement results, reference standards and reference materials.

BY MR. SLEIGH:

Q Now, both D and E have across the front of them something that says currently under review?

A They do.

Q Could you explain what that is and whether ASCLD has actually adopted these requirements at this point?

A These actually have been adopted. I have downloaded

copies that have the same approval date, the same effective date and the same number of pages as these documents.

Q But they're not generally accessible to the public over the Internet at this point?

A Yes, they are.

Q Oh, okay.

A Yes, they are.

Q All right. Okay. And E --

A E's documents, essentially, it's a trickledown. The international standard for establishing what uncertainty is and how it's empirically determined and how traceability works is there's a document that's affectionately known as GUM, guidelines for the estimation of uncertainty and measurement. And there's a trickledown that those guidelines have been distilled and presented in a more directly understandable manner by subordinate agencies.

So, ISO references back to these guidelines. This as -- these documents as ASCLD/LAB documents specifically the same requirements trickledown into these ASCLD/LAB requirements for both uncertainty and for traceability.

Q And let me show you what's been marked as E Prime.

A Yes.

Q And what's that?

A This is the document by the Commission on Laboratory Accreditation for the College of American Pathologists. It's

described as a chemistry and toxicology checklist. It's used by the College of American Pathologists for purposes of accrediting laboratories.

Q And when were these generated? Can you see on the bottom of the page there?

A 2003.

Q All right. And do they include instructions and concepts incorporating the requirements of traceability and uncertainty measurement?

A No. My understanding is they are -- it's been awhile since I've looked and it would take me a bit to go through and find the specific citation.

Q Okay. But you're familiar enough to know that they incorporate those requirements?

A Yes.

MR. SLEIGH: Your Honor, we move the admission of B, C, D Prime, D, E and E Prime.

MR. NAGURNEY: Your Honor, I guess I have an objection on the relevance grounds. I don’t understand how given the statutory scheme we're working with, the rules we're working with, how they'd be relevant to the ultimate determination we're asking you to make here. There's no requirement for accreditation.

In fact, some of them aren't even from accrediting bodies. They're simply guidelines to be considered by

accrediting bodies. So, I'm not certain how they're relevant at least on the foundation we have for them right now.

THE COURT: Mr. Sleigh?

MR. SLEIGH: Your Honor, what I'm trying to establish is that for some period of time from 2011 backwards, it was the generally accepted minimal scientific standard that testing laboratories express and incorporate notions of traceability and uncertainty measurement in their analytical work. And specifically, as we'll get to in a minute, in their -- in the Department of Health's effort to prove or establish that the DataMaster DMT devices met the performance criteria. They had to conduct their experiments and report their results consistent with minimal scientific standards which include traceability and uncertainty measurement.

All these documents are publically available. All of them predate the predeployment testing that we're going to talk about. All indicate that the generally accepted scientific norm was to include traceability and uncertainty and therefore it's relevant.

THE COURT: Anything further?

MR. NAGURNEY: No, Your Honor.

THE COURT: Okay. The documents are admitted. So, Defendant's B, C, D1 -- or D Prime rather, D, E and E Prime are all admitted. That's without any determination as to their impact on any decision the Court might make.

(Defendant's Exhibits B, C, D Prime, D, E and E Prime received)

MR. SLEIGH: Thank you.

BY MR. SLEIGH:

Q We had discussed in some detail the components of uncertainty measurement. Does traceability as a concept have component contributors as well?

A Traceability is inherently linked with uncertainty. That is, the uncertainty of a measurement cannot be empirically determined unless that measurement also is traceable. Measurements are traceable. Laboratories aren't traceable. Instruments are not traceable. Only measurements are traceable and traceability is associated with the contemporaneous documentation linking that measurement, that ultimate measurement, and this goes to those big green dots, all the way back to a primary reference standard.

And so, it's contemporaneous documentation that documents the actual components of uncertainty for that discreet measurement.

Q Is it important for laboratories to have standard operating procedures that govern not only the experimental procedures but the record-making of the laboratory?

A It is essential. Traceability is not a new concept. It has been around for a very, very long time. ASCLD/LAB, legacy laboratories under which the Vermont Lab is accredited,

has had traceability as a requirement for maybe all the way back to its very, very first manual. I only have a hard copy. I checked my electronic copy and as far back as 2001 traceability was mandated under legacy ASCLD/LAB requirements.

Q So --

THE COURT: Can you review again what traceability is?

THE WITNESS: Sure. Traceability is if -- for example, if I'm making a measurement on a gas chromatograph, that's an instrument that I essentially have to teach what concentration of ethanol solution gives what response from the instrument.

The way that that's done is by introducing what's called reference materials or solutions of known and documented concentration to the instrument and seeing what kind of response the instrument gives. So you teach it by doing a calibration curve through use of these known reference materials.

Under ASCLD lab requirements, under their accreditations scheme, the solutions that you use to calibrate need to be purchased from an ISO compliant supplier, from an accredited provider of these materials. That means it needs to be a traceable solution. When you purchase that solution, it will have a certificate analysis that will have an uncertainty associated with it. So it'll say point -- well, I have one

here I can give you, give you an example. It'll say -- it'll give you its concentration and it'll give you the associated uncertainty. So it'll say like .08, plus or minus .0005 or percent or whatever, to a given confidence level.

So it will tell you its component of the uncertainty. That way it's traceable. You can use that component in your computation of uncertainty.

Also, when you prepare for your measurement, you are weighing things out or you're measuring them volumetrically using pipettes. Those are the other components that have uncertainty associated, just like measuring the length of a pen, measuring the mass of ethanol or the volume of a solution has uncertainty associated with it.

So you can look up the tolerance for the volumetric flask that you dilute to volume. That's something that you can just look up from the provider. You have your pipettes calibrated by an accredited supplier annually, and then you check them periodically in the laboratory. So you have actual quantitative measures of the uncertainty of when you dispense a volume.

THE COURT: Okay. The thing that confused me was you said earlier only measurements are traceable. You said things like instruments or materials or -- I can't remember what it was, but.

THE WITNESS: Yes. Or laboratories are not

traceable. The characteristic of traceability is being able to have contemporaneous records documenting the uncertainty of each and every component of the measurement.

BY MR. SLEIGH:

Q So when you said labs aren't traceable, you couldn't say this laboratory in its entirety is traceable, right?

A That's correct.

Q So what you mean by traceability is the ability by looking at contemporaneous records to walk back from a result each step that it took to get to that result?

A Exactly. There's a procedure or a recipe that says how I made the measurement. They're usually called standard operating procedures. And that procedure will describe these are the volumetric measurements that are made, these are the mass measurements that are made, these are the temperature measurements that are made. And every one of those in order for a result to be traceable, must have the associated records to document the uncertainty.

Q Accompanied at each step by a calculation of uncertainty?

A Yes. It's an audit trail, if you will, so you know exactly what was done to generate that result.

Q So if you were to run, for example, you're doing your control on a GC, you're using a reference standard with a known concentration, you run that amount through the GC and you get a

result.

A Uh-huh.

Q What you want to be able to do is look at that result, anybody, and be able to walk back through the documents step by step of how you got there?

A Exactly.

Q And, once again, in each step with an accompanying uncertainty measurement and the sum of uncertainty that would accompany your end result?

A Yeah. And it's not just the number, it's the records, so that you don't have to make any assumptions about what solution was used to calibrate. That there are contemporaneous records that describe its preparation and you know what it was prepared from. It all links back.

Q Just let me do a little housekeeping and then we'll go on with a little bit more traceability. But are you aware of any State forensic laboratory that calculated measurement uncertainty for forensic breath alcohol analysis?

A Yes. Washington. I'm not sure the name of the laboratory. I believe it was the Washington State Laboratory.

Q Let me show you what I've marked as Exhibit F and ask you to identify that.

A Yes. This is an article published by Rod Gullberg titled "Estimating the Measurement Uncertainty in Forensic Breath Alcohol Analysis".

Q And when was that published?

A 2006.

Q Are you familiar with that article?

A Yes.

Q Does it comport with generally accepted scientific principles?

A Yes.

Q And was Mr. Gullberg able to calculate uncertainty measurement in connection with breath alcohol analysis in the State of Washington using DataMaster devices?

A Yes.

MR. SLEIGH: Your Honor, we'd move the admission of Defendant's F.

MR. NAGURNEY: Your Honor, at this point I guess I would object on foundation for the admission, just because I don't know if we're doing an apples to apples comparison. We have no evidence on the record about the State of Washington, their program, what their regulations look like, what their statutory scheme looks like, if at all. I had understood they used a completely different method. We find that 1203D is at issue here.

THE COURT: Mr. Sleigh?

MR. SLEIGH: Again, Your Honor, the proposition, our argument is, that the Health Departments failed to scientifically prove that these machines need to perform its

criteria. And the predicate of that argument, or the gravamen, is that they fail to comply with basic scientific requirements that include traceability and uncertainty.

One of their arguments might be that nobody's ever done that before, it's impossible, it's too much to demand, and this is evidence that it's been done. It was done well before 2011 and that it's at least within the realm of possibility.

THE COURT: So is your purpose, in other words the relevance of seeking to admit this, that testing has been done, can be done, incorporating uncertainty information, rather than --

MR. SLEIGH: It specifically --

THE COURT: -- excuse me -- rather than how it relates to a specific machine, either the one in Washington or this one.

MR. SLEIGH: Correct.

THE COURT: Okay. And did you want to say something?

MR. NAGURNEY: No.

THE COURT: Based on that, the Defendant's F is admitted.

(Defendant's Exhibit F received)

BY MR. SLEIGH:

Q Ms. Arvizu, are you -- or Arvizu, sorry -- I've been pronouncing it wrong for six months. Are you familiar with the National Research Council's report called "Strengthening

Forensic Science in the United States"?

A Yes. I've read it.

Q And are you aware that that was published in 2009?

A November, I think, yes.

Q What was the genesis of that publication?

A They were commissioned by Congress to investigate and assess the status of forensic science in the United States and make recommendations to Congress as to needed improvements. The country had been -- in previous decades been experiencing some very troubling instances in which forensic laboratories were found to be using test methods that were not scientifically valid and that actually, in some cases, as demonstrated by subsequent DNA testing, had convicted people of capital crimes of which they were innocent on the basis of flawed forensic testing. And I think that got the public's attention, got Congress's attention.

Q So Congress directed the National Research Council to review the forensic -- practice of forensic science in the United States?

A Yes. It was a several year study.

Q And did they make recommendations in 2009?

A They did. They published a book that you've referred to, the Strengthening title book.

Q And did they make recommendations specifically regarding traceability and incorporation of uncertainty

measurement?

A Uncertainty was very specifically addressed as in the report, including as a specific sample, dealing with breath alcohol testing and how important it was to make that -- to be able to scientifically make a valid comparison to a regulatory threshold.

MR. SLEIGH: Your Honor, we would move the admission of Exhibit O, which is a copy of the National Research Council Report. My understanding is that Mr. Nagurney does not have a copy of that. I thought he'd been provided one. So I certainly would not object to withholding a ruling on the offer until such time as he feels comfortable about it.

THE COURT: I'll defer ruling to give you a chance to look at it.

MR. NAGURNEY: Okay. It is a book, but okay.

THE WITNESS: I have it electronically. I can send it to you.

MR. SLEIGH: Your Honor, I would just point out that it is available online at the National Academy of Sciences website as a PDF document that can be downloaded free of charge.

THE COURT: All right. It is, however, being offered by the defense in this case, so rather than shift the burden to Mr. Nagurney to find it himself, it should be made available to him.

MR. SLEIGH: We'll do that, Your Honor.

BY MR. SLEIGH:

Q All right. I'd ask you to --

THE COURT: Let me just say if he prefers to look at it online, that's fine. You've got to do the leg work and not shift that burden to him.

MR. SLEIGH: I'll have it emailed to him here while we talk.

BY MR. SLEIGH:

Q I've asked you to answer the following question. Did the Department of -- did the State of Vermont determine that the DataMaster breath alcohol machines met the rules performance -- I mean precision and accuracy requirements in a reasonable scientific fashion; is that right?

A Yes.

Q And tell me what documents, besides the ones that we've looked at today already, that you reviewed in connection with that question.

A As you indicated, it's more than 1,000 pages of records were provided to me most recently. It includes certain --

THE COURT: Before you start in, would you restate the question that you put to her, please.

BY MR. SLEIGH:

Q I asked you, I guess it was two questions. I asked you (a) do the DataMaster devices meet the accuracy and precision

criteria set forth in the rule, which by necessity required you to ask whether that question was ever answered in a reasonably scientific way -- in a way that was reasonably scientific, right?

A Yes.

THE COURT: Try again, please.

BY MR. SLEIGH:

Q Okay. There's a rule that says these things have to meet certain precision and accuracy requirements, right?

A Yes.

Q And I asked you to determine, based on the record, whether the machines have been demonstrated to comply with those criteria.

A Yes.

Q All right. And you've looked at a lot of records to determine whether or not there's been a reasonable demonstration that the devices meet those performance criteria?

A Whether the demonstration was conducted in a scientifically acceptable manner.

Q And would lead to a scientifically reliable conclusion?

A Yes.

Q All right.

MR. SLEIGH: Is that better, Your Honor? Hearing no, I'll hope for the best.

THE COURT: Well, I was hoping for a very clear

statement of the question and now I've got fragments from the two of you, so let's try it again.

MR. SLEIGH: Okay.

BY MR. SLEIGH:

Q Can you conclude to a reasonable degree of scientific certainty that the DataMaster DMT devices meet the precision and accuracy requirements of the Rule?

A No.

THE COURT: Go ahead.

MR. SLEIGH: Okay.

BY MR. SLEIGH:

Q Now, in the course of attempting to determine whether they met the criteria or not, you've reviewed a lot of material; is that right?

A Yes.

Q Can you describe to the court what it is that you've reviewed.

A Included what are called bench notes from the laboratory for their preparation of simulator solutions and copies of the log books used in the laboratory. It included what are called certificates of analysis produced by the laboratory and relied upon by the lab.

It included dozens of sets of GC data for each of the solutions that were used to test the instrument. So each of those are described by -- for example, there's a set of these

GC packages for the simulator solutions. There's a set of them for the interference check solutions. There's sets of these GC data that purport to demonstrate the acceptability of those solutions for use in evaluating the performance of the instruments.

Q Okay.

MR. SLEIGH: Your Honor, it might be useful to have a discussion with the court and Mr. Nagurney and I about exactly how the Court wants to receive these supporting documents. We have them in several different formats. They're voluminous. I think each of us have them in different electronic files and literally I think a three second or maybe three minute conversation might reach some consensus that would be helpful to the court and allow this to proceed relatively quickly.

THE COURT: Have you discussed exactly what it is that you're going to submit to offer?

MR. SLEIGH: I think Mr. Nagurney and I probably need two minutes to just look in the boxes so we can tell you -- we can come up with names for these things. I mean, really, we have to come up with a title so you'll know what they are.

THE COURT: Okay. So one of the issues that you need to both review what they are, what they're named, and in what form they'll come to the Court?

MR. SLEIGH: Right.

THE COURT: That would be useful. All right, we'll

take a short break.

MR. SLEIGH: Thank you.

(Recess at 11:15 a.m., recommencing at 11:26 a.m.)

THE BAILIFF: All rise.

THE COURT: Please be seated.

MR. SLEIGH: So we have a group of documents that are best characterized as the Redeployment Certification Record for each of the machines in question in this motion. I've marked them together as Defendant's P, as in Paul. I'd be happy to subdivide them, but each has a machine number on it so you could refer to it as P104009 if you had to discriminate, but I don't think that that's likely to be necessary. And Mr. Nagurney, as I understand it, has no objection to the admissions of P.

THE COURT: You're in agreement?

MR. NAGURNEY: Yeah, that's fine, Your Honor.

THE COURT: So it looks as though there are several different components. They're all P. Let's have a number of how many different paperclips there are.

MR. SLEIGH: Ten.

THE COURT: Defendant's P is admitted.

(Defendant's Exhibit P received)

MR. SLEIGH: Excuse me, 11.

MR. NAGURNEY: Your Honor, (indiscernible) to make the record, maybe, by having two of us at the same time, but

just I guess as a way of explaining the significance of P and why there are 11 documents, each of the discreet documents in Exhibit P relates to a DataMaster that's involved in this particular bundle of cases that you're hearing today. And they're differentiated by a six digit serial number assigned to each. And that serial number is actually printed on the evidentiary ticket that the DataMaster produces in the completion of the tests. So there is a way to reference the test results with the testing that was done by the lab before the test result was given.

THE COURT: All right. So Defendant's P, consisting of 11 batches, papers, all collectively as Defendant's P is admitted.

(Defendant's Exhibit P, 11 documents collectively, received)

MR. SLEIGH: Thank you. And then, Your Honor, what is, I think, best referred to as the quality assurance documents --

THE WITNESS: Quality control.

MR. SLEIGH: Quality control documents, which consists of almost 1800 pages if it was to be printed out, we've marked as Defendant's Q. It's a CD Rom disc that was provided by the Vermont Department of Public Safety in connection with this litigation. And it will have all those documents on it.

If for whatever reason the court prefers paper documents, I have them in a box.

THE COURT: CD's fine.

MR. SLEIGH: All right. So understanding that Mr. Nagurney had no objection, we'd offer Defendant's Q.

MR. NAGURNEY: That's fine, Your Honor.

THE COURT: Defendant's Q is admitted.

(Defendant's Exhibit Q received)

BY MR. SLEIGH:

Q All right. So let's get to the heart of things here. If you, as a scientist, were to generate a traceable measurement, what would you do?

A I would be working in an accredited laboratory because accreditation is one of the means of demonstrating competence. You would have a written procedure that describes the performance of that measurement. And that procedure would have been reviewed and approved and adhered to by the people who make those measurements. And it's a very detailed procedure. It describes the equipment that is used, the instrumentation that's used, the performance specifications of the measurement process, all the criteria that have to be met in order to generate an acceptable result. And it would have been in effect at the time the measurement was made.

That procedure would describe, as I said, the kinds of equipment and instrumentation that are used. For example,

it will also describe the reference materials that are used. Reference materials in this application are solutions of known and documented quality that are traceable to NIST. And it would actually specify that as a prerequisite of performing the measurement that you use this specific reference material.

So I would have purchased that standard solution from an accredited reference material provider. They would have provided a Certificate of Analysis that provides the uncertainty for that solution. That would be part of the record trail for this traceable measurement.

If I used an analytical balance to weigh out one of the components for a control sample, for example, that means weighing out a standard solution of ethanol. You start with absolute ethanol.

There would be a Certificate of Analysis for that solution of ethanol. And I would document contemporaneously at the time I prepared the solution that this was the lot number of the material that I used to prepare my control sample.

I would document the device that was used. If I made the measurement on an analytical balance, I would document it was this serial number of analytical balance that I used to weigh out this control material.

I would document the temperature at which the solution was prepared. I would document the serial number of the thermometer that I used to make the temperature

measurement.

The reason I'm writing all these things down and documenting all these things down is because those are all components to the uncertainty, so that I can then go look up the accreditation calibration, the accrediting agency's calibration records for that balance that I used, and see what its tolerance was. And I can go to the laboratory and I can look up the calibration verification check that was done the day before I prepared that solution or that morning that I prepared that solution to make sure it was operating within tolerance at the time that that measurement was made. That means that I can then use that uncertainty to compute my final result.

If I use a pipette, an automatic pipette, to deliver a known volume of solution, I would have used a pipette that within the last year had been sent to an accredited provider of calibration services and they would have provided a certificate of performance for that pipette. I would have that in my repertoire.

I would have checked the performance of that pipette before I used it to verify that it was operating within tolerance and those records would be available.

And if all those contemporaneous records are available, then all the components necessary to show traceability are available.

So at the time I'm preparing the solution, either with a balance or with pipettes, I have Class A volumetric flasks. Most typically, procedures require the use of Class A volumetrics. That way you don't have to document it every time you make a solution.

I would use a Class A volumetric and be able to look up the tolerance of that flask to know the uncertainty associated with preparation of a solution using that particular piece of equipment.

The traceability means essentially every time you're touching a piece of equipment or a device or a solution that has the ability to impact the final quality of the measurement, it's documented that it's -- the uncertainty of that measurement has been calibrated and determined and documented and that it's been verified prior to use.

So there's a great deal of paperwork associated with all this.

If there's a solution that I prepared in house in my laboratory, rather than purchasing it from an accredited supplier, then the burden of proof is essentially on me to verify that that solution is appropriate before I use it as a control solution. That is, I can prepare it using a calibrated balance and Class A volumetric glassware and have all that written down, but once it's prepared, I have to go that extra step and verify its concentration before I use it for control

purposes. So there's a whole set of paperwork associated with that verification process.

I hope it's leading to some sense of the literally voluminous amounts of paperwork that this takes. As I said earlier, the difficulty isn't in making the measurement. The difficulty is putting in place the systems to systematically generate, collect, maintain, all these records on an ongoing basis. Because once I make a measurement, I'm not having to go back and try to recreate this stuff after the fact. If I've got the systems in place so every time I purchase a pipette or a balance or a reference material, if my processes already require that I collect that Certificate of Analysis and it's uniquely identified and it's retrievable and the information's captured, I don't have to do this every time I make a measurement. They're all there, they all exist. And they can be produced to show the basis for my uncertainty determination and to show the traceability of my measurement.

Q Now, these requirements that you're talking about, they're not idiosyncratic requirements that you've created yourself; is that right?

A No.

Q They are part of the ISO 1725 requirements?

A And subordinate documents, yes.

Q And those requirements have been well known to the scientific community prior to 2010?

A Well prior. As I said, the requirement for traceability has been part of ASCLD lab for more than a decade that I have current records for and probably much longer than that.

Q So if in 2010 or 2011 you were trying to determine whether a given device met a certain precision and accuracy criteria, would you test that device in compliance with 1725 if you were a reasonable scientist?

A Yes.

Q And is that a requirement or a set of requirements, again, that is generally understood in the forensic scientific community?

A Generally understood in the forensic community, certainly for many years. Generally understood scientifically for many years. The concept of traceability is not new. Probably in terms of understand it at a very lay level, when we encounter a problem in the food supply in this country and have an E.coli contamination of hamburger, that's lot control, that's traceable. So they know what was prepared which day using which equipment and where that ground beef got sent to which states and which grocery stores. So it can be traced and it can be recalled off the product shelves. That's done with very similar kinds of documentations of lot control and which piece of equipment and which materials were used in preparation.

So the concept is not anything new or anything unique to forensics.

Q Now, let me just -- we're starting the edge of some sort of specifics here, but you said that one of the things that you would require would be this written procedure. Would that be a sort of standard operating procedure manual?

A That is exactly what it is, standard operating procedures that prescribe precisely what equipment is used, what instrumentation is used, what reference materials are used, and the manner in which they are used to generate a result.

Q And you said that the reference materials should be obtained from a certified reference material provider, is that --

A It's actually an accredited reference material provider, yes, who provides the Certificate of Analysis with an associated uncertainty.

Q Are you aware of an outfit called Goth or Guth Laboratories?

A Yes.

Q Do they purport to be an accredited reference provider?

A No.

Q But do they provide reference materials to laboratories?

A They do. There are a large number of suppliers in this

country who produce materials used as reference materials who are not accredited as a reference material provider. It's very much a situation where that, under quality standards, needs to be written into your quality manual as a policy that you purchase these things from accredited suppliers, because there are a lot out there who do not meet those standards.

Q Do you have some familiarity with the Guth; do you know who they are?

A I do. And in this case I reviewed their Certificate of Analysis that they had provided.

Q And did you find deficiencies in that certificate?

A Yes. It does not contain anywhere close to the necessary information that's provided by an accredited supplier of reference materials.

Q And I think you said that if you were doing this traceable measurement, you'd be working at an accredited lab; is that right?

A Yes.

Q Are you aware that neither the Department of Health nor the Department of Public Safety Breath Alcohol Program has ever been accredited by any agency?

A That's my understanding.

Q Is it your understanding that at the time of these redeployment certifications on the machines that the Department of Public Safety, the Department of Public Health, did not have

a standard operating procedures manual?

A That would be a very troubling status.

MR. SLEIGH: Your Honor, I want to move to an area where I need to set up my projector for some slides. I'd be perfectly willing to come back early. I think I probably have another 45 minutes, half hour, 45 minutes, with the witness.

I think we'll probably be able to get done today. But if we could adjourn a little early so I could get my screen and stuff up here, that'd be great.

THE COURT: I am going to need to take up some other matters at 1 o'clock, some out of county and in county arraignments.

So we won't be able to start right at 1:00. We'll be starting as soon as that's ready.

MR. SLEIGH: Will we have access to this room?

THE COURT: Yes, we can do that. We can do the arraignments --

MR. SLEIGH: That's okay, because then I can get everything set up while that's going on.

THE COURT: Right. That's fine. You can do that. So even with that, even with -- my question is, is there anything else useful we can do for 15 minutes so that you could set up during the noon hour?

MR. SLEIGH: I'm really at a spot where I have to display stuff if it's going to make any sense.

THE COURT: Okay. All right. We'll break for lunch now, then, and start as soon after 1 o'clock as we can, but it's not going to be before 1:20 or so.

MR. SLEIGH: We'll be ready to go. Thank you very much.

THE BAILIFF: All rise.

(Recess at 11:45 a.m., recommencing at 1:15 p.m.)

THE COURT: Mr. Sleigh?

MR. SLEIGH: Thank you.

BY MR. SLEIGH:

Q All right. Did the State of Vermont scientifically, in a reliable fashion, determine that the DataMaster DMT met the performance criteria of the rule?

A No.

Q And how did they fail in doing that?

A Because their measurements did not provide an uncertainty and were not traceable. So compliance could not be demonstrated.

Q All right. So can you show us some specific examples of how they failed both to abide my traceability requirements and to take into consideration the requisite on certainty measurements.

A Yes.

Q Okay.

A May I?

Q Sure.

MR. SLEIGH: First of all, Your Honor, what's displayed is Exhibit R.

BY MR. SLEIGH:

Q Could you identify what R is? You have the hard copy there.

A Yes. This is an example of a Certificate of Analysis prepared by Cerilliant, which is an accredited -- an ISO accredited supplier of reference materials. And I think I actually even mentioned it earlier in my testimony, Cerilliant was such a provider.

And it provides the kind of information necessary to support the traceability of measurements and describes a level of detail that is far in excess of that provided locally by certificates.

MR. SLEIGH: Your Honor, we'd move the admission of Defendant's R.

MR. NAGURNEY: No objection.

THE COURT: Defendant's R is admitted.

(Defendant's Exhibit R received)

MR. SLEIGH: And with your permission, Your Honor, if the witness could approach the screen, I have some questions that would allow her to point out why this is an adequate certification document.

THE COURT: That's fine.

BY MR. SLEIGH:

Q And I caution you, I've got cords all over the place, so be careful.

THE COURT: And if either of you attorneys need to move your seat, you're welcome to do so.

MR. NAGURNEY: Okay, thank you.

BY MR. SLEIGH:

Q All right. So can you point out the critical aspects of this Certificate of Analysis which makes it scientifically reliable and traceable and provides for uncertainty measurement disclosure.

A This Certificate of Analysis is described as -- for a certified reference standard that is NIST traceable. It was prepared by Cerilliant. And as indicated here, the Cerilliant manufacturer is accredited to Isodine 34, which is specific to suppliers of reference materials. They're also accredited to ISO IEC 17025, which is for testing laboratories. So that's an indication that they have demonstrated compliance with both of those requirements, that is, preparation of the reference materials and testing of the prepared materials.

And as you scroll down you see a lot of information. There's unique identifier, a lot number that specifically identifies that particular lot of reference material, an expiration date with an indication as to how that expiration date was determined. It's not just an assigned number, it's

actually empirically determined expiration date has been established through real time stability studies and applies to the ampule store unopened at the recommended storage conditions. So it actually tells you that it needs to be refrigerated, it should not be frozen. That essentially means that you have to be able to demonstrate that this solution was stored under refrigeration, and not allowed to freeze during its entire shelf life, which in this case goes to 2014.

In the ampules, these solutions are stable for a very long time and can be used, and their expiration date has been for a very long time. But as you notice, right here, it says

"The standard should be used immediately after opening to avoid concentration changes due to evaporation."

That's an indication that once you -- it's a glass -- actually a glass vile, it doesn't have a screw off cap or a pop off cap, it's a glass vile. You actually have to break the glass seal in order to open it. Once you open it, this tells you that it can only be used immediately after opening to ensure that it's of the expected concentration.

The practice in a lot of laboratories is to use it for a period of weeks. And if you will scroll down to the bottom of this page, it actually explains to you that that's possibly acceptable, as long as you conduct the necessary testing.

Okay. The warranty applies to ampules stored unopened and under the recommended storage condition. It does not extend a dissolution into which this product has been incorporated, establishing a shelf life of all such products is the responsibility of the user. So that puts the burden on the user for demonstrating that.

But what's really interesting about this certificate is all the information it provides about the necessary components for traceability. It says it was prepared and certified under the requirements of the ISO standard. It's an accredited organization.

They prepared this, what's called gravimetrically, which means that they weighed out the ethanol that they prepared the solution from using qualified balances, calibrated semi-annually. According to all these requirements, they use NIST traceable weights. It gives some descriptions about the environmental conditions and how each of the balances are calibrated, and it adds the fact that they verify the calibration of the balance prior to each use. I made reference to that earlier.

I've been using calibrated balance that I have an accreditation from the supplier. In addition, I would check it prior to use, and there would be records of that check using these traceable weights.

Weight tapes from the balance calibration are

included in the production batch record for the standard. So they, in their batch record, in their WAT (phonetic) analysis record, there are actually copies of those records. Weight stat stick is an explanation for how they are prepared and the concentration of the standard has been analytically verified against the new standard reference material. So even after they prepared it with all those controls, they then verified its concentration analytically.

So this is the kind of information that's included in a certificate of analysis for a traceable reference material.

We compare and contrast that with the next document. This -- you need to do something with this one.

Q Oh.

A Next -- no, this is Page 2 of that same one. Let's go to Page 3, sorry about that.

Q That's all right. Now --

MR. SLEIGH: Well, that's our -- our nomenclature, Your Honor.

THE COURT: Okay.

MR. SLEIGH: These things have been used in so many different -- so I have a group of documents of which I've put Exhibit S as in Sam. This is derived from Exhibit R, the quality documents that are on the CD. I'm unable, at this moment to list the pages of --

THE COURT: In Q?

MR. SLEIGH: Q, sorry, sorry.

THE COURT: Go ahead.

MR. SLEIGH: Q, R, S, so Q. But I've talked to Mr. Nagurney, we will provide the Q file identifiers after the hearing, but this group is S. They are already in evidence, so this is just marked for identification purposes. Would you like the hard copy, Your Honor?

THE COURT: Let me just ask Mr. Nagurney. Do you agree?

MR. NAGURNEY: Yes, Your Honor. I think those documents are all contained within Q. Sure, that's not an issue.

THE COURT: All right. So Defendant's S is admitted. I know it's a duplication, but it's in a different form, so.

(Defendant's Exhibit S received)

BY MR. SLEIGH:

Q So what do we see on the first page of Defendant's S?

A This is a certificate analysis that was provided by the Vermont laboratory in the large amount of material that was provided in an attempt to show traceability. And this is a certificate of analysis provided by Guth Laboratories for a reference solution that was used for the simulator.

If you could scroll down just a little bit.

Q Let me just ask a couple of questions. When you said the reference solution for the simulator, that's the solution

that the Health Department used in order to determine whether these machines met the precision and accuracy requirements; is that right?

A Yes. I would have to go see exactly what the (indiscernible) was used for, but yes.

Q Okay.

THE COURT: I'm still not clear what a simulator is.

THE WITNESS: Oh. A simulator is used --

MR. NAGURNEY: Your Honor, I guess at this point I would object only because that would be a foundational deficiency. I don't think Ms. Arvizu's given sufficient testimony for the Court to conclude she would have the basis to testify about composition or the construction of the DataMaster DMT.

THE COURT: I didn't hear everything you said, so --

MR. NAGURNEY: I'm sorry. I couldn't hear you through the microphones.

THE COURT: Your voice just dropped down towards the end of the sentence.

MR. NAGURNEY: Sure. Your Honor, I don't know that Ms. Arvizu -- I mean given the limited qualification of her expertise, which is in the lab procedural area, I don't know that she would have the foundation to testify about what a simulator is or how it's applied in this context. She hasn't, certainly, made any foundation through Attorney Sleigh that

would be sufficient for you to conclude that she would have a basis for expertise on that testimony.

THE COURT: The objection's sustained. You can ask her foundation questions if she knows what a simulator is.

MR. SLEIGH: Sure.

BY MR. SLEIGH:

Q This says it's a certified alcohol reference solution for a simulator, right?

A Yes.

Q What does that mean?

A This is a certificate of analysis for container of acqueous solution with a known concentration of alcohol, that was prepared by Guth Laboratories, and that they provide as a vendor to the users of their products and services. This particular one is provided as a solution to be introduced in a simulator for a breath alcohol instrument.

Q Okay. What is a simulator for a breath alcohol instrument?

A I don't claim to be an expert in the breath alcohol instrument, but the simulator is a device that introduces known material to the breath alcohol instrument, and so what's relevant is whether or not this solution is of the stated concentration.

Q Okay. So we were examining this particular certificate of analysis in contrast to that of the one that we looked at,

produced by Cerilliant.

A Yes. They did assign a lot number, and it -- that is key. Every single discreet solution must have a completely unique identifying lot number associated with it, as a prerequisite. They indicate that in this case, you will see that they prepared the solution, they analyzed it by GC and got a concentration.

Now compare and contrast that with the previous reference material supplier, their analysis was to verify the preparation conditions for their solution, to verify the acceptability.

In this case, they did not even attempt to address the preparation of the material, they simply did the verification step. So all the uncertainty components associated with the preparation, the balance calibration and verification of the weights, and all that, was not even part of their process.

Also very importantly, they report a concentration without an uncertainty. By definition, a reference solution, a reference material without an uncertainty cannot serve as a reference material. They don't have one. They do assign a lot number.

Q Okay.

A Okay? The next document --

Q And this is still part of Defendant's S?

A It's the next page of that same exhibit. This is

prepared by the Vermont Laboratory, again, it's titled "Certificate of Analysis of the DataMaster Calibration Solution." This is a calibration solution prepared in the laboratory for use outside the laboratory. And this purports to be a certificate analysis, but again, it doesn't even come close to containing all the necessary material.

It does describe when it was prepared. It indicates that it was prepared per standard laboratory practice. That would require a very detailed procedure, describing procedurally exactly how that was prepared, using what equipment and what materials.

It was assigned a lot number, and it was assigned an expiration date. The interesting thing here is how long this expiration date is. This expiration date -- they prepared this material in May of 2011, and it's assigned an expiration date of May of 2012, that's a year. That's a long time for solutions prepared in-house. There would need to be actual in -- empirical testing studies to demonstrate that that was an acceptable shelf life, that it would stay within specifications, stored as prescribed for that whole length of time in order to support that.

Q As Cerilliant did?

A As was the case for Cerilliant, the reason that Cerilliant can get away with such a long hold time, if you will, or such a long shelf life, is because there's are very

tightly controlled, they're in sealed glass vials.

Q How was this sample sealed?

A These are not sealed, they're in bottles. They're prepared in bottles. That automatically imposes a much reduced shelf life on them.

They indicate that the solution was analyzed and the analysis of that solution was found in the -- and that required specs, so they indicate that the solution, in fact, was verified very similar to what Guth had done. There is no information on this certificate as to how the material was prepared, except per standard laboratory practice.

Q Is there any accounting for uncertainty in these measurements?

A There is not. As you can see, it gives here a concentration .100 grams per 210 liters simulated breath alcohol -- breath ethanol concentration, but no uncertainty is associated with it. As is always the case for a certified reference material, it must include an uncertainty.

And the next document.

Okay. This is actually -- I told -- remember what the title of this form is. Can you scroll up? There you go. Just a little bit.

It's titled "Simulator Solution Preparation Log," and a variety of different types of solutions are documented on this form. This is a form, sometimes referred to as a bench

form or a bench log, that represents a contemporaneous record of the preparation of solutions. And it identifies the lot number. I'm guessing that this is a date right here, in 2011. And it assigns a unique lot number to each and every prepared solution -- ah, there we go. Very good. Prepared on May the 4th of 2011. They prepared a solution that they assigned that lot number to. So far, so good. All that's necessary information.

They indicate the total volume of the prepared solution and what the components of the solution are. They indicate what the target concentration -- and if I could show this second line here, they prepared five liters of an ethanol solution with a target concentration of 0.1. It indicates who made that solution, and then this later information, those last three columns are entered after the fact because those are the assay results. So this documents the preparation, and that documents the verification solution.

So what would be necessary if this was going to be traceable was that there would be a procedure describing this, and from this, I would essentially be able to identify all the components of uncertainty that would be associated with the preparation of a solution of this concentration.

Well, I can't tell that from this information. For one thing, I can't tell what the source of the ethanol was, the parent solution, the original source of the ethanol. I can't

tell where that was -- where that was purchased from, of what origin, of what purity. So I can't factor in its uncertainty.

They say that they prepared five liters of this solution. Volumetric glassware, and I've made several references earlier this morning to Class A volumetric glassware. That's glassware with very tight tolerance for preparing these kinds of standard solutions. They don't come that large. They're -- you typically are making them on the order of a liter or so. And they may have made multiple solutions, and from them, prepared one lot. They may have not made it according to volumetric tolerance, as they may not have used Class A glassware and Class A pipettes to prepare the solution; in which case, it can't be a reference material.

But in any case, it has to be documented, and none of that information is documented here. You can't -- you can't even re-compute, just to make sure they made the right concentration solution. What they should be telling you is I used this quantity of this concentration stock solution, and I diluted it to this volume to get a new solution of this concentration. Then I can go in stoichiometrically, which is basically chemistry for the recipe process, and figure out if they did it right, but you can't figure any of that out from this, none of it is documented.

This, these last three columns, are done after the fact, and yeah, there's dates here, May 25th and 6th and -- I

can't -- 03 525 -- oh, 5/20 -- May 25th and June 3rd, after the date of preparation, they went into the laboratory and did analytical work to presumably verify and get a result that they hope matches the original result. And we'll talk about that in a few minutes.

Q Okay.

A I should mention that those solutions --

You can go to the next one.

-- there's a whole series of these in the materials that we received. There's several, probably ten pages or so of these forms over a period of many months. The solutions that are prepared and documented in this manner are for a variety of intended uses. Here, for example, interference solutions, calibration solutions. So it's a general solution prep log, it's not just for one intended purpose, but they also have the same problem in terms of not documenting the traceability. If they did them gravimetrically, they would have to identify the balance that was used. If they used volumetric ware, they would have to identify that equipment.

So we can go to the next document, and I don't remember how far these go, yeah.

There's a whole bunch more, interference solutions and calibration solutions.

Q Again, with the same deficiencies as to all of them?

A Always the same deficiencies, never -- you never know

where their source was, where the parent was, the original source of any of those materials. By definition, those cannot be traceable.

Q Okay.

A Okay, next. Let's -- I don't -- I'm trying to remember, but let's go to Document 10, because there's several pages and they all suffer the same problem. No, one more. Keep going.

UNIDENTIFIED SPEAKER: This is 10.

THE WITNESS: Oh, that's 10? Okay, can we go to next --

UNIDENTIFIED SPEAKER: Group?

THE WITNESS: Next --

UNIDENTIFIED SPEAKER: Yeah.

THE WITNESS: -- letter? Next document.

MR. SLEIGH: All right, hold on. I've got to make a record here.

THE WITNESS: We'll find it while you're making a record.

MR. SLEIGH: It's the next group of documents, I believe are contained in what's been marked as Exhibit T.

THE WITNESS: Oh, you know what, this whole exhibit is just more pages, more sequence of time of the same issue.

MR. SLEIGH: Okay.

THE WITNESS: So go to the 30 there.

(Counsel confer)

MR. SLEIGH: Your Honor, Exhibit T, I'll have the witness identify, but again, these are extracts from Q.

THE COURT: Any objection to T?

MR. NAGURNEY: No, Your Honor.

THE COURT: Then it's -- T is admitted.

(Defendant's Exhibit T received)

THE WITNESS: T starts with some more pages of the simulator prep log, but a few pages into it, and that's what we just finished. Yeah, that's all -- that's all simulator prep log.

Then the next one --

BY MR. SLEIGH:

Q All right. So I'm going to show you what's been marked as U, which is another extraction from the -- from Q. Can you just identify that for me?

A This is a set of documents that starts with a headspace alcohol analysis standards logbook pages, and there are several -- several -- the whole things consists of those forms completed.

Q Okay. Thank you. How many pages does this take, I mean U?

A It is 7 pages long.

Q Well, you're the last one left.

MR. SLEIGH: Any objection to that?

MR. NAGURNEY: It came from Q, right?

MR. SLEIGH: Yeah.

MR. NAGURNEY: Why not? Sure. No.

MR. SLEIGH: Thank you.

THE COURT: Defendant's U --

MR. SLEIGH: Your Honor, I'm going to move the admission of Exhibit U.

THE COURT: Defendant's U is admitted.

(Defendant's Exhibit U received)

BY MR. SLEIGH:

Q So what is this?

A Well, you will remember the previous log book recorded the preparation of simulator solutions, and those three columns on the right talked about GC verification of those solutions. These documents describe the preparation of the standard solutions that were used to calibrate the GC instrument. And so again, these are solutions that contribute to the overall measurement uncertainty of the concentration of that solution.

In this case, the laboratory documents when the solutions were prepared and who prepared them, they assign a lot number, they assign the same lot number to all four of these solutions, Standards A through D; and they assign an expiration date. In this case, three months from the date of preparation here to the expiration date there.

And I should just mention that this actually is a

good recordkeeping practice. You should never, ever obliterate records, you should simply line them out and enter who made that change. It's not legible on the screen, but probably on the original document.

Okay. In this case, it is apparent from the record, that these standards were prepared, what's called gravimetrically. That is, the same way that they did it at Cerilliant, in general. They weighed out a quantity of ethanol, and then diluted it to volume to make standards with these different concentrations, and these represent the weighed values. But again, you can't tell what they're weighing, what the origin and purity and traceability of the material that they were weighing on January 18th of 2011. You can't rely on anybody's memory, it has to be documented at the time the work was done.

In addition, it does not document what balance, what analytical balance or scale those measurements were made on, so you can't demonstrate and include the uncertainty components from that unit. So that information is just missing here.

In this case, the laboratory appears to have just applied a standard plus or minus ten percent in terms of what they assign as the acceptance limits, rather than an empirically determined number.

Q And again, is there any expression of uncertainty measurement in any of these calculations?

A There is not. They compute a percentage of ethanol and express it as an absolute number, rather than as is necessary for a reference material, a number plus or minus, and a certainty at a given time.

Okay. You can scroll down or -- that's okay. Go to the next document, that will work.

There's a whole series of these documents that describe the solutions that were tested in the GC data, that represented the majority of the 1800 pages that I received.

Q And just to make it clear, the GC testing was done to do what?

A The GC testing was done to verify the concentration of the solutions that were used -- that were described in the simulator preparation log.

Q All right.

A They did GC testing of the calibration solution and of the other solutions. So always, without belaboring a point, it's simply not possible to reconstruct and identify the relevant uncertainty components because the information is simply not documented, and the results are reported without an uncertainty, just as a discreet number is.

Q Do you need to scroll down here? Is there anything on the bottom.

A I -- I just --

THE COURT: I need to back up. I -- I'm not yet

fully familiar with all the terms that are being used. Could you review again what the GT -- GC testing was done to verify?

THE WITNESS: Yes. They went into the laboratory, and in that first set of documents, described preparation of a series of different simulator solutions. Those are the simulator solutions that are introduced to the breath testing instrument. Those are essentially the known concentration solutions that are used on the breath testing instrument.

In order to determine whether those solutions were appropriate for that use, and to attempt to verify those solutions, they took those solutions into the laboratory and tested them, using a GC, or a Gas Chromatograph technique, an analytical technique. So the GC testing was not -- was done purely as verification of prepared solutions.

THE COURT: And I thought I heard you say verifications of -- and then you described two different things, not just one. You just now talked about the simulator, but I thought you described two different kinds of solutions.

MR. SLEIGH: You're talking calibration and interference.

THE WITNESS: Oh, there were several --

THE COURT: No, that wasn't it.

MR. SLEIGH: No?

THE COURT: But if that's what this is, that's fine, we'll go on.

THE WITNESS: Okay.

These calibration solutions on this page are -- don't have anything directly to do with the breath testing instrument. These are the solutions that they used to calibrate their GC. So this is an indication that they used an untraceable GC measurement to attempt to verify an untraceable simulator solution.

BY MR. SLEIGH:

Q All right. So let me -- maybe we can help a little bit with the picture here of this regression.

THE COURT: Are the two different solutions the simulator solution and the calibration solutions?

THE WITNESS: Can we go back to one of those simulator pages, simulator simulation pages?

There's a series of different simulator solutions. And some of them are described as calibration solutions, but they're talking about calibrating the breath instrument.

BY MR. SLEIGH:

Q So there are two -- let me ask --

A That's a good one, that's good.

Q -- a question and maybe we can shed some light on this. This is where it gets regressive. There's a simulator solution that's used in the devices, that’s the known, right?

A Yes.

Q So that's used to see if the machine is correctly

reading a known sample?

A Yes.

MR. NAGURNEY: Judge, again I have an objection to the foundation, this expert's expertise. He's asking an expert that he hasn't qualified as an expert in the DataMaster DMT, questions specific to the function of that very instrument.

THE COURT: Mr. Sleigh?

MR. SLEIGH: Well, she had a particular charge here, which was to determine whether the testing of the DataMaster machine was adequate to prove that it met the precision and accuracy criteria. She has testified extensively that she knows what that -- those criteria are. She knows, as a scientist, to test the accuracy and precision, you have to introduce a known sample with a certain degree of uncertainty measurement, and see if the machine properly analyzes that known sample. So that's one simulator solution.

So she's said so far, is that simulator solution, the one that's in the machine, was prepared by the lab, that -- and that's what we've been looking at, that that simulator solution was, itself, analyzed to see if it met the known criteria by the gas chromatograph, and that there were even subsequent tests, regressive tests, to determine if the gas chromatograph was working correctly.

So, I mean I think she's laid this out abundantly clearly. Now there is some confusion because there's

calibration going on here at different levels, so you can prepare a calibration solution that's used to calibrate the gas chromatograph --

THE COURT: I think you're addressing the basis of the objection.

MR. SLEIGH: Well, what I'm saying is that she -- her testimony has revealed extensive knowledge about how this entire process works, vis-à-vis the DataMaster, and so I think she's exhibited not just a minimal foundational level of knowledge, but pretty particularized knowledge.

THE COURT: Mr. Nagurney?

MR. NAGURNEY: Your Honor, I think there's a significant difference between testifying about the sufficiency of the reference materials that we use for testing, and the application of those reference materials, both in the testing and an instrument, itself.

And she can certainly say that certain components of the testing she's reviewed are insufficient, based on her estimation as an expert in laboratory quality analysis; but to the extent that she's going to get into an opinion that focuses on the function and the design of the DataMaster instrument, and it would necessarily implicate that she had a greater understanding about the function and use of the simulator solution is simply whether it met her standard for measurement uncertainty, I think is an entirely different area, where you

still have a foundation for her expertise.

And I didn't voir dire on that area, but I would wager that she likely couldn't lay one from what I --

THE COURT: Well, that does not appear to be the function of her testimony. So your objection's overruled.

MR. NAGURNEY: Thank you.

BY MR. SLEIGH:

Q Okay. So we've got this kind of series of solution testing, right, you've mapped that out? All right. So why don't you tell --

THE COURT: Well, you all -- you have because you know it, so --

MR. SLEIGH: Okay. Well, please, if there's any -- obviously --

THE COURT: You were in the middle of giving an -- eliciting from the witness an explanation. The objection came and it kind of interrupted that explanation --

MR. SLEIGH: All right.

THE COURT: -- and I would like to go back and get it.

MR. SLEIGH: Okay.

BY MR. SLEIGH:

Q Let's start from the top, or bottom, depending on how you want to look at it.

A simulator solution is prepared, supposedly with the

known concentration to test the DataMaster's vitality, so to speak. Is that right?

A To calibrate and check, yes.

Q Right. The lab prepares that simulator solution?

A They do.

Q And we've looked at the documents regarding the creation of that simulator solution?

A Yes.

Q They created that -- they tested that simulator solution to see if it met, in their view, the appropriate criteria by using a gas chromatograph?

A Correct.

Q And then they tested the gas chromatograph, itself, to see if it was capable of performing the test, sort of the second level test?

A In the same manner, they have to calibrate and check the performance of the GC, just -- that's how we always do it in science, we prepare knowns to calibrate the device and to check its performance. So there are solutions to calibrate and solutions to check, both at the simulators level and at the GC level.

Q All right. And at each level, have you found deficiencies in the traceability of the information provided by the lab?

A Yes.

Q And at each level, have you found total absence of uncertainty measurements?

A Yes.

Q All right. So what are we looking at now? You've had Mr. Hatt go back, sort of to the beginning to maybe shed some light on this trail of results.

A This shows that they were a whole series of different solutions used to calibrate and check the performance of the simulator for a variety of different purposes. So we have them for calibration, calibration check, external standard, interference, with the same level of documentation exists for each of these.

Down here, I'm noticing -- notice here, it looks like they used, if I -- I can't read it on the screen, but it looks like it might have been 200 microliters or -- I can't really tell exactly, but --

So this was prepared volumetrically, this was prepared gravimetrically. So this was prepared by weighing out a quantity of ethanol and diluting it to volume; this was prepared by measuring out and delivering an aliquot of known volume of, in this case, methanol; but again, the balance that they used, or the equipment that they used here, is not documented, so I can't evaluate its uncertainty.

Q All right. So do you want to go back to the -- is it the third e-mail we were in, or the fourth?

A Yeah. I don't remember where we were. See if you can.

Okay. This is the preparation log, just like we had a prep log for preparing those calibrators and check solutions, in the simulator solutions, this one is in the GC lab, the instrument lab that runs gas chromatography, how they document preparation of their standards.

THE COURT: Just for the record, this is that you --

MR. SLEIGH: Right. Thank you.

BY MR. SLEIGH:

Q Okay. So what can you tell us about this?

A Well, it suffers those same problems. The balance that this used is not documented, so you cannot evaluate its calibration status and its uncertainty component, and the uncertainty is not determined. It purports to provide a concentration of reference material, but it doesn't provide its uncertainty. There's no temperature.

And those are just more of the same. And so I think probably we're down to the last one.

Q Okay.

MR. SLEIGH: I think this will be now what's marked as Exhibit V, as in Victory, another extraction from Q. We move the admission -- oh, I'll have her identify it first.

BY MR. SLEIGH:

Q Can you tell me what V is?

A A large volume of records that I received, consisted of

primarily sets of GC data, and these materials that we're going to see here, for each of the solutions, for each of the calibrator solutions and simulators.

Q So when you say each of the solutions, be very specific now, we're talking about the simulator solution --

A Correct.

Q -- and the GC solution, or what solutions?

A We're talking about the different kind of simulator solutions. Some of them used for calibration, some of them used for calibration of check, those solutions that were verified, those three columns on the right, verified by GC. There was a set of documents that we're going to be reviewing here, for each one of those solutions.

MR. SLEIGH: So we would move the admission of V, Your Honor.

MR. NAGURNEY: No objection.

THE COURT: Defendant's V is admitted.

(Defendant's Exhibit V received)

BY MR. SLEIGH:

Q All right. So go ahead. What is this showing -- first of all, what is it?

A This is a summary sheet that summarizes the results of GC testing that follows. The testing was performed on samples from this lot number of simulator solution.

If you went back and looked back at those simulator

forms that we looked at first, there would be one of them that would have this lot number, and it would be identified as a .10 calibration solution. So this just describes the actual physical solution that they tested by GC, and when it -- and when that solution was prepared. So this is just repeating information from the previous documents.

This actually represents the results of two sets of GC tests that were done.

If you could scroll down on that solution?

And you could see that they computed an average, a standard deviation. These are basic summaries, they're descriptive statistics for these repeat runs of the -- that solution.

So we naturally get to the next page, and it will start to show what they did with this. This shows you that the output, remember, they had made five liters of this solution that they were testing, they essentially allocated that five liters into individual bottles, and these were the labels that they printed to identify those individual bottles to distribute them out throughout the State, presumably, for use as calibration solutions in the DataMaster instrument.

In each case, they identify the lot number of the solution, they identify a range which is set, not determined, it's just set at plus or minus ten percent, and then they describe the preparation and the expiration date.

Q So that range doesn't reflect a calculated uncertainly measure, does it?

A It absolutely does not. That was, when I was trying to make it, does not. In --

THE COURT: What range?

THE WITNESS: This range right here. When it provides a range, that is not the uncertainty associated with the result. They simply report the concentration as .10, and they give a range of .095 to .105. Presumably, that reflects an in-use range for the users of that solution, that that's what you want the results to be. It does not represent the uncertainty associated with this. There is no uncertainty associated with this.

BY MR. SLEIGH:

Q Okay. So you talked earlier about how uncertainty is calculated scientifically by referenced GUM, by examining data, by understanding the cumulative uncertainty from each aspect of the analytical process, right?

A Yes.

Q That range reflects no such calculation?

A It does not.

Q All right.

THE COURT: What does it reflect, if you know? You may not know.

THE WITNESS: It's assigned as a fixed percentage of

this theoretical number.

BY MR. SLEIGH:

Q So they just express plus or minus ten percent without -- again, there's no particularized uncertainty measurement going on there?

A Correct.

Q Right.

A Okay. If you go to the next document.

In order to run the GC instrument to analyze those -- that .10 solution, they have to calibrate their instrument. This is instrument output from their GC, describing the calibration of that instrument.

And if you can scroll down. There we go, that's it.

You can tell that on May 24th, the morning of May 24th, 2011, they ran a series of samples of different concentration. This is how they calibrate their GC, but as we saw on that (indiscernible) organic headspace form, that wasn't traceable either. They did it gravimetrically, but it's not traceable known uncertainty. They ran these solutions, they determined -- it's very difficult to see on this, but they ran a series of these solutions, and then determined the calibration curve for their GC instrument, and that was the basis for then subsequently testing all those simulator solutions. So they used untraceable calibration standards to teach the instrument to test simulator solutions that were also

untraceable.

And if you go to the next document, I think that's where we actually get to the GC data. No, this is the prep.

This is the cover sheet. They started it on May 24th. We saw on the previous day, that's when they had -- previous slide, that's where they actually calculated it.

They tell which calibration standards they used. They have a set that they prepared on April 12th of 2011. They're within -- they're sort of arbitrarily assigned expiration date. There are the four calibration standards that they used to teach the instrument.

And if you can scroll down.

Every time you run a GC, for the most part, it's run as a batch of samples. You calibrate the instrument and you run some opening QC to make sure it's operating in control, and then you run your unknown samples interspersed with control samples. So this is what's often referred to as a batch sheet, to describe the composition of that batch.

So their first vial was a blank; their second vile is what they call a timing mix. That's probably a resolution check sample to evaluate whether or not the GC instrument is effectively separating or resolving all the components that might be present in it; then they ran their four standards, and a whole blood control. When they actually started running the solutions, would have been after this. The -- what their

similar solutions that they're checking the concentration of.

So in this case, they're -- he missed it right in here, but there was a clinica sample that they used as their whole blood control, yeah, clinica sample. It's lot number is documented right there. And it has a target value and an acceptance range. Without going back and seeing the clinica certificate by the manufacturer, I can't tell whether they're using the manufacturer's supplied range or whether they tested it themselves and determined their own range.

Q Or arbitrarily assigned a range?

A Or arbitrarily assigned a range, which it looks like they may have done it, it's plus or minus ten percent, like everything else.

So now if you go to the next page. Now we're probably going to get to the GC results. Yep.

And this is the output from a gas chromatogram. It's probably well beyond the scope of this hearing to explain how this works, but this is essentially the instrument output that the laboratory is using quantitatively to verify what they refer to on their form as a GC assay, the results of their appropriation of their reference materials.

So the problem is that we have too many places in this process where the links aren't just broken, they're just missing in this unbroken chain of comparisons.

Q Okay. Thank you.

UNIDENTIFIED SPEAKER: Are you all set with this?

MR. SLEIGH: I have no -- yeah, but you should leave it on. Mr. Nagurney might want it. I'm not sure.

(Counsel confer)

BY MR. SLEIGH:

Q Let me show you just a portion of what previously was admitted as Defendant's P, as it refers to Machine Number 103609. I'm just going to ask you if you've taken a look at that kind of report for each of the DataMaster machines involving this case?

A Yes.

Q And what did those proofs of documents purport to tell us about each of the machines?

A This is like the verification testing of these devices. They include linearity tests, interference checks, calibration checks.

Q Do you understand that the State has -- or experts for the State, have testified that these DataMaster machines meet the accuracy and precision requirements to the rule; is that right?

A Yes.

Q Looking at the verification reports in Defendant's P, and all the testing that you've reviewed in terms of these preparation of the simulator solutions, the calibration checks, and the calibration of GC, do you see any evidence of adequate

traceability that would lead you to conclude that these machines meet the precision requirements?

A No.

MR. SLEIGH: Your Honor, the Defense rests.

THE COURT: Mr. Nagurney?

MR. NAGURNEY: Thanks, Your Honor.

CROSS-EXAMINATION

BY MR. NAGURNEY:

Q So Ms. Arvizu, I know we've been discussing measurements, certainly to some extent obviously through testimony, but I do want to confirm that you've never worked with a DataMaster DMT instrument?

A I have not.

Q And you've never worked with or for an alcohol breath testing laboratory?

A No.

Q And you've never been here to Vermont and seen the Department of Health's laboratory or the Department of Public Safety's laboratory?

A No, I have not.

Q Have you reviewed any documents those laboratories keep, that have not been provided you by Attorney Sleigh?

A That this laboratory keeps? No, I have not, only those provided in this case.

Q And you said that you do some -- or your curriculum

vitae states that you do some significant work with laboratory quality analysis. And that -- is that another way of saying auditing laboratory processing --

A That's part of it, yes.

Q How do you typically do a good laboratory audit?

A How do you do a good laboratory audit? It depends what the intended purpose of the audit is. Audit can -- you can do process audits, you can do compliance audits, you can do data audits, you can do audits for a variety of purposes. It just depends what the intended purpose is.

Q Well, let's talk about process audits, since that sounds pretty close to the purpose of your testimony here today. Essentially, you talked about what you see as sufficiencies in the process of the lab. Is that the right area of audit to be talking about with you?

A It's not really process audit, but I can work with you here.

Q Well, you tell me, what kind of an audit have you done to produce your testimony today?

A This is probably more appropriately described as a data audit, an attempt to reconstruct through the available records, all the necessary components.

Q Okay. So it's a data audit. Have you looked at all of the data the labs have produced?

A I have not looked at all the data that the lab has

produced. No, certainly not. I have looked at the records that were provided in this case.

Q Uh-huh. The records David Sleigh has provided you?

A Yes. I also reviewed records in a previous case.

Q And who provided you those records in that case?

A Bill Cristman.

Q And do you know whether you reviewed all of the records the lab keeps in that case?

A I only reviewed the records I was provided with.

Q So that's a no?

A That's a no.

Q Okay. Before I forget, and as long as I have Exhibit N in my hand, you said you got an ABD in chemistry from the University.

A It's not a degree, it's just a designation, essentially.

Q Is ABD inaccurate?

A It is, all but dissertation.

Q So have you written a dissertation?

A No.

Q Do you have a dissertation topic?

A Uh-huh.

Q What would the topic of the dissertation be?

A It dealt with amino phosphine coordination chemistry.

Q Was the topic related to measurements or --

A It was not, it was not related to quantitation, it was related to structure.

Q Okay. And was it related to traceability at all?

A No.

Q As far as other qualifications and the skills, I see you've got a Certified Quality Auditor's Certification or Quality Auditor's Certification, I guess, and a Trained ISO Lead Auditor's Certification. As I understand it from your testimony, ISO is a governing body, I suppose, for lack of a better word, for laboratory purposes, am I correct in that?

A That's correct.

Q And if you're an auditor for ISO, tell me what kind of documents you would look at to do an ISO sanctioned audit?

A ISO doesn't sanction audits. You're not an ISO Auditor, per se.

Q But you are, according to your CV.

A No. You may be trained in the ISO standard and in the conduct of audits against the ISO standard, which I have been --

Q Okay.

A -- but ISO doesn't --

Q Certify audits.

A Yeah, right.

Q So tell me about the ISO audit standard. What does it involve, what steps?

A The -- oh, the -- not ISO 17025? Is what you're asking me about?

Q 17025, it says you're a trained ISO Lead Auditor.

A Yes.

Q So if you were going to do an audit, according to your ISO training, the 17025, what would you do, tell me the steps.

A Well, typically, an ISO audit, where you're looking at compliance with an ISO standard, includes a variety of things. One of the most important is the definition of the scope of the technical work performed by the laboratory, at least subject to the assessment.

Q Uh-huh.

A And because the ISO standard includes both elements related to the management operation of the laboratory and to the specific technical methods employed within their scope. So you have to get that kind of definition right up front.

Typically before going onsite for an onsite audit, you would request copies of the laboratory's quality policies and procedures to understand sort of the baseline functioning of their quality system.

Q So we're getting into a lot of details.

A Oh, sorry.

Q So let me just to make sure we don't -- no, that's fine, and I, you know, want to get into this, but I want to make sure, you know, you said so you go onsite. Did you go

onsite here?

A I did not.

Q Okay. And you said you would request policies and procedures.

A Yes.

Q Did you review the policies and procedures of this lab?

A I did not.

Q Why not?

A Well, at least for some period of time, my understanding is that they did not have any procedures, written -- approved procedures that were subject to document control and actually implemented in accordance with the provisions of things like ISO.

Q Okay. And who's understanding, where did you get that from?

A From my client.

Q So Mr. Sleigh told you that?

A I actually don't remember if it was Mr. Sleigh or Mr. Cristman?

Q Fair to say a Defense attorney told you that?

A A Defense attorney.

Q Fair enough. So I interrupted you, onsite testing and review of procedures.

A I should mention I also listened to testimony from analysts. It's been many, many months since then, but my

recollection is that I heard testimony regarding the fact that at the time in question, they did not have written procedures.

Q And where would that have been.

A A little town, Saint Albans --

MR. NAGURNEY: Mr. Cristman, if you could not whisper to her --

THE WITNESS: St. Albans.

MR. NAGURNEY: -- that would be great.

THE WITNESS: St. Albans, is that right?

MR. NAGURNEY: Do I get to cross-examine, Mr. Cristman?

BY MR. NAGURNEY:

Q So, okay. Other than an onsite visit and the review of the procedures, neither of which were done here, what else would you do if you're going to do an ISO audit of a lab?

A Other than an onsite audit and review of the procedures?

Q Uh-huh.

A Well, it wouldn't be a full ISO audit if I couldn't go onsite and look at all the operations. So I guess I don't know how to answer your question.

Q Okay. So you didn't do a full ISO audit here?

A Oh no, no.

Q Okay.

A Absolutely not.

Q How about your ASQ certification? What steps would an ASQ quality audit require?

A Again, I can't give you a very short fixed answer because it depends on the intended use. Is it a data audit, which I meant, for example, attempting to reconstruct one measurement result to evaluate its traceability, or is it a compliance with a prescriptive requirement, or whether it's more -- a broader scope as in an ISO audit. It depends on the intended use of the results.

Q Okay. So if you were going to apply that audit here, what would you do to this laboratory and to these regulations --

A I was going to --

Q -- to this program?

A I'm sorry, what? If I was going to apply what?

Q If you were going to apply the IS -- the ASQ quality audit -- if you were going to do an ASQ audit on this laboratory and this DataMaster program, designed at giving to the point of, does this instrument meet these regulations, does this testing show that this instrument meets these regulations, what steps would you take?

A If it was based on more than just the record, if it was more than a data audit, it would require an onsite visit to the laboratory to evaluate all the policies and procedures that were in place at the time the subject work was performed.

Q Okay. Again, not done here?

A Not done here, no.

Q Okay. Is there any audit standard? Is there any -- no, strike that. I'll start over.

Under either the certified quality auditor standard or the ISO auditor standards that you would be applying in these situations, would either of them contemplate looking at a universe of data that was provided to you by a third party?

A It's not all that different than what happens when you go into a laboratory and actually conduct an onsite inspection. For example, when asked how a lab conducts its inspections of laboratories, they actually ask for the lab to provide them with, for example, three to five case files from each analyst for review by the auditors. Probably a better approach is for them to select those at random, then to allow them to be peremptorily provided in advance, but auditing is always a sampling exercise. There is no expectation, and certainly no practical ability to evaluate everything that a laboratory does. It's only a sampling.

Q Sure, because we're talking thousands of pages?

A Yes.

Q Okay. But here, you haven't even reviewed the policies and procedures. Is there any audit where you wouldn't review policy and procedures?

A I've actually had to conduct data audits many times

when the lab did not have policies and procedures at the time the work was performed.

Q That -- that's not quite what I asked, though, which is if the lab had policies and procedures and you didn't review them would it be a good audit?

A It wouldn't be as broad a -- it would not be as broad a scope, an audit. You can certainly do a data audit, just reconstruct it based on the record. If you really want to understand operationally what maybe the origin of some of their deficiencies were, it would be certainly far better to have the policies and procedures that were in place at that time.

Q Okay. So what was the exhibit that was related to the marker board? Because I want to make sure we covered that, and I didn't want it to get erased in the interim.

A I don't remember.

Q Oh, I'm sorry, this --

THE COURT: N?

MR. NAGURNEY: I'm sorry, Your Honor?

THE WITNESS: N, she said?

MR. NAGURNEY: N?

THE COURT: Is the one you're referring to?

THE WITNESS: Yes.

MR. NAGURNEY: Yes, it is.

BY MR. NAGURNEY:

Q So you drew Exhibit N, if I'm understanding you

correctly, in attempt to sort of illustrate what measurement uncertainty is, what it -- the concept, this expresses the concept of measurements, if I understood you correctly?

A It expresses the -- how it's so important when you're trying to compare a result to a threshold.

Q Okay. Okay. So .08 is the threshold, if I'm understanding your example?

A Yes. It's what I'm making my comparison to.

Q Okay. So there's some limits to measuring uncertainty, are there not?

A Oh, absolutely.

Q Okay. And if I understand you correctly, if I go above .08, I replace the .08 with a .16 measurement, and I'll say BAC rather than percent, because that's the expression that they use, but if I change that threshold to a .16, you would agree with me that measurement of uncertainty becomes substantially less of an issue for the consideration of whether a BAC test is accurate or valid?

MR. SLEIGH: Your Honor, I don't think she ever offered any testimony about the accuracy or validity of BAC tests, and that was a illustrative example of showing how uncertainty measurement relates to a known threshold. So I don't see that she's testified to anything about breath tests.

THE COURT: What was the question again?

MR. NAGURNEY: I can restate the question, Your

Honor.

THE COURT: Okay.

BY MR. NAGURNEY:

Q So if I were to -- if you were to use my example with a .16 BAC, rather than your example of a .08 BAC, as (indiscernible), in whose example is measurement uncertainty a greater concern in your mind? Would you want to know about the measurement of uncertainty in the .08 test or the .16 test?

A I would want to know measurement of uncertainty in every test, but you might be misunderstanding me. When I used .08, that was not as the result for an unknown sample, that's a regulatory imposed value that I'm comparing a result to. I think you're talking about where the dots are.

Q Well, if I had a .16 BAC, and I -- doesn't that leave me .08 -- can't it be off by 50 percent and still be at or above a .08?

A I've seen analytical labs whose measurement uncertainty was greater than 100 percent.

Q Sure. And I mean -- and I guess that's not the question, the question is mathematically, if you -- the higher your BAC becomes, the more margin for error there is, and the less of a factor the measurement of uncertainty comes, isn't that true?

A Yeah. I'm not going to get into the trap of calling it a margin of error, because we went down that road before, but

yes, the higher you -- the result is, the larger the uncertainty would have to be before this became an issue. That's a very true statement.

Q Okay.

(Pause)

BY MR. NAGURNEY:

Q So you've reviewed the rules of the Department of Health and -- I should say the contents of the alcohol breath-testing rules, I guess it doesn't matter if it's Department of Health or Department of Public Safety, the rules are the same between the two. They're actually were produced in your affidavit, correct?

A Yes.

Q Okay. So you're familiar with them?

A I am.

Q And I think Mr. Sleigh mentioned it in his opening, though I want to make certain I understand your position as well. They don’t contain the word uncertainty anywhere, do they?

A They do not.

Q They don't contain the word traceability anywhere?

A They do not.

Q So fair to say you are -- and I understand that you have the training and a background field, but those terms are imputed by you to that?

A They are.

Q Okay. So what's controlled by the rules, the testing rules, what are they written specifically for?

A I'm not sure I can answer that question, that's sounds like a question for a Legislator. I don't understand -- if it's meant from a scientific perspective, I don't understand it.

Q Well, that's actually -- is further to my point. The rules control the performance of the DataMaster, correct?

A I think there are many things that control the performance of a DataMaster, but --

Q But the Court is concerned with whether the DataMaster meets the Rule, and that's what Mr. Sleigh has asked you to look at, correct?

A Yes.

Q So you would agree with me then, that the rules, the breath testing rules for alcohol, are specific to the DataMaster instrument itself?

A I guess I have to go back and look. I don't know if it actually said it was a DataMaster or not.

Q Well, there are standards the instrument must meet, right?

A Yes. The rules essentially establish a performance standard.

Q Okay. And they say what the instrument shall be

capable of, correct?

A Yes.

Q So then they relate to the instrument?

A Yes, the performance of that measurement system, yes.

Q So as I understand measurement uncertainty, and I guess traceability, which is something of a subset of measurement, uncertainty, as you've explained it to me. Don't those relate to processes rather than things?

A No, it relates to the result.

Q And how do you -- isn't that another way of saying process?

A Actually, a result is typically a product of a process.

Q So you employ a series of processes in your reaching a result?

A Yes.

Q And that's what measurement uncertainty measures, the failings of each one of those little processes, as they've been applied in the production of that result?

A The inherent uncertainties rather than failings. It's just a -- inherent limitations of that measurement system.

Q So if I understand measurement uncertainty, and I'm starting to, the more of these I do with you, measurement uncertainty is determined partly -- well, it affects method validation -- or explain to me, I guess, the relationship between uncertainty and validation.

A Oftentimes, the ultimate product of a method validation study is the uncertainty associated with the measurement of a particular measurement -- measurement system, because when you're doing a method validation study, you're actually collecting the empirical data to evaluate accuracy and precision. The -- and so you can collect both of the Type A and the Type B data necessary to compute an uncertainty.

Q Are there any established criteria for method validation?

A There are a lot of guidelines, because as with everything in science, it depends on what you're trying to use a result for, the scope and the rigor of the process that you go through.

Q Ultimately, though, it sounds like what you've said is the method validation is, just being able to validate your method, what you've done, explain your steps and why you've done them.

A It's more than explaining your steps, it's actually collecting data to measure when it works and when it doesn't, and when it does work, how well does it work, how confident can you be in a given result?

Q So -- but you would agree with me, there are no specific method validation criteria for the DataMaster DMT instrument?

A No.

Q Are there specific method validation criteria for alcohol forensic labs?

A There are a lot of guidelines put forth, and direction in standard documents, but no -- there's no one master rule for the entire universe.

Q And that's what you get at when you audit, right? I mean you would look at all of the things that were done and give an opinion based upon the totality of the data you would -- whether those things were, in your mind, sufficient?

A Yeah, it's -- as the importance of a given decision increases, the rigor essentially, it also increases in laboratories for quality control. So if they're not as severe a consequences for a wrong conclusion, you can accept a much greater uncertainty.

Q Uh-huh. So explain for how a plus or minus ten percent accuracy of regulation is not the same as measurement uncertainty.

A Okay. I'm not sure I understand the question. Explain for you why, when they say -- I am looking -- I know it's here somewhere, but when the regulations say --

THE COURT: Do you need to look at something?

THE WITNESS: Yes, please. Thank you. Okay, here we go.

"Shall be capable of determining the blood or breath alcohol concentration of the person sampled with an

accuracy of plus or minus ten percent."

Okay? And you want to know why that is not the same thing as uncertainty?

BY MR. NAGURNEY:

Q Uh-huh.

A It's essentially telling you that your -- when it says "within plus or minus ten percent," it's essentially giving you, as I would interpret it, the boundaries of performance. That as long as I get a result that is within plus or minus ten percent of the true value, then that's performing acceptably. So it's speaking both to accuracy and essentially to precision, once you've got your boundaries around it.

That can't be the same thing as measurement uncertainty, because measurement uncertainty is empirically determined as opposed to an imposed standard. I guess I really just don't understand your question.

Q Uh-huh.

A Because a measurement uncertainty is an empirically determined result, whereas this is, this is like the .08. It's an established performance level, it's not an empirically determined -- maybe I'm just not understanding you. I'm sorry.

Q Sure. Well, I'll rephrase it for you. So in certain DUI cases in Vermont, one of the elements of the State's proof is proving that the Defendant was at or above a .08 BAC.

A Okay.

Q And the regulations say that you have to be accurate to within plus or minus ten percent of that .08.

A Okay.

Q And if your instrument is accurate to within plus or minus ten percent at that .08, the result becomes admissible.

A Okay.

Q So doesn't that beg the question that the rules have already created an uncertainty --

A Oh, okay. I --

Q -- of plus or minus ten percent?

A I think I understand.

Q I mean because theoretically, correct me if I'm wrong, but I could have evidence of someone at a .08, and if rules of plus or minus ten percent, the rules already conflict, that person could be a .072.

A Okay. I -- I --

Q So isn't there a plus or minus ten percent of uncertainty already in the rule?

A I would say that it is not, and the reason is, for any one of my results that are up there, it is a misinterpretation for you to take the result of .08 and use that. You should actually be using, and I'm just going to pick numbers out of the sky, .07 to .09. I cannot tell you if it's .07 or .09. In fact, I can't even tell you if it's more probable that's it's .07 or .09. All I can tell you is it's somewhere in that

range.

So when you compare a discreet result to a threshold, that's directly misunderstanding the circumstance. When I have a result of .08 plus or minus .01, all I can tell you is its somewhere in that range. I have to compare the range to the result, because your example is predicated on that the .08 is the actual determined value. It really isn't. I'm really determining a range, not a value.

Q So you testified in Franklin County back in -- I guess it was April of this year; does that sound --

A It was spring, I don't know.

Q Didn't you say there that scientifically what the regulation means is accuracy -- I'm sorry, scientifically what the accuracy regulation means is uncertainty of ten percent around the reported result?

A Yes. That --

THE COURT: Excuse me, your voice fell down again.

MR. NAGURNEY: I'm sorry, Your Honor.

BY MR. NAGURNEY:

Q Your testimony in that hearing was that scientifically what the accuracy regulation means is an uncertainty of ten percent around the reported result.

A Around a reported result. That you would have to achieve -- demonstrate uncertainty within that range, that is, the size of your uncertainty bars.

Q So it sound like, from what I've understood from your testimony, that you don't really feel that a lab -- or you don't feel that the lab should make its own reference solution for the testing?

A Actually, ASCLAD Lab, in their supplemental requirements, addresses that and states that they should be purchased from -- externally from ISO suppliers.

Q So I'll show you -- well, I'll bring to your attention Exhibit B, and this is what has been marked and admitted as the ILAC Guidelines for Forensic Science Lab.

A Uh-huh.

Q Section 5.6.2.2.2, doesn't it say that,

> "For many types of analysis, calibration may be carried out using synthetic standards containing (indiscernible) test prepared within the laboratory from chemicals of known purity and composition, or matrix max standards. Alternatively, standard solutions may be purchased."

A Yes, it certainly does, because forensic labs do a very wide variety of testing, and in some cases, there are no externally prepared ISO accredited suppliers for calibrators and reference materials, so that's your only option. When that occurs, the burden is placed on the laboratory to essentially emulate the performance of a referenced material supplier.

Q So I guess in your mind the real peril or shortcoming

of not using a third party vendor for those reference materials is that the lab then has to document the steps sufficient for uncertainty measurement to be associated with that?

A That is very true. As each step in the chain increases, the uncertainty increases, so it increases additional uncertainty. In addition, it just puts a very significant burden on them to maintain the necessary documentation.

Q Okay.

A But sometimes you have no other option.

Q Okay. But your testimony about the propriety, or the correctness of purchasing the solution of reference standards in the third party, if possible, it's premised on the assumption that an uncertainty measurement needs to be included with the measurement process?

A It is. It's also a part of the ASCLD Lab supplemental requirements for labs that hold ASCLD Lab International Accreditation.

Q Okay. So further on in Exhibit B, under Section 5.9.1, Assuring the Quality of Testing Calibration Results, and it lists a number of quality control activities available to laboratories, and those include replicate testing and -- well, let's ask about replicate testing first.

You reviewed this testing, is that replicate testing down here

A In some cases yes, there certainly is.

Q Okay. And then the second one is independent checks, and then it goes on to say "Verification by other authorized personnel."

A Uh-huh.

Q Do you see any evidence of that done in the testing here?

A They call, for example, the GS Assay and independent verification.

Q Uh-huh. I don't expect you to be familiar with our DUI statutes, but let me ask you, the DUI statute provides the opportunity for a Defendant who's being tested on our DataMaster DMT to provide an independent sample of their alcohol concentration for testing on a gas chromatograph. Is that an independent check?

A Their breath?

Q I believe it's a blood sample.

A Oh, okay. Their blood -- what lab does it go to?

Q I believe our lab would analyze or they can have it verified by another party.

A Oh, I was unaware of that.

Q But is that an independent check on a process?

A It has some potential to be. Again, then it introduces a whole other set of factors that have to be controlled, because split samples, for example, are a common -- here's

commonly a perception that as long as I split a sample and the results are the same, it must be the right answer, but that isn't always necessarily the case. So it introduces a whole other set of coals, but it's another approach.

Q Okay. ILAC, just again, are they an accrediting body? Are there any ILAC accredited labs out there?

A No, ILAC isn't an accrediting body, it's an organization of accrediting bodies.

Q Okay. And the -- so they -- various accrediting bodies put their qualifications for accreditation together and then ILAC issues guidelines to meet them?

A Exactly.

Q And all of those various accrediting bodies all say that in lab preparation of reference materials is acceptable?

A Oh, sometimes it's the only option.

Q Okay. With regard to Exhibit C, are either SOFT or AAFS, accrediting agencies?

A No, SOFT is more a trade organization, I guess, if you will, of practicing forensic toxicologists, and the same thing for American Academy of Forensic Sciences.

Q Okay. So even if SOFT or AAFS were accrediting bodies, is there any mention in Exhibit C of measuring uncertainty traceability?

A Again, I would have to look to find any specific reference. I just don't have that right at my --

Q Do you know whether they speak to reference materials?

A I believe there are sections on reference materials, yes.

Q So Mr. Sleigh admitted Exhibits D and E, and they're both stamped "Currently Under Review." Are the ASCLD Lab policies on measurement uncertainty that are stamped currently under review? I mean are there currently -- are these policies currently used by ASCLD?

A They are. They are available online. The current approvers, and it doesn't say currently under review on them. Interestingly enough, it has exactly the same dates that that one does, in terms of its effective date and the date.

Q Mr. Sleigh admitted Exhibit F, and this is the Rod Gullberg article?

A Yes.

Q He's estimating the measurement of uncertainty in forensic breath alcohol analysis. Have you reviewed the article?

A Yes.

Q The first sentence of the abstract says,

"The evidentiary weight attributed to forensic breath alcohol results in drunk driving prosecution."

Excuse me,

"Attributed forensic breath alcohol results in drunk driving prosecutions requires a measurement

uncertainty established and showing to be fit for purpose."

So isn't the Gullberg article speaking entirely about the weight to be assigned to a test result based upon the calculation of measurement uncertainty?

A That sounds like a legal question. From -- for a layperson, evidentiary weight sounds like the fact that the jury's given a lot of weight. I don't know. It -- but for me, scientifically, it sounds like uncertainty is an essential component of the measurement result.

Q So, I mean that was your testimony earlier, right? You couldn't create measurement results without an uncertainty.

A You certainly can. People do it all the time.

Q But you just don't think they should be given much weight, for lack of a better word?

A Users should be cautioned to not try to use those results, particularly for comparison to a threshold unless they understand the uncertainty. In fact, it's even very difficult to compare to numbers and see if they really represent one is higher than the other, if you don't know the uncertainty. So depending on the intended use of a result, measurement uncertainty is always essential to understand and be able to use data in a proper manner.

Q Tell me about some of the other types of laboratories you've worked in. How about the DOE Idaho National Engineering

Laboratory? What sort of things go on there? How --

A What --

Q What type of science is being done there?

A Science is being done. At the time I was there, it is a facility that was in past life, the national reactor test site. So it was where prototype nuclear reactors were evaluated. There were a large number of facilities present on that site, and a large number of legacy problems on that site as a result, that required analytical work to try to figure them out.

So there was chemical testing, there was radiological testing of matrices that ranged from air to water to soil to almost anything else that could be containerized and brought into the laboratory.

Q And how precise was the testing that was done on that laboratory? I guess I don't understand, there is obviously numbers being produced.

A Uh-huh.

Q And so you need to have an uncertainty for the measurements that used those numbers?

A Radiologically, their numbers were always reports with an associated uncertainty. From a chemistry perspective, when testing was first begun, it did not, it did not have uncertainties associated with it, and that was a problem. They were -- they were new in the practice of making those kinds of

measurements, and we're learning not -- I suppose in some respects, not unlike the forensic community, being new to the business.

Q So tell me about some of the radiological numbers that would be reported at that lab. How were they expressed?

A As, for example, the number of picocuries per unit of whatever mass or volume, with a plus or minus uncertainty associated with it.

Q So it would be as a decimal, a picocurie, is that --

A Yeah.

Q -- a small fraction or a small decimal?

A We always hoped they were small, sometimes they were large.

Q Okay. So if I were to express a picocurie as a decimal, how would I do that, point what, zero point what?

A I don’t understand your question. I’m sorry.

Q Well, you're saying a picocurie is a -- I understand it. I mean, keep in mind, I'm the guy who went to law school, because I learned in medical school that chemistry probably wasn't for me at the high school.

A And look what you're doing now.

Q I know, right? That's what it's come to, but for what we measure, what you measure in this lab, these picocuries, aren't these infinitesimally small?

A Oh, you betcha. From a radio analytical perspective,

we have the ability, for example, to detect a hundred atoms of a particular radionuclide. We don't detect a hundred atoms of ethanol. That's orders of -- many orders of magnitude difference --

Q So it sounds like --

A -- in terms of detection ability.

Q So it sounds like measurement uncertainty is a lot more critical in a nuclear laboratory than in an alcohol breath testing lab?

A Oh, I don't think so at all. I think they're both important. In a nuclear laboratory, what was important was, is it about background or not? So we had to get a good understanding of background, and it's variability, not unlike the little diagram we've got drawn up there, to be able to distinguish what's the significance and difference between a given radionuclide at environmental levels, does it represent have we had a release, is there an exposure or not? So it's -- many of the very same principles apply.

Q Some of your later exhibits you covered with Mr. Sleigh, were culled out of Exhibit Q, involved the gas chromatograph measurement, and using that as a quality control check --

A Uh-huh.

Q -- on the referenced solutions that were made. Why do you -- why is that insufficient in your mind?

A I'll refer you back to the accredited supplier. They use a very well understood, well documented system to prepare their solutions. So they used calibrated balances and so forth to prepare their solution, and they figured out all the uncertainty of those components, and then they verified the concentration by using GC. In contrast, this lab just started with doing the GC measurement. There was no -- none of the information necessary to initially determine the uncertainty of the solution.

Q Such as you were talking about the balance.

A Yes.

Q Do you know anything about the balance this laboratory used?

A I don't, because they didn't document which one they used or what its calibration status was.

Q How would you get that information if you were doing an audit on a lab?

A You would look at the preparation log -- that's usually what they're called -- for the solution, which we looked at to see whether or not they documented which particular equipment item they used so that you could then go look to the calibration records for that instrument. But they didn't document what they used at the time they made it.

Q Okay. And tell me who you talked to at either DOH lab or DPS lab --

A I have not.

Q -- to ask these questions. You haven't talked to anybody?

A No.

Q So you're assuming that that documentation is not there?

A I'm assuming that there's not a second prep log for the same solution with different information.

Q Same question with regard to the volumetric things. Are we talking about some sort of graduated cylinder, a five liter something?

A That would be Class B.

Q You haven't been to the lab, so you haven't seen --

A I have not been to the lab, no.

Q And you don't know -- haven't seen it to know if they have one?

A No. I don't know if they're using Class A glass volumetric ware or whether they're using automatic pipettes or a combination thereof.

Q But if you knew that stuff, that would only help the uncertainty --

A Well, I can tell you that they --

Q -- of your opinion, right?

A -- that they were measuring in the microliter range and there aren't glass pipettes that will go in that range. So at

least once they were using an automatic pipette.

Q Let me ask you just sort of a general question about measurement uncertainty. Where does it end? I mean, there's always going to be a process -- there's always going to be a spot in the process where you're not going to know. I mean, wouldn't temperature affect the volume of a liquid?

A And it does. And that's why it should be recorded.

Q Wouldn't atmospheric pressure affect the volume of a liquid?

A Yeah. Here's the thing, when you go through this process and you identify all these factors, once you've identified them and quantified them and put them all together, you make a determination as to which ones are essentially de minimis, which ones are too small to have contributed in any meaningful fashion to the final result. And it's perfectly acceptable to exclude those from consideration. And in fact, I think if you look at the Cerilliant standard, it actually describes some that were excluded from consideration because they were found not to be significant. That is entirely appropriate.

However, the ability to go trace back to a primary reference material is not -- you can't just stop before you get there. That still needs to happen.

MR. NAGURNEY: I don't think I have anything further for the witness, Judge.

THE COURT: I would like to ask one clarifying question based on a question Mr. Nagurney had, and both attorneys can follow-up. Referring back to Defendant's N, the diagram that you --

THE WITNESS: Uh-huh.

THE COURT: -- had drawn up on the board and referring also to the rule that I believe you have in front of you -- it's Defendant's A -- Mr. Nagurney asked you a question about paragraph 1-3, the one that says, "Instrumentation must be capable of determining concentration of the person sampled with an accuracy of plus or minus ten percent."

THE WITNESS: Uh-huh.

THE COURT: Did I understand you to say that -- well, first of all, let's back up.

In describing your Defendant's N, you have what you call the uncertainty bars --

THE WITNESS: Uh-huh.

THE COURT: -- where the -- a test result is not an absolute because there's an uncertainty factor above and below?

THE WITNESS: Uh-huh.

THE COURT: And that can be -- they can be long bars or they can be short bars.

THE WITNESS: Yes.

THE COURT: And do I understand you to be -- did I understand you to answer Mr. Nagurney's question by saying that

the Rule number three means that the uncertainty -- the length of the uncertainty bar should be no more than ten percent up or down?

THE WITNESS: That's the way I would interpret it, that that's what they're essentially adopting as they want you to make sure that your measurement system is operating well enough that your -- you have a -- essentially a 20 percent spread in any given measurement. And then that's what you can compare to a threshold.

THE COURT: Okay. And --

THE WITNESS: So you've essentially decided whether it's a really small bar or a very big bar -- and I went through each of those -- that you're going to use to make your comparison to the threshold.

THE COURT: And you've used Exhibit R, the Cerilliant certificate as an example of a good analysis that has --

THE WITNESS: Yes.

THE COURT: -- uncertainty in traceability?

THE WITNESS: Yes.

THE COURT: Where does it say here what the percentage up and down would be? In other words, what would the --

THE WITNESS: I can show you that.

THE COURT: How would you know what the bars were?

THE WITNESS: If I may? Here --

THE COURT: You need to stand back in your --

THE WITNESS: Sorry.

THE COURT: You can hold it up. That's fine.

THE WITNESS: Okay. It's right here.

THE COURT: And can you hold it so the attorneys can see?

THE WITNESS: Yes. It's right there, concentration plus or minus. And it's also expressed at a concentration.

THE COURT: Okay. Where it says plus or minus 0.4, you're saying that is the uncertainty --

THE WITNESS: Yes.

THE COURT: -- determination for this --

THE WITNESS: That is correct.

THE COURT: -- particular item? And you're saying there isn't such a thing for the solutions used --

THE WITNESS: That's correct.

THE COURT: -- by the Vermont lab?

THE WITNESS: And as a result, there can be no such uncertainty determination for the breath alcohol results reported here.

THE COURT: So you're saying because of the way the Vermont lab has tested the machines, they would never know whether it's within the plus or minus ten percent?

THE WITNESS: That's correct.

THE COURT: Okay.

Any follow-up question?

MR. NAGURNEY: No, Your Honor.

THE COURT: Mr. Sleigh?

MR. SLEIGH: No. Thank you, Your Honor.

THE COURT: That completes your testimony. You can step down.

THE WITNESS: Thank you, ma'am.

THE COURT: You can leave that piece of paper.

THE WITNESS: Yeah.

THE COURT: Thank you.

I think this is a good time to take a break.

MR. NAGURNEY: Thank you.

THE BAILIFF: All rise.

(Recess at 2:58 p.m., recommencing at 3:23 p.m.)

THE COURT: Mr. Sleigh, that completes your evidence, correct?

MR. SLEIGH: It does, Your Honor. Thank you.

DEFENSE RESTS

THE COURT: Okay. Mr. Nagurney?

MR. NAGURNEY: Before I call any witnesses, I just -- Mr. Sleigh is here and I thought it might make sense to clarify on the record quickly that I just -- he had spoken to me earlier this morning saying, effectively, that we were going to conduct the hearing under the assumption that the State has filed its general chemist's affidavit about the acceptance of

the test by the instrument and that it's a valid test result and that the (indiscernible) will be controlled by the contents of the general chemist's affidavit and the DataMaster ticket that the chemist might review.

I understand we're here litigating the issue of the admissibility of the test vis-à-vis the regulations. I just wanted to make certain that Your Honor wasn't expecting to hear -- Mr. Sleigh wasn't expecting to contest whether the DataMaster tickets that were produced showing the test results for each Defendant's case contained any errors that he wanted to have addressed at the hearing. I understood this matter as being solely related to the legal academic issue, if you can call it that, of the admissibility of the test results vis-à-vis the issue of measurement uncertainty.

I have the DataMaster tickets for each Defendant available as exhibits. I just didn't know whether Mr. -- that was an issue Mr. Sleigh wanted to litigate or not.

MR. SLEIGH: I viewed this as a 104(A) hearing preliminary to any merits determination. So I don't think that'd be necessary.

MR. NAGURNEY: Okay. It'll save us some time then.

THE COURT: All right.

MR. NAGURNEY: So I can call Mr. Kimball from the Department of Health lab.

THE CLERK: Raise your right hand, please.

KIRK KIMBALL

called as a witness for the State, having been duly sworn, testified as follows:

THE CLERK: Thank you.

DIRECT EXAMINATION

BY MR. NAGURNEY:

Q Good afternoon. I'll ask you to state your name for the record, please.

A My name is Kirk Kimball.

Q And can you spell your name, please?

A K-i-r-k, K-i-m-b-a-l-l.

Q And Mr. Kimball, how are you employed?

A I am currently the organic chemistry program chief at the Vermont Department of Health Laboratory.

Q And how long have you been so-employed?

A With that title, for the last two years.

Q And prior to that?

A Prior to that, I was the chemistry -- or no, the toxicology program chief. The title changed a month after I took the job. And before that, I was a Chemist IV for the Vermont Department of Health Laboratory.

Q And how long have you been, in total, with the Vermont Department of Health?

A Since 2005.

Q And before --

A So that's seven years.

Q Okay. And before that?

A Before that, I was a carpenter for a couple years and a stay-at-home dad for approximately six. And before that, I was a chemist for an engineering firm in Wisconsin called RMT, Incorporated as an analytical chemist in the environmental field doing GC -- gas chromatograph mass spectrometry. And before that -- I started that job in 1990. For three years before that, I worked in Vermont for the Aquatec, an environmental lab that was part of the chemistry lab program, the CLP program for the U.S. EPA.

Q So do you have a degree?

A Yes, I do. I have two.

Q And describe those for me, please.

A I have a bachelor's of science in chemistry from Beloit College, Beloit, Wisconsin, and a masters in science -- of science in chemistry from the University Of Vermont, Burlington, Vermont.

Q And are you familiar with the DataMaster DMT breath testing instrument?

A Yes, I am.

Q How are you familiar?

A When I took over as program chief, I was put in charge of that program. I've took part in the revalidation of the instruments after new software was put on. I also have been to

NPAS for training and maintenance.

Q Tell the Court, please, who NPAS is.

A National Patent Analytical Services. They're the manufacturer of the DataMaster DMT.

Q And you're familiar with the DataMaster DMT from your period as program chief in the Department of Health?

A Yes.

Q And in 19 -- or excuse me, in March 1st of 2012, the program was transferred to the Department of Public Safety?

A Yes, it was.

Q So were you involved with the decision to purchase, I guess, or to implement the DataMaster DMT as an evidentiary tester?

A No.

Q Were you involved with the testing prior -- were you involved with the oversight of the testing of the instrument once it was purchased?

A Not the initial testing, no.

Q What involvement have you had with the DataMaster DMT program?

A When I took over, it was pretty much business as usual with the DataMaster. They were being deployed throughout the state, the new DataMaster DMTs. The protocols were established for the deployment at that time. Then in, I think, May of that year --

THE COURT: Which year?

THE WITNESS: 2011, I believe it was. It might -- yeah, I think it was 2011. Or let me think. It's been a while. It's been a year, so a year would be '12. I believe it was 2011 that we -- during the time from when I took over in 2010 in the fall to 2011 in the spring, we were discussing upgrading the software. And then some problems popped up in Royalton with an instrument that made us reexamine it. And it was determined that they needed to go back to NPAS to get the software upgrade. And at that time, we decided to have them recertified that they had not been tampered with and that they were still working within the manufacturer's specifications.

Q Okay. So let me ask you this then: all of the DataMasters involved in this challenge have been returned to NPAS for recertification?

A Yes, they have.

Q And you were familiar with the process and oversaw it?

A Yes, I did.

Q What does the manufacturer certification mean for the instrument?

A It meets the criteria that the manufacturer has set out for performance and stability. And it also, I believe, meets the National Highway Safety criteria for a breath analyzer with infrared technology.

Q And did there come a time when Mr. Sleigh in the fall

of 2012 asked you to produce a number of documents to him?

A Yes.

Q And can you tell me about that process, please?

A I received a call asking that I acquire the data that we produced for the GC solution characterization of the simulator solutions for the six instruments, which took a while to gather and get together the 1,800 pieces of documents, at which point we sent them to Mr. Sleigh.

Q Okay. So you're the custodian -- you're -- currently, the Department of Health is still the custodian of those GC documents? And those are --

A Yes, we are.

Q Are those gas chromatograph documents?

A Yes, they are.

Q Tell me what those gas chromatograph documents -- tell me why the Department kept them and what purpose they were created for.

A That is a tracking of the certification of those solutions that are used -- that were used to test the DataMaster DMT in house to make sure they met the rules and regulations set forth by the Department of Health and the other one solution that is used in the field to make sure that the instruments are still operating within parameters.

Q And is that solution used in the field also known as simulator solution?

THE COURT: I'm sorry?

BY MR. NAGURNEY:

Q What's the more formal name of the solution also used within the field?

A It is a simulator solution of .1.

Q So you were present in the courtroom this morning?

A Yes, I was.

Q And did you hear the testimony of Ms. Arvizu, the Defendant's expert witness?

A Most of it.

Q And did you have occasion to hear her testimony regarding the gas chromatograph documents that you disclosed to Mr. Sleigh?

A Yes.

Q The documents that you disclosed to Mr. Sleigh regarding the gas chromatograph, did they include any procedural -- standard laboratory operating procedures?

A No, they did not. I wasn't asked for those.

Q Does the Department Of Health in fact have standard operating procedures for its laboratory?

A Yes, we do.

Q And describe the areas that are controlled by those standard operating procedures.

A Every area of testing has their -- depending on the specific method, there is a standard operating procedure for

that specific method. Also, there is a quality systems manual that is the overriding guiding principle for the laboratory that we need to have for the accreditations that we have.

Q And did Ms. Arvizu ask to see your quality systems manual?

A No.

Q So are there procedures specifically related to the testing of the DataMaster DMT instrument?

A Yes, there are.

Q And does the quality control manual speak to any of those procedures?

A Not directly that I'm aware of. It speaks to the general processes in the lab for --

Q Oh, I see. So the manual -- the quality control manual is further to your ASCLD legacy certification?

A No. We're not ASCLD at all. We have certification from NELAC, which is a Northeast Laboratory Accreditation Program for environmental, and CLIA certification for our toxicology and microbiology.

Q Okay. And that's what the manual speaks to?

A Yep.

Q Okay.

A And -- yeah. And also, just general good practices without -- throughout the lab. Whether you have -- under our -- whether you're under the CLIA or the NELAC, you're still

required to follow the practices in the QSM.

Q Uh-huh. So Ms. Arvizu spoke about the creation in the laboratory of gravimetric creation of reference solutions.

A Uh-huh.

Q Are you familiar with that term?

A Yeah.

Q What does that involve?

A That involves taking a known standard at a specific purity and weighing it out to a specific decimal place to come up with a solution that you want.

Q What do you use to weight it with?

A A Mettler balance.

Q How many balances are in your laboratory?

A There's two, one for the organic section and one for the inorganic.

Q And are records maintained for those balances?

A Yeah. They're recertified yearly by QC Services.

Q How about a volumetric creation of reference solution?

A Depending on the volume we're preparing -- at the time we prepared both two-liter and five-liter and also a 20-liter. And we used Class A volumetric flasks.

Q And the laboratory in fact has that equipment?

A Yes, we do.

Q And has Ms. Arvizu received any documentation relating to that equipment?

A No.

Q What's Parafilm?

A It's wax paper that's very malleable. It's non-permeable to gasses.

Q When the Department Of Health Laboratory had oversight of the alcohol breath testing program, did it use Parafilm?

A Yes, we did.

Q How did it use Parafilm?

A It was used when we parsed out our solutions from the volumetric flask into the bottles. The bottles were then screw-capped and then Parafilm the top to keep any outside interference from getting in.

Q So Mr. Sleigh in his exhibits -- I believe it was Exhibit S -- included a simulator solution preparation log.

A Uh-huh.

Q Are you familiar with that document?

A Yes, I am.

Q What was the purpose of that document when the laboratory created it?

A It was to have traceability of the standards back to a lot so that we could follow the preparation and make sure it was made correctly.

Q But the simulator solution preparation log does not contain any notations regarding uncertainty on its face?

A No, it does not.

THE COURT: Regarding what?

MR. NAGURNEY: Measurement uncertainty.

THE WITNESS: No, it does not.

BY MR. NAGURNEY:

Q As you understand simulator solution preparation logs, though, is that information that's typically included on the face of a simulator solution preparation log?

A No.

Q Where is that information typically found?

A The traceability or the percent uncertainty?

Q The uncertainty information.

A We have not determined uncertainties. The way the solution is used, it was determined that it was not needed. The standards we make up for the GC are gravimetric from a -- what's considered a pure standard, which we have certificates of analysis for.

Q And sorry to interrupt you --

A Uh-huh.

Q -- but by standard, are you saying a reference solution?

A It is not a solution. It's a pure -- like the ethanol that we purchase is 200 proof certified. You have to have a license to get it, to be able to purchase it because it's pure alcohol. That's considered -- is a hundred percent alcohol -- ethanol.

Q Uh-huh.

A That solution is weighed out to prep the -- all our ethanol solutions. You have to buy liter -- a case of liter bottles. And that lasts a real long time. I think the whole last seven years of the program, that we're two lots, and one was purchased at the end of the program before it was transferred. So that lot was a specific lot for six years. There was no expiration date that I'm aware of on the bottles. It was recertified every year by the manufacturer -- or by -- every couple of years by the manufacturer. They put out for that particular lot, so they did the stability studies.

Q Okay. I want to make certain I get absolutely sure what process in the laboratory the records you provided to Mr. Sleigh demonstrate. And am I correct in understanding that you made gravimetric or volumetric solutions?

A Yes.

Q That you kept records regarding the traceability of those solutions?

A Yes.

Q That while not necessarily on the face of the simulator solution preparation log were available?

A Can you repeat that?

Q Certainly. The traceability information for the components of those simulator solutions, while not reflected directly on the face of the simulator solution log we saw as

Exhibit S, were available to -- were kept and available in the lab?

A Yes.

Q And those documents were not reviewed by Janine, I presume?

A I don't know if she reviewed them or not.

Q And tell me again the gas chromatograph, what -- how that bookends the process.

A In science, to determine a value, an instrument is calibrated, as Ms. Arvizu said, with known standards of a specific concentration to describe a linear or quadratic line that you can then -- given a response by the instrument, you can then extrapolate back to a specific concentration. So the simulator solutions, when we made them up either gravimetrically or volumetrically to a specific target concentration of say .01, that target concentration was just that; it was a target. It was not an absolute concentration.

The GC with that -- with our calibration, we determine through -- I think it was 28 specific runs, analyzing 28 aliquots of that solution by two -- at least two analysts over two different days to determine the concentration, the average concentration of those 28 runs. So that a solution that we tried to make up at .1 gravimetrically or volumetrically may come out on the GC as a .101 solution.

So the number that we target is not necessarily the

true value we assign to the solution. And that's why the certification paperwork is made, so that that number that we determined from the GC is the number that gets put on the solution, and that's the number that you use to determine whether it meets the rules and regs for plus or minus the five -- three percent in house, five percent out of house.

Q Okay. So you just talked about --

THE COURT: I'm sorry. Which number do you put on it?

THE WITNESS: The number determined from the GC data.

THE COURT: The average concentration of --

THE WITNESS: It's an average of 28 runs. And those runs need to be within three standard deviations. Each of those runs needs to be within three standard deviations of the average.

THE COURT: Okay. But then you put the average number on all of them?

THE WITNESS: On the solution --

THE COURT: Of all --

THE WITNESS: On that particular bottle.

THE COURT: On every bottle of solution?

THE WITNESS: Every bottle of solution that came from that preparation.

BY MR. NAGURNEY:

Q And you talked about an in-house and out-of-house

standard. And I'll ask you if you could explain what you meant by that.

A Our in-house standards were strict. It was three percent of the certified value of the solution. So if it was .1 when we ran it on the DMT for the pre-redeployment testing, it needed to be between .97 and 103 to be able to consider it to be a good run and to be acceptable data from that instrument. In the field, at an agency, a police agency, for the instrument to be considered still within specs, as in it's running properly, it was plus or minus five percent. So it was 95 to 105.

Q So is it fair to say that the Department of Health tested to tighter tolerances than the regulations required?

A Yes.

MR. NAGURNEY: I don't have anything further for the witness, Your Honor.

THE COURT: Mr. Sleigh?

MR. SLEIGH: Your Honor, may I have just a moment to consult with my expert?

THE COURT: All right.

(Counsel confer)

THE COURT: We'll take a break so you can stand up and stretch.

THE BAILIFF: All rise.

(Recess at 3:46 p.m., recommencing at 3:50 p.m.)

THE BAILIFF: All rise.

THE COURT: Please be seated.

CROSS-EXAMINATION

BY MR. SLEIGH:

Q Good afternoon, Mr. Kimball. How are you?

A Good.

Q Now as I understand it, at some point during your tenure in supervising the breath alcohol program, the devices were sent back to Ohio to get recertified in advance of deployment; is that right?

A They were sent back for software upgrade. And we asked them at that time to also make sure that they were operating within their manufacturer specifications.

Q All right. You said that there was some problems that popped up in one of the machines in Royalton?

A A tolerance was turned off. The system's flag for it being out of spec was disabled during -- because the instrument was used for training. And that was not returned -- turned back on before it was deployed in the field.

Q And how long did it stay in that state in the field?

MR. NAGURNEY: Judge --

THE WITNESS: I don't remember.

MR. NAGURNEY: If I may just quickly for the record? I understand this was covered in Mr. Kimball's direct. But I think absent a showing that any of the instruments here were

affected in the same way, I'm not sure how it's relevant to what you're ultimately being asked to determine by Mr. Sleigh's motion.

MR. SLEIGH: He's the one who brought it up. I'm just trying to explore it a little bit.

THE COURT: Uh-huh. Yeah. Since you raised it on direct, he's entitled to cross-examine on it.

BY MR. SLEIGH:

Q So how long do the machines -- was that machine in service with the tolerance check turned off?

A I do not remember exactly. I think it was a couple months.

Q Uh-huh. And how did you find out about that?

A It was brought to my attention I think by Amanda.

Q Okay.

A It might have been through Stuart Shure (phonetic) also.

Q All right. Do you know that it was actually me who told the Department about that?

A No, I don't remember that.

Q Okay. Now, I take it because you used the word that you're familiar with the concept of traceability?

A Yes, I am.

Q All right. Now, let's get this straight. The Department of Health breath alcohol program was never

accredited by any outside agency; is that right?

A Correct.

Q Never inspected by any outside agency?

A Correct.

Q Never audited by any outside agency?

A Correct.

Q So did you adhere to generally accepted notions of traceability or did you make it up on your own?

A I adhered to general practices.

Q Well, whose general practices: yours, the Department's, ASCLD/LAB, ISO 1725?

A Well, it was the lab's general practices and my experiences as a chemist.

Q All right. At no time during the administration of the breath alcohol program did the Department Of Health comply with ISO 1725 standards, did it?

A As far as I know, I -- during my tenure, no, not to the whole statute.

Q All right. Now, were you aware of ISO 1725 standards during the time that you administered the breath alcohol program?

A I was aware of the existence of it, not the particulars, no.

Q Okay. Now, is it your understanding that traceability requires contemporaneous documentation of testing?

A Yes.

Q Now, you saw Ms. Arvizu go through the list of your GC results; is that right?

A Correct.

Q Did you see any references in those results contemporaneously made by the analysts about the either volumetric or gravimetric devices that were used to produce those samples?

A Not in those particular documents. But we only have one scale that we used ever.

Q So it --

A It is in our SOP to use that particular scale.

Q But, so no analyst wrote down which scale they were using; is that right?

A No. It was in a locked room where the standards were prepared.

Q All right. So you would agree with her that there were at least some aspects of a full contemporaneous record that are missing from those GC records? You'd have to go look someplace else to see where those records are?

A According to what she said about ISO, those are missing, yes.

Q All right.

A But according to our other criteria, no, they're not.

Q Okay. They exist in separate places. You've got two

sets of books, basically?

A No. I said according to --

Q Well --

A -- according to ISO, we did not follow -- we were not under the auspices of an ISO-accredited program, so we did not document according to ISO.

Q Okay. When you created the GC solution that -- and tell me -- I may have got this wrong. But you used a outside obtained ethanol sample, pure ethanol?

A Yes, we did.

Q All right.

A Purchased from Pharmco.

Q Okay. Do you remember being asked in November of this year as to whether you had any documents readily available pertaining to the strength of the ethanol used to make the simulator solutions?

A Pertaining to the strength?

Q Let me show you, if I may, Exhibit I. Just read that to yourself.

A Uh-huh.

(Witness reviews document)

THE WITNESS: At that time, no.

BY MR. NAGURNEY:

Q Well, let's just --

A I mean -- yeah.

Q -- back up a little.

A Yeah. I remember that now. And we did not. I had to call the manufacturer to get that documentation.

Q So the lab --

A Which I did provide to Mr. Nagurney.

Q -- the lab didn't have any documentation regarding the strength of the ethanol used in those GC runs in the lab, right?

A That I could not -- I could not find one, yes.

Q So you got one and sent it to Mr. Nagurney sometime in December?

A I think when he came to copy, that's when I had gotten it. It was not an easy process to obtain. But it was obtained.

Q So at least up until December of this year, you couldn't trace your GC run back to its mother source, could you?

A That's not correct. The bottle has a lot number on it, a manufacturer that can be traced. It was not an easy trace, no, but it can be traced.

MR. SLEIGH: Your Honor, we'd move the admission of Defendant's I as a prior inconsistent statement.

MR. NAGURNEY: Judge, I have no objection to the authenticity of the document.

THE COURT: Defendant's I is admitted.

(Defendant's Exhibit I received)

MR. SLEIGH: Thank you.

BY MR. SLEIGH:

Q I believe you said to Mr. Nagurney that the lab used Parafilm to cover the various containers in which solution samples were parsed out; is that right?

A Correct.

Q Did the lab ever perform stability studies to test the deterioration or alteration of the samples content over time when sealed with Parafilm?

A Not that I'm aware of but it's possible.

Q Have you ever read Rod Gullberg's article regarding uncertainty in measurements in forensic breath testing?

A No.

Q Under your tenure did the lab attempt at all to establish uncertainty measurements in the generation of simulator solution, the calibration of the DMTs or the GCUs to generate the simulator solutions?

A We do generate or did generate the standard deviation of solutions from the average, which is --

Q Is it your testimony --

A -- which is a slight measurement of uncertainty that what some are based on.

Q You have advanced degrees in chemistry; right?

A Yes, I do.

Q You understand the general concept of uncertainty measurements?

A Yes, I do.

Q You understand the ISO definition of uncertainty measurement?

A Yes, I do.

Q Did the Department of Health ever undertake an attempt to quantify uncertainty measurement in the breath alcohol program of the State of Vermont?

A No.

MR. SLEIGH: No further questions.

REDIRECT EXAMINATION

BY MR. NAGURNEY:

Q Mr. Kimball, with respect to Exhibit I you mentioned to the -- to Mr. Sleigh that there was a lot number that you used to trace and I wanted you to explain that more fully please.

A The lot number is specific that the manufacturer assigns to a specific quantity of solution that's produced at one time and tested. Each bottle, if it's 1,000 liters and it is parsed out into 1-liter bottles, each one of those bottles will have that lot number on it so that it can be traced back to their analytical protocol that determine the concentration.

Q And Mr. Sleigh asked you a number of questions about various certification and the accreditations for the Department of Health laboratory. Are those required by any statute or

regulation that the laboratory would assign it by the State of Vermont?

A Not that I'm aware of.

Q The same question with respect to measurement uncertainty. You said you calculated standard deviations but you just didn't calculate them any amount of uncertainty. Explain why.

A It wasn't required. When I took over the program it had been accepted practice for I think two decades that that was not a needed entity because the rules and regs did not directly address uncertainty. It was assigned that it needed to meet 10 percent; that a value assigned needed to be within plus or minus 10 percent.

MR. NAGURNEY: Nothing further, Your Honor. Thank you.

MR. SLEIGH: Just one follow-up.

THE COURT: All right.

RECROSS-EXAMINATION

BY MR. SLEIGH:

Q You understand that the rules generated pursuant to the statute require that the DataMaster meet certain precision and accuracy criteria; is that right?

A Correct.

Q In your view did the Health Department have a duty to determine whether the machines met those criteria using

minimal -- minimum scientific standards?

A Yes.

MR. SLEIGH: Thank you.

THE COURT: Anything further?

MR. NAGURNEY: Nothing further.

THE COURT: That completes your testimony. You may step down. Thank you.

Mr. Nagurney?

MR. NAGURNEY: Amanda Bolduc, Your Honor.

Judge, it's worth mentioning that I expect this is going to go longer than the probably 25 minutes the Court has left in its day.

THE COURT: Okay. Well, we might as well get started.

MR. NAGURNEY: Sure.

AMANDA BULDOC

called as a witness for the State, having been duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. NAGURNEY:

Q Good afternoon, Ms. Bolduc. How are you?

A Good.

Q I'll ask if you will state your name for the record please.

A Amanda Bolduc, B-O-L-D-U-C.

Q And, Ms. Bolduc, how are you employed?

A I'm a forensic chemist for the Vermont Forensic Lab.

Q And where were you employed prior to that?

A The Vermont Department of Health Lab.

Q And how long have you been employed -- how long were you employed with the Department of Health Lab?

A I began there in 2005.

Q And what's your background and your training?

A I have a bachelor's degree in biology from the University of Vermont and a master's in forensic science from National University in San Diego. I also received additional training from Indiana University specifically on alcohol testing.

Q And when you started at the Department of Health in 2005 were you -- did you begin to work with the DataMaster?

A I did.

Q And are you familiar with the DataMaster DMT?

A I am.

Q Can you explain to the Court briefly how you're familiar with the DataMaster DMT?

A When I began work at the Department of Health in 2005 we started looking at the four different manufacturers that were available for breath testing instruments and it was part of my job as a team to work with the other analysts and determine which of those four manufacturers would have an

instrument that would be suitable for the lab to purchase. In 2006 we decided that the DataMaster DMT would be the instrument that we purchased and then it became my position as the lead analyst for the breath program to actually test the DataMaster DMTs and to work with the other analysts to make sure that all of the testing was sufficient before the instruments were deployed in 2008.

Q Okay. And relative to that testing is that what we saw today as Exhibit P? That was the volumes of pre -- or deployment testing performed on each of the specific DataMaster instruments.

A There was two sets of deployment testing. There was the first round for 2008, '9, and '10 on the instruments before they went in the field the first time after the instruments went back to Ohio where they had their new software installed and they were just recertified by the manufacturer. When they came back to Vermont they were redeployed and at that point before redeployment they went through another barrage of testing.

Q Okay. And tell me about this testing that you did.

A We did accuracy and precision checks, looking at four different levels of ethanol targeting -- to make sure that the instrument could see the ethanol at these different target values, that the instruments were linear so that they weren't biased one direction or the other at either the high end or the

low end.

We did interferent testing to ensure that the instruments were targeting specifically for ethanol and not any other chemical. We tested to make sure that the -- the alcohol profile that the instrument reported was appropriate. So, if there was a negative slope the instrument would identify that properly and would abort the test. We tested to make sure that the instrument identified radio frequency appropriately and would abort a test. We tested the software in the instrument to make sure that the user interface was how we designed it to be.

Q So, let's talk about accuracy and precision testing.

A Sure.

Q And the point of the testing was to see whether the instrument -- that being the DataMaster DMT -- was compliant with the DOH, now Department of Public Safety, regulations; correct?

A Yes.

Q So, tell me about the testing that the Department of Health did or that you did at Department of Health to ensure that the DataMaster DMT instruments met the regulation regarding precision.

A We looked at four different concentrations and actually on some of the instruments even five concentrations of alcohol over a range of .02 all the way up to .40 and we analyzed the

instrument 10 times for each repetition so you would look at each of the four concentrations; 02, 08, 16, and 40. Each of those solutions would be analyzed 10 times for all four solutions and that would be considered one set of linearity data. That was done on some of the instruments as many as 10 times.

On some of the instruments we saw that they were quite linear and that their accuracy was so good that we just decided that five linearity tests was sufficient on the later batches of instruments.

MR. NAGURNEY: Okay. And I should catch myself here and make sure for the record.

Your Honor, I will be offering Ms. Bolduc as an expert in the DataMaster DMT instrument.

THE COURT: Mr. Sleigh?

MR. SLEIGH: No objection.

BY MR. NAGURNEY:

Q And if you could tell --

THE COURT: She is so qualified.

MR. NAGURNEY: Thank you, Your Honor.

BY MR. NAGURNEY:

Q If you could tell Her Honor briefly how many times you've testified in your capacity as an expert on the DataMaster DMT?

A Over 1,000.

Q So, before I interrupted you I was asking you about the various testing and you had stated you tested in 02 and 08 of 16 and several other levels.

A Yes.

Q When you talk about these 02, 08, 16 and other levels what -- are those the reference solutions that Ms. Arvizu was referring to?

A Yes.

Q And tell me how often each reference solution was tested.

A Each one -- when you had an 02 solution you would analyze that 10 times and that would be one accuracy and precision check. You would then go on to the next higher concentration and once you've had all four that would be considered one linearity. Each instrument had to do at least five linearity sets and that -- that was then done on every single instrument.

The solutions themselves were characterized by GC, so they were analyzed 28 times before we assigned a target value and it as that target value that we then analyzed the DataMaster against.

Q Okay. So, you characterized the reference solution on each --

THE COURT: I'm sorry. That was --

MR. NAGURNEY: Sure.

THE COURT: -- a little fast.

THE WITNESS: Sorry.

THE COURT: Go through that again please.

THE WITNESS: Sure. You would make the solution. We would make a batch of simulator solution at a target concentration; for example, .02. It would be analyzed 28 times on the GC. So, over two different days over at least two different analysts each one would have to prepare seven replicates and that would be analyzed on two different calibrations.

So, you would have a total of 28 aliquots of that solution. You would analyze that by GC and the average of all of those would then give you the target value of the solution. That solution would then be analyzed by the DataMaster.

BY MR. NAGURNEY:

Q So, when you say that you were making these solutions, these reference solutions that you were then verifying on the gas chromatograph, explain the process of actually making them.

A The solutions would be made either in one, two, or five-liter batches as far as the linearity solutions, the 02, 08, 16, and 40. So we would make a container of it. It would be in a five-liter, one-liter, or two-liter batch. It would be Class A volumetric glassware. Sometimes we would estimate the concentration volumetrically.

So, you would measure using pipettes and add the

alcohol volumetrically and then analyze it by GC.

Sometimes we would weigh the ethanol and determine how much to add based on weight, so gravimetrically. But the eventual target concentration was based on the GC result, not on the estimated amount of alcohol that was added in the beginning.

Q So, if I'm understanding you correctly, I want to make sure that I am, the gas chromatograph value was what was used to verify that the reference solution was what you were testing it at?

MR. SLEIGH: Objection, Your Honor. I don't think that's what she said.

THE COURT: Could you rephrase the question?

MR. NAGURNEY: Sure.

BY MR. NAGURNEY:

Q You used the gas chromatograph test to be certain that you had created the proper volumetric or gravimetric concentration ethanol solution?

A We use the GC to determine what concentration it was that we had made. We would estimate our target either volumetrically or gravimetrically but we based the target value on the GC result.

Q So, why did you use the gas chromatograph?

A It's pretty much the gold standard for alcohol testing. That's how we test all the blood results. We have put in place

our quality control checks so we have a lot of faith in the results that come out of the instrument; especially when you analyze it 28 times it gives you a very high level of certainty when you calculate your results.

Q Okay. Tell me about the quality control checks that are in place on the gas chromatograph.

A The instrument is calibrated prior to use. we run an external quality control sample with that. So, we would get a sample from a reference lab that would be certified. It would come with a certificate of analysis. So, we would analyze that quality control check at the time of --

THE COURT: I'm sorry. Slow down again. I'm not quite sure what you're talking about.

THE WITNESS: When you run the GC you run a whole bunch of samples. So, the auto sampler, it would hold about 60 samples. So, the first set of samples on there is your calibration. So, we would calibrate the instrument, show it different concentrations of ethanol and tell it what those different levels are and then look at the response at those levels to determine the performance of the instrument.

We would get an external quality control sample from a vendor that would come certified to the lab where we would analyze that quality control check against our calibration to make sure that the instrument was performing appropriately. We would also run CCS samples or continuing check standards. So,

these are samples that are made in the lab but they're just an ongoing quality control check. Every 10 samples you analyze the CCS to make sure that your instrument is still functioning properly throughout the run.

The blood alcohol programs of the GC instrument is -- actually there are PT samples that come in -- proficiency samples that come in that we analyze and the instrument has to pass. Every analyst in the lab has to run at least one proficiency a year on the GC.

That way we know that our lab as a whole -- that instrument is working properly. So, this -- these quality control checks ensure that our GC was meeting all of these appropriate standards.

BY MR. NAGURNEY:

Q And you were here when Mr. Sleigh introduced Exhibit Q? That was the docu -- that was the information he obtained from Mr. Kimball from the Department of Health lab about the gas chromatograph.

A Okay.

Q And then after Exhibit Q we did, I believe it was R and S, and those were the certificate of analysis and then some of the solution preparation logs for the gas chromatograph?

A Yes.

Q Do the documents taken from Exhibit Q that are found in Exhibits R and S reflect the total universe, for lack of a

better word, of data available about the quality control measures your -- the Department of Health laboratory took with the gas chromatograph?

A No.

Q What's missing from those?

A The PT result data from our blood alcohol PTs. The --

Q And does the lab keep that?

A Yes, it does. The balance information. Our balance is calibrated every year. The pipettes are calibrated every year.

Q Did you hear Ms. Arvizu's concern about your pipe -- the pipettes the laboratory used?

A Yes.

Q And is she correct in that concern?

A No. Our pipettes are just -- are used appropriately and they are maintained appropriately.

Q And how -- what's the appropriate use and maintenance for the instrument?

A Ours are calibrated annually by a certified pipette calibration company.

Q And was that documentation kept by the laboratory?

A Yes.

Q But was it included in Exhibit Q?

A No.

Q And did Ms. Arvizu request it?

A I don't know.

Q So, you mentioned the balances. How many balances are in the organic chemistry run?

A One.

Q And Mr. Kimball that that balance was reviewed annually?

A Yes.

Q And records were kept?

A Yes.

Q So, he's correct in those statements?

A Yes.

Q So, I'm sorry, I keep interrupting your breakdown. What you're saying is that you were -- essentially I believe there was a point where you were saying the quality control processes the laboratory kept in place on the gas chromatograph?

A Yes.

Q And the gas chromatograph was used to establish a variable -- excuse me -- a value for the reference solutions in the DataMaster DMT?

A Yes.

Q And then, so I've covered precision testing and you've talked about a linearity curve. And I wanted to actually -- if you're okay with me taking this --

MR. SLEIGH: Yeah. Sure.

MR. NAGURNEY: It's part of Exhibit B.

BY MR. NAGURNEY:

Q So, Ms. Bolduc --

MR. NAGURNEY: If I may approach the witness, Your Honor?

THE COURT: Yes.

BY MR. NAGURNEY:

Q I will give you a -- this document I'll represent to you as part of Exhibit P and it's the deployment testing, for I believe it's Instrument 104009.

A Yes.

Q And ask you to open that document and if you can just illustrate for the Court where the portion of the testing dealing with the precision is contained in that test report.

A Both the accuracy and the precision, there is a spreadsheet on -- I think it's like the fifth page in here that shows the linearity testing which documents the accuracy and precision of the instrument

Q And was it the practice of the lab to write any information regarding traceability on the face of the testing documents?

A No.

Q How was that information typically accumulated?

A In this particular format when we did the deployment packages, for the redeployment packages we started implementing a spreadsheet which would document when the testing was done

and who did it and the dates. There are log sheets that will correspond with the particular lot numbers of simulator solutions on those dates, which instruments they were run on.

If you go to the specific accuracy and precision report that would have been printed by the DataMaster it will tell you which lot number of solution was analyzed and the target concentration and who was performing the analysis.

Q So each testing volume for each DataMaster instrument contains that information?

A Yes.

Q So, I'll ask you the same question again with respect to the accuracy regulation. How did the Department of Health laboratory when you were there test for the accuracy regulation?

A We would run accuracy and precision checks on each instrument. At the time of calibration the instrument was held to a 3 percent margin of error or 3 percent accuracy. So, we would analyze -- or we would calibrate the instrument and then run a calibration check, which is an accuracy and precision check using a .1 concentration of ethanol. It had to read that target concentration within plus or minus 3 percent. So, it was held to a 3 percent accuracy at the time of calibration.

We would then run a certification on the instrument where we would look at a whole range of concentrations from .02 as high as a .40 and ensure that the instrument could see

within plus or minus 10 percent at each one of those concentrations. And, in fact, we held it to plus or minus 5 percent at everything at a .08 or above.

Q So is that what Mr. Kimball was talking about when he spoke about the difference between the in-house and out-of-house standards?

MR. SLEIGH: I'd object as to her opinion of what it was Kimball was saying.

BY MR. NAGURNEY:

Q Well, you heard Mr. Kimball's testimony?

A Uh-huh.

Q And did he correctly say that the Department of Health held the instrument to a higher standard for its internal testing --

A Yes.

Q -- than was required by the regulations?

A yes.

Q Each instrument is tested for accuracy?

A Yes.

Q So, Ms. Arvizu testified that she had concerns that the storage of the reference solutions that your laboratory created may have been inadequate. Tell the Court how you stored those reference solutions.

A Once a simulator solution is prepared it would be transferred to a 500-millileter Nalgene bottle with a screw top

that was then sealed with Parafilm. We assign them a one-year expiration date. We actually had talked about possibly doing two-year because there was a study that we had looked at that Debowski (phonetic) had done where they had actually taken 26-year-old simulator solution that had been sealed in a bottle and they analyzed it and depending on the concentration, some of the higher concentrations had degradation, but anything around the .1 level, which is what most of our solutions were at, didn't show significant degradation after 26 years.

So, we chose one year just so that we could, you know, have a regular turnover of our simulator solutions. But one year in a sealed bottle there is no degradation.

Q And what's Parafilm?

A Parafilm is just like a waxy tape that we would use to seal the bottle shut.

MR. NAGURNEY: If I may approach to have an exhibit marked, Your Honor?

THE COURT: Yes.

MR. SLEIGH: Thank you.

BY MR. NAGURNEY:

Q Ms. Bolduc, I'll show you what the Court has marked for identification as State's Exhibit 1 and I'll ask you if you recognize that document?

A I do.

Q Who prepared that document?

A This was prepared by a chemist for the forensic lab and there was also some information that I had put on here as well.

Q And you've reviewed the contents of the document?

A I have.

Q And does the document fairly and accurately depict the information it contains?

A Yes.

Q And why did you compile that document with the assistance of your colleague?

A This document was put together just for ease of finding lot numbers. So, it shows which instrument, the instrument number, and which lot numbers of solution were analyzed on that instrument.

Q And the document contains a number of columns on it; is that correct?

A Yes.

Q And is there a column for each DataMaster instrument?

A Yes.

Q And then below the list of DataMaster instrument numbers we'll see a series of three-digit -- excuse me -- six-digit numbers; for example, 11-37-100, and then the calibration linearity, and a bunch of -- are those lot numbers that are listed?

A Yes.

Q And does that document illustrate that each DataMaster

instrument was tested with all those various lots?

A Yes.

Q Okay. Now let me ask you, for each of those various lots of reference materials that were used to test each DataMaster instrument, which quality control checks did you perform?

A For the lot of the solution?

Q Uh-huh.

A It would depend on the situation. For some of the instruments I would have done everything from preparing the solution right up to testing the instrument. Solutions were made by other analysts, instruments were analyzed by other analysts but I would have done some of --

Q All right.

A -- some of these.

Q So, you had standard operating procedures in place at the Department of Health lab?

A Yes.

Q And you are familiar with them?

A I am.

Q And they affected and controlled the preparation of those referenced -- the lot numbers of reference material that were used for testing?

A Yes.

Q So, every single lot number on that exhibit, State's 1,

is in fact something that was tested according to standard procedure by the lab?

A Yes.

MR. NAGURNEY: I'd offer State's Exhibit 1, Your Honor, if I haven't already.

MR. SLEIGH: No objection; understanding it's a summary I guess.

MR. NAGURNEY: Yeah. I guess, Your Honor, my intention was to summarize that in all of Exhibit P, which is, you know, each -- the pre-deployment testing for each instrument, those various lot numbers from the Department of Health laboratory were used in the testing. But it's a link between Exhibit P and Q.

THE COURT: All right.

MR. NAGURNEY: Although, Your Honor, if I may just -- with Mr. Sleigh, if you'll confirm as much, when Mr. Sleigh initially retrieved the documents that were Exhibit Q from Mr. Kimball I don't think we had aggregated all of the cases into this hearing that are now in it.

So Exhibit Q is really only -- I think he'll agree, is really only somewhat illustrative of the lot numbers that were tested because he -- in November when he retrieved the documents to Exhibit Q he didn't have the benefit of knowing that additional lot numbers involving additional instruments were still out there.

So, if that makes sense?

THE COURT: Do you agree with that?

MR. SLEIGH: I do.

THE COURT: Okay. State's 1 is admitted.

(State's Exhibit 1 received)

THE COURT: This might be a good breaking point. I think everyone is going to have a lot of packing to do. So, we will continue tomorrow.

And, just, can you give a general idea of what you expect as far as use of time?

MR. NAGURNEY: Your Honor, I have a few more questions for Ms. Bolduc just because she's really the institutional memory link between the Department of Health and the Department of Public Safety Program.

And then I'm going to call Ms. Conti who is the forensic toxicologist who is involved with the oversight of this program now that it's under DPS supervision. And I would expect her testimony will take not as much time as Ms. Arvizu's because Ms. Arvizu has sort of done some of the groundwork for the concepts we're talking about, but I would expect probably an hour of testimony from her tomorrow.

THE COURT: All right. And, Mr. Sleigh, do you have any projections?

MR. SLEIGH: Eight to twelve inches.

THE COURT: Okay. We'll continue tomorrow.

MR. SLEIGH: Thank you.

THE CLERK: All rise.

(Proceedings adjourned at 4:27 p.m., recommencing on February 2, 2013 at 9:00 a.m. in Volume II)

CERTIFICATION

I, Karen Samcoe, a court approved proofreader, do hereby certify that the forgoing is a correct transcript from the official electronic sound recording of the proceedings in the above-entitled matter, to the best of my professional skills and abilities.

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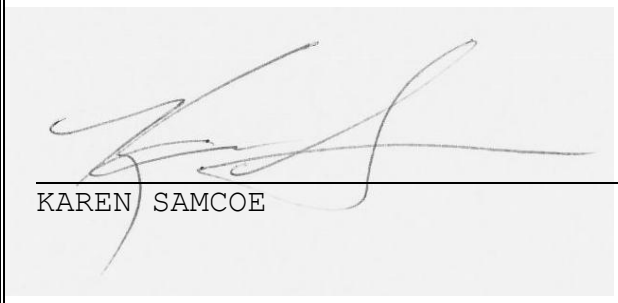

KAREN SAMCOE FEBRUARY 23, 2013