IN THE COUNTY COURT OF THE NINTH JUDICIAL CIRCUIT, IN AND FOR ORANGE COUNTY, FLORIDA TRAFFIC DIVISION

STATE OF FLORIDA,

Plaintiff,

vs.

ROBERT ATKINS, ET AL,,

Defendant.
_____/

VOLUME II OF II

CASE NUMBER: 48-2008-CT-673-E

DIVISION NUMBER: 82

EN BANC HEARING

BEFORE

THE HONORABLE WAYNE SHOEMAKER

Recorded by Digital Court Reporters
In the Orange County Courthouse
425 North Orange Avenue
Courtroom 4-C
Orlando, Florida 32801
Commencing at 4:27 p.m.
Friday, February 1, 2008, 2008
Transcribed by Diane S. Hebel

APPEARANCES:

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I N D E X

P R O C E E D I N G S

WHEREUPON: This is a continuation of the En Banc Hearing as contained in Volume I, and the proceedings were as follows:

THE COURT: How many more witnesses do you have today?

MR. HYMAN: We would call Janine Arvizu at this time.

MR. WOOTEN: Before she testifies, I asked Mr. Hyman's office which witnesses are actually being called -- they were actually going to call and they advised me of Dr. Rose, Dr. Hlastala and Dr. Myler.

I assume they can do the direct examination but I will probably will need an opportunity to prepare for cross-examination at some later point in time.

MR. HYMAN: She's on our witness list.

MR. WOOTEN: Okay. And I asked who you were calling and your office advised me of those three people.

MR. HYMAN: I never advised you of those three people. I don't know what you -- what you...

MR. WOOTEN: Your assistant, Vicky, e-mailed me specifically three names -- I think I have it laying around here -- these are the witnesses that you're calling.

MR. HYMAN: Well, she's been on our witness list since forever.

MR. WOOTEN: Okay.

THE COURT: Okay. Let's proceed.

* * * * *

WHEREUPON:

JANINE ARVIZU

having been called as a witness in this cause, was duly sworn, examined and testified as

follows:

DIRECT EXAMINATION

BY MR. HYMAN:

Q Would you tell us your name for the record, please?

A Janine, J-A-N-I-N-E; Arvizu, A-R-V-I-Z-U.

Q And what is your occupation?

A I'm a laboratory auditor, quality assurance consultant.

Q And what is -- what does a quality auditor and laboratory assurance person do?

A We essentially assist people who use laboratory results to make important decisions to understand how reliable and how valid those results are. And many decades of experience in the measurement community have demonstrated that the best way to consistently and reliably produce acceptable quality data is through a quality assurance program. So in the laboratory business or in the measurement testing business, quality assurance, that is putting in place quality control practices and quality assessment tools is how we ensure the reliable and consistent production of data that are of acceptable quality.

Q And what type of facilities, in your experience, have you been responsible for examining?

A I've audited labs primarily on behalf of federal agencies, so for the Department of Energy in the National Laboratory Complex and the Navy, both commercial and government laboratories throughout the country.

Q And what is your educational background?

A I have a Bachelor of Science Degree in Chemistry from Cal Poly State University in San Luis Obispo and ADD in chemistry from the University of New

Mexico, which is essentially of the course work and exams to be admitted to candidacy. But I went to work and did not complete my dissertation.

Q And what is -- what is your relevant employment history in this area?

A I -- when I left graduate school I went to work for an operating contractor for the National Laboratory Complex, Department of Energy. And I established and managed a full service analytical testing laboratory. And while I worked for the Department of Energy they were in the process of coming up to speed in the quality assurance field. And so I got involved in a lot of inner agency quality assurance initiatives involving the Department of Energy, Department of Defense, Environmental Protection Agency and establishing quality programs for testing laboratories across all the disciplines.

Q And do you know what a standard operating procedure is?

A Absolutely.

Q Okay. Can you tell us what a standard operating procedure is?

A A standard operating procedure is essentially one of the means through which we control science in a testing laboratory. Because what we're essentially asking a laboratory to do is to do science on a production scale. That's a hard thing to do.

The world is a multi-varied equations. There's a lot of things that change. And so a standard operating procedure is one of the ways of controlling the variables so you get a reliable consistent result out.

It's not like -- it's not like grandma's baking powder biscuits where she does it without measuring. It's somebody like me following a recipe absolutely explicitly. So it's very much like a scientific recipe. It defines all the parameters. It doesn't leave things to judgment, so that if you gave the same standard operating procedure to different analysts who were qualified analysts, they would execute that method in precisely the

same way and get comparable results.

In my experience as a laboratory auditor, if that level of control is not specified in a standard operating procedure, you do not get comparable results.

Q Now, what types of areas have you examined laboratories in, all different fields?

A Yes. The principles of quality assurance are essentially independent of the particular type of testing that is applied to John Taylor's book, which is Quality Assurance and Chemical Measurements. It's sort of one of the foundational texts on the subject. And you don't hear a lot of discussion about its specific application. Because the -- the principles of quality control practices identify and control your variables and quality assessment to -- to put in place a means of measuring how well your system is in control is largely independent. So I've done everything from toxicology, DNA, fingerprints, heavy metals analysis, pretty much the full suite of organic...

WHEREUPON: There was a malfunction in the audio recording from 4:33 p.m. to 4:34 p.m., after which the proceedings were as follows:

BY MR. HYMAN:

Q ...you, what I refer to as the FDLE rules pertaining to the breath testing.

A Yes. They started as -- I forget the acronym, some department of health kind of thing and then transitioned...

Q HRS.

A Yes. And then transitioned into FDLE, yes.

Q All right. And have you examined the 1989 HRS rules?

A Yes.

Q Have you examined the 1990 HRS rules?

A Yes.

Q Have you examined the 1993 FDLE rules?

A Yes.

Q Have you examined the 1997 FDLE rules?

A Yes.

Q Have you examined the 2001 FDLE rules?

A Yes.

Q Have you examined the 2002 FDLE rules?

A Yes.

Q And have you examined the 2004 FDLE rules?

A Yes.

Q Have you examined the 2006 FDLE rules?

A And it was just about as interesting as that, yes.

Q Okay. And in reviewing those particular rules, did you examine those rules in the manner that you would examine, for instance, a standard operating procedure?

A Yes. And it's my understanding that those essentially are the controlling rules, if you will, for the testing. And so that was very much my approach to an assessment of their ethicacy in ensuring consistent and reliable results.

Q All right. With regards to the -- and I'm kind of abbreviating this because of the time constraints, but did you notice a change that occurred in the rules over time from 1989 when HRS had it up until 2006 when FDLE just promulgated what would be their final version so far of the FDLE rules?

A Yes. It's quite striking.

Q Okay. And when you say it's quite striking, what do you mean by that?

A A lot of the technical rigor has been removed from the rules over the course of the revisions throughout the years. A lot of requirements that were in place early in the

program have not been altered or -- or modified, they've simply been removed in their entirety.

Q And comparing some of the earlier versions of the rules for FDLE, such as 2003, 2007, 2001 and 2002 with the current version of 2004 and 2006, has the scientific reliability of the rules increased or decreased?

A It has decreased.

Q And with regards to the 2006 version of the FDLE rules and looking at them, do you find them to be scientifically sufficient?

A Not for ensuring consistently that this program generates reliable and technically valid data.

Q Okay. Have you had occasion to be able to review the data that's on the FDLE website?

A Very limited, yes; because it's not exactly in a very user friendly format. It's not like it's in a database where you can do logical searches and string things together.

But I did take the opportunity to go through and just at random pull out -- one of the most important things that this program appears to rely on is that they assess on a regular basis every month instrument performance by having these guys they call agency inspectors conduct testing on -- on the instruments.

And since that represented the best or the most sort of concentrated source of quality control data, that is where I started pulling some data out of random to look at.

And there were, you know, probably, I don't know, a couple dozen links and the first link I pulled up had about 800 -- 700 or 800 pages in it, so I didn't attempt to do a rigorous analysis. But just in the first one that I pulled up, there were a very large number of very troubling indications that told me that this was a measurement system that was significantly and seriously out of control. And my basis for that conclusion is both

the discrete failures that were recognized in this case but also the fact that this essentially represented a best case for these instruments. Because these were not instruments being operated in the field by the people who would actually be conducting breath testing in an evidentiary -- or in a legal setting, but these were being tested -- the real instruments were being tested each month by individuals that have received extra special training, and they're called agency inspectors. So presumably that would represent a better case, a more controlled case, if you will, than operation in the field. Nevertheless given the number and nature of problems identified in that situation it was -- it was a very clear indication to me that this was a measurement system that was out of control.

Q All right. Let's -- let's start with FDLE Rule 11D-8.003, which -- do you recognize that? That's the approval...

A I recognize the number, yeah.

Q Right. That's the approval rule for the approval of breath-testing machines.

A Um-hum.

MR. WOOTEN: I'm sorry, which one did you ask about?

MR. HYMAN: 11D-8.003.

BY MR. HYMAN:

Q We should have in those boxes -- there should be a composite exhibit of all of the 11D-8.003, 11D-8.0035 and 11D-8.0036 that were in one composite exhibit, which would have been Exhibit 95.

(Pause)

It should be Exhibit 75.

(Pause)

It's Exhibit 75. It should be a composite exhibit of just FDLE Rule 11D-8.00 -- from all the years, from the beginning to the end, just to make it easier.

(Pause)

And the statute, that will be the forms that are made reference to.

(Pause)

I'm -- what I'm going to do is I'm going to call your attention first back to 1989, which would be 10D-42.022, which was the HRS rules.

A Um-hum.

Q In reviewing FDLE rule 11D -- I'm sorry, HRS rule 10D-42.022, there was a requirement for the manufacturer seeking approval to provide certain information; is that correct?

A That's correct.

Q Some of the information that the rule called for to be provided was an instrument model designation, a description of the instrument, the operator's manual. Would you -- if you're going to approve an instrument to determine whether it's scientifically reliable, how important is it to have the operator's manual?

A It's essential.

Q Why?

A Because it's not black book science. It really does matter, the operating specifics of the instrumentation, the conditions of the controls, the criteria that the manufacturer imposes under which it's been demonstrated to produce acceptable results.

Q When it comes to the area of blood testing, you're familiar with gas chromatographs?

A Yes.

Q When a gas chromatograph is provided to a laboratory, is there a manual that's usually provided with it?

A Yes, that would be a requirement.

Q And is it usually a very extensive manual?

A Quite. Typically it includes everything from how to set it up to how to qualify it. There's schematics. There's -- they can be -- depending on the complexity of a particular piece of instrumentation, it can be a whole shelf full of binders.

Q A whole shelf full of binders?

A Yes.

Q Okay. And that's for blood-alcohol testing?

A That's correct.

Q Okay. And with regards to going back to that rule, the maximum and minimum temperatures of which the instrument may be used and still provide an accurate answer, would that be important?

A It's essential. Temperature is a critical variable in any gas analysis.

Q And with regard...

MR. WOOTEN: Are we talking about gas chromatographs?

THE WITNESS: No. Any gas analysis. A gas is sample.

BY MR. HYMAN:

Q And if you're trying to determine the alcohol levels of individuals, would it be important to do blood-breath correlations?

A Absolutely.

Q And...

A In fact, it was early on in the program.

Q They required for the approval of an instrument blood-breath correlations?

A That's correct. That -- that requirement was subsequently just omitted.

Q But -- we're going to get to that.

In the 1990 version of the HRS rules, which was the subsequent version of

it, they still required those types of items; is that correct?

A You know what -- I don't remember the specific years that the things came out and left.

Q Okay. Well...

A But I know it did leave.

Q All right. With respect to the FDLE rules, did the FDLE rules subsequently do away with the blood-breath correlations?

A Yes.

Q And if you're going to be testing human beings to determine whether or not the machine works as far as on human beings as opposed to simulators, should you be doing blood-breath correlations?

A It's absolutely essential. Because one of the most important components of method validity is that you ensure that a method is appropriate for its intended use. And if all I was going to do was to use a particular device to go out and test dry gas -- compressed gas samples, then what they're doing would be entirely acceptable and appropriate.

But for method validity purposes, in order to prove that a method is appropriate for its intended use, you have to take it all the way back to the source. One of the constraints of an analytical laboratory is that the actual sample that's introduced to the instrument, that very microscopically small, little bitty sample is the -- is the part of the sample that actually gives you an instrumental response and gives you a result.

But it's incumbent on you as an analytical chemist to ensure that that sample has some measure of representativeness back to -- to its source, because frankly, the concentration of a sample in an instrument is not very interesting to a data user. They need to know whether or not that result can, in some meaningful fashion, be correlated

with a particular point in space and time out in the field where the sample is originally collected. So you can't just put on blinders and say, my analytical measurement is nice and accurate and precise, that's good enough. You have to actually consider it back to its point of origin and where you're drawing that conclusion. In the case of a breath-alcohol test, you're looking at the sample provided by a person and as in the previous testimony has shown that is an area that is fraught with problems, and that's a general conclusion in the analytical arena. It's always a lot easier to do the analysis than it is to ensure that you have a sample with -- that is valid and has integrity for purposes of drawing your conclusion.

The sampling part is hard, hard work.

Q How important would it be to have the maintenance manual or the vice as well?

A Absolutely very important. Maintenance manual gives the user an understanding of what are the components of the instrument that are subject to failure over what period of time and it's a very essential troubleshooting guide.

Q And how important would the -- it be to have the schematics for the device?

A Again, same argument. It's not black book science. As -- as practicing scientists, we're supposed to be able to understand the underlying principles and how they are applied for any given measurement.

Q Now, in reviewing the FDLE -- the HRS rules as well as the FDLE rules, did you note that the rules used to require that a manufacturer seeking approval of a breath-testing machine in Florida provide an operator's manual?

A Yes.

Q Provide a maintenance manual?

A Yes.

Q Provide schematics?

A Yes.

Q A diagram of the machine?

A Yes.

Q The -- provide at least two machines to be tested?

A Yes.

Q And various other -- I'm not going to go into it for time sake, but various things that are set forth in those rules?

A Yes. I've -- I've spent a million dollars of the Government's money buying analytical instrumentation. And I can assure you, I have never bought an instrument without all that information.

Q And with respect to the 2006 rule, 11D-8.003, did you note -- well, actually starting in 2004 and up to 2006, that those requirements were done away with?

A Yes.

Q And how does that affect the scientific reliability of these rules as far as approving a breath test issue?

A Taking as they currently exist, they have diminished essentially the confidence that the user can have that that's sufficient to ensure reliable data.

Q Now, with respect to the old rules, they required that the operator -- or that the manufacturer notify the agency when they made a modification to the electrical and computer component configuration or to the machine?

A Yes.

Q Did you note that that has been taken out in the newer rule?

A Yes.

Q And how does that affect the scientific reliability of these rules?

A Well, when you validate an analytical method it's -- you're validating it at a set of conditions. And when you change those conditions, it's incumbent on the laboratory to go back and revalidate the method to show -- to ensure that it's, again, appropriate for its intended use. That is essentially removed, that requirement, as near as I can tell that they -- they allow changes to be made to presumably the fundamental operating system and do not require a formal revalidation process.

Q And when you modify an instrument -- let's say you decide you want to use an instrument and then subsequently modified by the manufacturer, should it go through the same protocol that it went through originally for the approval of it?

A It -- it depends on the nature of the modification, you know, if you're changing the color of the housing or something, clearly that's not appropriate. But that decision should not be made by the -- frankly by the instrument manufacturer. They should come to you and tell you what the nature of the change is and then you can make a scientific determination as to whether or not it's necessary and appropriate to revalidate the method.

Q If the -- if the machine is based in part on computer software and they make modifications to the versions of the computer software, should that software be put back through the original protocol?

A Certainly.

Q Now, did you notice also that the earlier versions of the FDLE rules required that FDLE approve the machine and approve the software. And then in the last version of it, they merely have to evaluate the machine and merely have to evaluate the software?

A Yes.

Q And does that lessen the burden of what they're supposed to do from a

scientific standpoint?

A I have approved labs. I have evaluated labs. I've evaluated some labs that were just terrible. So, yes, I would certainly say for me personally that would be a distinct difference.

Approval implies that there is some bar and some set standard and that entity met that standard.

Evaluation simply means you've done some sort of objective assessment. It doesn't -- it doesn't address whether or not -- the conclusion was that it was acceptable or not.

Q All right. Moving this along to -- with respect to FDLE Rule 11D -- 11D -- the definition section of the rule, which would be -- I think it's 11D-.002, dealing with the -- having an approved breath test that's within .02 of one another.

A Yes.

Q Have you reviewed that rule?

A Yes.

Q And in reviewing that particular rule, did you see any problems with that methodology from a scientific standpoint in a laboratory auditing standpoint?

A They have essentially put in place a precision rule that multiple -- that replicate analysis have to agree within a prescribed value. But the problem is that they don't necessarily have comparable samples. And so it's completely not meaningful from a precision perspective to compare the results of two different samples when those samples are not comparable -- may not have had -- as we've heard earlier today, not had comparable volume.

Q And if you don't control the volume -- or you don't control one of the variables, how does that -- there's something called the scientific method; is there not?

A Yes.

Q What -- what is the scientific method?

A It's -- it's a process through which you make an observation, you pose a hypothesis, conduct testing and then validate and verify the process. And it -- it relies on our ability to control discrete variables when we need to to -- to evaluate the effects of -- of variables on final results. And what they're trying to do is draw conclusions about a numerical value and try to lend credence to the reliability of a result simply because two results agree within .02 when foundation wise, those are not comparable values because of the differences in the sample. So it's -- it's really a meaningless conclusion.

Q So when you vary the volume from sample to sample, then you're not taking control of one of the variables in the experiment?

A That's correct.

Q And when you don't take control of the variables in the experiment, what is the scientific reliability of the experiment?

A It's not.

Q And with regards to -- do you know what replica testing is?

A Yes.

Q What is replica testing?

A Conducting duplicate or triplicate or multiple tests of the same sample.

Q Now, is that scientifically required?

A It is -- it's required in order to understand the performance characteristics of your method to understand how much precision is associated with the measurement process.

Q So with regards to that rule where they have to be within .02 of one another, should there be replicate testing of each sample...

A Yes.

Q ...as a -- it's -- if you can, explain that.

A Yeah. And there's been testimony earlier today about split samples being used in blood alcohol. That way you can assess the precision of the measurement portion and of the sampling portion of the measurement portion. If you do a split after it's introduced to the instrument and you can look at the precision of the entire process by doing actually replicate samples.

Q Now, in blood testing, do they do replicate samples?

A They...

Q Replica testing, I mean.

A They do replicate analysis. They do -- they require duplicate analysis -- instrumental analysis and they also require collection of duplicate samples.

Q And on the same sample do they do a second analysis?

A Yes.

Q Under the .02 rule in the FDLE rules, are they doing a separate test on each sample?

A They're not.

Q And is that scientifically required?

A Yes. In order to get that precision, yes.

Q The failure to have that in the rule, does that make it scientifically insufficient?

A Yes.

Q Now, in reviewing the -- the individuals who you referred to earlier as the agency inspectors...

A Yes.

Q ...what type of scientific training should they have?

A In the rule it describes the qualification criteria that they have to meet and I vaguely have to review to get it in detail, but it's basically a high school diploma, be an employee of the agency and then complete the operator's test -- course plus one additional training session.

Q And do you think that's scientifically sufficient for what's occurring?

A Not as evidenced by the records that I reviewed.

Q And what about those records would indicate to you that that is not scientifically reliable?

A The requirement of the protocol -- or of the rule is that when they run these tests, they run triplicate tests on the -- on the instruments during their monthly inspections. And any time a sample gives an out-of-control response, anything that doesn't give the expected response, they're expected to give an explanation in the remarks section, which is perfectly reasonable.

And I -- I draw part of my conclusion on the things that I saw. Sometimes they would have out-of-control situations and would have absolutely no explanation for that observed situation.

Sometimes they would have the same situation on multiple runs and give different explanations as to why it was occurring.

It was -- it was evident from the kinds of descriptions that were given that these folks were not trained scientists. They would have, under remarks, their explanation for the problem was improper sample, yet, that was viewed as an acceptable past compliant test, but it had an improper sample.

Q Okay. I'm going to show you what's been marked as Exhibit 105. Is this a Composite Exhibit of some of the things that you found?

A Yes.

Q And do you know what a mulligan is?

A I do know what a mulligan is. My dad was a scratch golfer.

Q And were those individuals who may not be familiar with the game of golf and a mulligan, what is a mulligan?

A It's -- it's overs -- little kids now. It's overs. It's when you hit -- you have a bad play and you get to take overs.

Q So if you don't hit it down the fairway the first time, you get to hit it again to see if you can get it down the middle of the fairway?

A As practiced here, and you don't even take a shot.

Q And how does the mulligan relate to science?

A It is not a desirable option. I'm pretty stunned to see it actually codified in the instructional procedures here that it allows the agency inspectors when they're doing their little monthly inspections and they are running a check standard -- essentially they're running a control sample. This is a sample of known concentration and purity ostensibly, so it should give the right result if the instrument is operating in control.

Under their own protocol if the first time they run it, if it's a problem, they get one mulligan -- they get one retry. And as long as the retry is in, that's okay, they can still pass. And familiarity, it's sort of intuitively obvious. But we don't retry unknown samples. If it was my breath that they were testing, they wouldn't be retrying it to see if they get a better or more desirable result.

The premise of quality control samples is that they are pass or fail, they're not overs. So quite frankly, I have never actually seen it written down in a procedure that that was allowed under a testing protocol I've seen people do it in practice unacceptably and outside the bounds of their protocols, but I've never actually seen it written down as

an acceptable practice.

Q Okay. So that practice of -- I'll call it a mulligan on these tests, is not scientifically reliable?

A No. Because it essentially allows you to run along until there is a problem and then try it again on just that one, and then run along until you have a problem and try it again on just that one. That does not accurately represent real world testing scenarios if you envision the situation with running your unknown samples, everything has to be in control in order for me to have any confidence that the unknown is in control.

Q And is that a problem further exasperated by the individuals who are trying to make determinations as to why things are out of control?

A Yes. As -- as you can see, if you actually spend some time going through these records, it's -- it's quite evident having looked at thousands of these over the years that the people making the judgments as to the source of the problems don't necessarily have a lot of experience in -- in really understanding the root cause of performance problems.

Q Now, with regards to FDLE rule 11D-8.0035, which is the alcohol reference solution rule...

A Yes.

Q ...were you able to review from the varied versions over the years and compare them?

A Yes.

Q And did you notice something occurring with regards to the testing on the alcohol reference solutions and the scientific reliability of that?

A Originally they -- they've adopted a fairly unusual practice. I don't recall I've ever seen it done anywhere else, in that FDLE essentially approves and is the

certifying entity for reference solutions that are approaches from approved suppliers. There are apparently no real criteria for the suppliers except that they would be able to produce sufficient material in a -- in a given amount of time frame. There are no requirements for them to use traceable standards. You've heard reference earlier today to NIST, which is the -- it used to be called the National Bureau or Standards, the old NBS. It's not National Institute of Standards and Technology. But essentially traceability, which is required for dry gas standards is not required for the reference standards. And FDLE actually receives lots of -- lots of reference solutions. And then they experimentally test those reference solutions and essentially become the certifying entity for those referenced solutions. It's a very unusual practice.

Q So those things usually are farmed out to an independent?

A Yes.

Q And there should be an independent review of that?

A Yes.

Q Okay. Now, at one point in time they required that the solutions be made up of the agent grade ethanol and distilled with the ionized water?

A Yes.

Q Did they do away with those requirements?

A Yes.

Q And what does that signify from a scientific standpoint?

A Well, so much for traceability, which is a fundamental component of every national and international quality standard for testing laboratories.

When -- when the testing is conducted by FDLE, they started off by running 50 samples. Over the course of the years they reduced it to only testing 25 replicates. And they've also sort of degraded in their expectations of specifications around the

composition, specifically things like specifying the grade impurity of the materials used for the standards.

Q And does that make the rules scientifically insufficient in your opinion?

A Yeah. It's not that somebody may not be using acceptable quality materials, it's just that it's not required anymore by the rule. So an individual practice may happen to be acceptable but under the rules if all they're doing is following the rules, then it's insufficient.

Q And should there be some methodology to ensure that those types of substances are being used in these solutions?

A I'm sorry, I don't understand.

Q Should there be something written in the rules like it used to be that the solutions are made up of U.S.P. grade ethanol and -- or reagent grade ethanol and distilled with the ionized water?

A Yeah. That's -- that's pretty much a routine expectation of standard prep rules.

Q Do you know what a post-distribution analysis is?

A I presume so.

Q Okay.

A That is analysis after the materials have been distributed for use to the field.

Q And did you see in the rules where there used to be a requirement that there would be a post-distribution analysis and there is no longer a requirement of distribution analysis?

A That's correct. Again, degradation of the requirements.

Q And with respect to FDLE rule 11D-8.0036, which is the dry gas standards...

A Yes.

Q ...did you see in reviewing the rules that there was a change in those as well?

A I don't remember when that was.

Q Okay. But do you recall the change?

A My recollection is -- let's see.

Q You can look at the rule if you want.

A I can't, because you didn't give me a copy.

Q Okay. I'll give you, I guess, it's Exhibit 75 in Evidence. And I want you to read dry gas standard rule.

(Pause)

A Okay. This particular rule back in -- this looks like the 2002 version, actually required verification of the composition of the standard upon receipt. That was subsequently removed in -- and I suspect the more current one is here too.

(Pause)

Well, it...

Q The way this version -- it goes in order.

A Oh, okay.

(Pause)

Q 2006 should be towards the -- next to the last page, I think it is.

A Back here?

(Pause)

Ah, okay. Yeah, that requirement has been completely deleted.

Q And have there been other requirements that have been deleted as well?

A Well, yeah. It's -- it starts off with only -- let's see -- I'm going to try to do a

side-by-side here.

(Pause)

They have to increase their production capacity. That's a good -- good change.

Q What about the testing? They -- they used to be required to test the -- the dry gas...

A Yeah, that's what I was referring to earlier, that they did originally require testing and that requirement -- that requirement has been completely deleted.

Q And so therefore there's nobody testing the manufacturer?

A That's correct.

Q And is that scientifically reliable?

A You know, all -- all of these requirements essentially are means of us ensuring the control of the process. And so every time you strip away controls, you introduce the potential for problems. And more importantly you've lost the data. So if there's a problem, you won't know it.

Q All right. Should there be rules promulgated as to when the records for these machines should be reviewed by FDLE and how often and...

A It's one of the most stunning omissions of this whole alcohol testing program, quite frankly. There's a lot of data that are -- that are collected. There's a lot of data that's published on the website available for public review. But there doesn't seem to be a requirement for anybody to actually go in and do an objective scientific assessment, gee, how well the system is doing.

They do a little discrete test of, did I meet this discrete requirement, but nobody is looking systematically at it to see whether or not the program is having its desired effect.

Q If one of the requirements from these Intoxilyzer machines is that you have a formula where you have to have volume, time and slope to have a scientifically reliable fashion, should there be something in the protocol to be able to test whether the machine can accurately measure the volume?

A Absolutely. And in the procedures it does address a minimum sample volume, but there's absolutely nothing about how you ensure that minimum and there is -- it does not address a maximum.

Q So without that kind of procedure, how is one to know whether the machine is accurately measuring volume?

A You don't -- it's the -- I'm going to be picky here. But the accuracy of the measurement is what's delivered to the instrument. But it is how representative it is of the sample and it's not representative of the sample, if that's the case. So in the conventional wisdom, that's an inaccurate sample.

Q Without having any means of verifying the volume?

A That's correct.

Q And have you also looked at the acetone testing procedures that...

A Yes.

Q And have you noticed that there was a difference over the rules as to how the acetone testing was done?

A Yes.

Q Go ahead.

A In -- in the early years the acetone testing was done in a sample that also had alcohol present. In subsequent years they've essentially reduced the complexity by having a sample where -- where only acetone is present.

Q And by doing that, are they diminishing the ability to test whether the

machine can be -- is able to distinguish between acetone and alcohol?

A That's correct. They're simply addressing whether it can identify or respond to acetone but not whether it can distinguish between acetone and ethanol.

Q You're familiar with blood testing; is that correct?

A Yes.

Q And is there a control in blood testing that's designed to be able to establish that the device can discriminate between, amongst other things, acetone methanol from alcohol?

A Yes.

Q And if you're attempting to measure the alcohol and breath and you're attempting to measure the alcohol and blood, is there any reason to make the measurements or the procedures for the breath alcohol any less sufficient than the ones for the blood-alcohol level?

A Not if you're using them to make the same decision. It's the fundamental precept of quality assurance that your quality assurance needs to be tailored to the intended use of the data. So if you're using -- if you're using this breath testing instrument as a screening test to decide when to take a blood sample, I probably wouldn't be sitting here. I would probably say that this is an appropriate level of quality assurance for a screening application.

But if you're trying to make exactly the same decision, did this person have -- have whatever the law has decided as an unacceptable level of alcohol...

Q .08.

A .08 in -- in Florida.

Q You have a .08 blood-alcohol level or .08 breath-alcohol level, you go to jail.

A Well, then, if that's the decision that's being made, then this quality assurance program is completely inadequate to ensure the reliability of a result for that kind of an application.

I would simply refer you to your own even blood-alcohol program which has it's own issues but is certainly dramatically better than this.

Q And in our blood regulations they require the machine to be able to discriminate where in that case the gas chromatograph you have to discriminate between acetone, methanol, isopropanol and all those kinds of alcohols that are...

A That's correct. There's a requirement that you analyzing mixed standard and demonstrate that you're able to resolve and differentiate between each of those components.

Q I don't believe that -- well, just as a conclusion, and I think you've said this, but just finally, do you find that these particular rules are scientifically sufficient to be able to determine an accurate measurement of somebody's breath-alcohol level?

A No.

Q Okay. The Exhibit that you -- you made your own documents and we put them together in an Exhibit that's in Evidence.

A Yeah. I wouldn't have written all over them if I had known you were going to make an Exhibit out of them.

Q Okay. Can you explain what you -- by page-by-page what you perceive...

A If you'll let me see. This is your Exhibit 75?

MR. WOOTEN: 75.

BY MR. HYMAN:

A Thank you. Okay. Well, we can just start with the first page. This is an example of an instrument that was tested in December of 2007.

JUDGE CHEEK: What Exhibit number is this?

THE WITNESS: I'm sorry, 105.

MR. HYMAN: 105.

JUDGE CHEEK: 105?

THE WITNESS: Yes.

BY MR. HYMAN:

A And it's the monthly agency inspection so it's not one being run by a cop out in the field, this is somebody who presumably knows what he's doing. And you can see as you run down the series of tests that he retried the blank sample all three times. He retried the .08 gram reference sample all three times. He retried the interferent detect test all three times and .20. Not exactly stellar performance. And so, obviously, I'm very interested in what -- to what did he attribute this -- this low performance.

Well, down at the bottom under remarks, for the blank sample it says -- the explanation was hose connection loose. Okay. For interference detective it says, wrong solution. I keep trying to remind myself that this is the experienced agency inspector.

For the .08 sample, the control being outside tolerance. It says low temp. And for the .20 control outside tolerance it says, I hope this is low -- LOE temp -- low temp again.

There's no basis for those kinds of -- of explanations. It's not -- it's really striking that that kind of repetitive failure simply just -- and it still shows up as a compliant test when you have to retry that many tests. Also the very experienced analyst who has the hose connection loose and uses the wrong solution.

The next sample on the page is from January of 2007. Again, an agency inspection and again, having to retry the -- having to retry the .08 and .20. All three times that they were tested, they failed the first time and he had to retest them. Absolutely no

explanation for those failed controls. It's a job -- they're just mulligans, no harm, no foul.

There's a whole series -- sometimes the software version is 26, sometimes the software version is 27. And let's see, some of the other remarks kind of give you idea of -- of the operator's system, one, when they're doing retries on reference solutions, the remark explanation is jar fit loose. Leak at simulator.

Q Let me ask you a question.

A Um-hum.

Q In a scientific reliable protocol, would there be some type of methodology that's specified as to how you determine what's causing these problems?

A Well, yeah. And the problem is the -- the answer isn't that you just get to keep running them again. When you fail you stop and you start over. You stop, you investigate, you figure out what the problem was and then you start over.

Q So normally protocols for that?

A It's more on the fly, yeah.

Q All right. Because of the time...

A And explaining something as out of range results hardly gives any, yeah, well, then that could be my sample that was the out of range result that you didn't retry it.

MR. HYMAN: And at this time I don't have anything further just for time sake.

THE COURT: State?

MR. KATZ: Your Honor, can I ask one question?

THE COURT: Go ahead.

* * * * *

DIRECT EXAMINATION

BY MR. KATZ:

Q I just want to go back to the acetone question -- acetone -- the agency inspection.

The acetone testing is always done at the same step in the agency inspection; correct?

A That's correct.

Q And so we don't even know if the machine -- the machine knows that an agency inspection is being done when it's being done, right?

A That's correct.

Q Okay. So all we know is that the instrument is actually detecting something that is during the step called acetone testing?

A Yeah. I don't know if they call it acetone testing, but, yes. And that's why you would want the source code so you could understand that.

Q But we don't even know that it is -- it knows that's acetone, just that something is found at that step in the process?

A That's correct.

MR. KATZ: Thank you.

THE COURT: Thank you.

Cross?

MR. WOOTEN: How long do I have?

THE COURT: Well...

MR. WOOTEN: I believe it was about 45...

THE COURT: They started at 4:30, so about 42 minutes. But I don't know if any Judges will be left here.

* * * * *

CROSS-EXAMINATION

BY MR. WOOTEN:

Q Have you ever run a -- well, are you a forensic toxicologist?

A No, I'm not.

Q All right. Do you have any involvement in any forensic toxicology professional associations?

A No.

Q All right. Have you ever run a forensic toxicology program for a state or local government?

A No.

Q Have you ever reviewed any forensic toxicology programs other than your review of the FDLE breath -- rules for Mr. Hyman, and my perception is you've also reviewed the FDLE blood rules for Mr. Hyman; is that correct?

A Yes, that's correct.

Q Other than those two, have you evaluated breath-testing programs in other states?

A Not programs, just analytical results.

Q I'm sorry?

A Not programs, just analytical results.

Q Okay. And is it your testimony that you find that the FDLE blood-testing rules are scientifically valid?

A No.

Q All right. So you don't find them to be valid?

A No. And it's basically insufficient again.

Q All right. And you don't find the breath testing program valid?

A That's correct.

Q And again, this is in your opinion?

A Yes.

Q All right. You would agree that scientists can have different opinions?

A Indeed we do.

Q All right. And have you ever testified for the prosecution -- the State -- the United States of America about a breath testing program or blood-testing program?

A No.

Q All right. In fact, what percentage of your testimony involves testimony for criminal defendants or defense attorneys?

A What percentage of my testimony?

Q (No Verbal Response)

A All of it.

Q Okay. What percentage of your consulting work with lawyers is with defense lawyers?

A With lawyers it's defense lawyers and in civil it's different. I don't know what you call it, but, yeah, civil cases as well.

Q Okay. Now, you indicated one of your concerns was a lack of rigor in the FDLE breath-testing rules?

A Yes.

Q All right. And specifically what rigor would you insert into those rules in order to make them acceptable in your opinion?

A A diminishment of rigor has occurred just over -- over the years that the program has been in existence. So requirements that used to be in place were perfectly reasonable and legitimate requirements and the kinds of things that are seen in -- in testing programs throughout the county has been removed.

Q I'm sorry, what testing programs -- breath testing programs around the country have you evaluated?

A I'm talking just analytical testing programs.

Q So you, in fact, have not compared the FDLE breath testing rules with breath testing rules anywhere else in the United States of America?

A No, I have not. No, I have not.

Q Any territories in the United States?

A No.

Q Any United States governmental agencies that use breath test -- breath testing for any type of purpose?

A No.

Q All right. So your -- as Mr. Hyman said, when you compare apples and oranges you might find out you've got mixed fruits; would that be fair to say?

A I'm sorry, I just don't understand the analogy.

Q Well, part of determining what would be scientifically acceptable, we would be looking at the entire community of that particular science and how things are done there, correct?

A Okay. I guess I need to explain something to you about quality assurance. It's not Janine's rules for what's necessary for -- for quality assurance and analytical testing.

There are national and international quality standards that have been promulgated. An example in the forensic arena is that the American Society of Crime Laboratory Directors have a set of standards that they require. There are international standards, again, that are independent of the application of the testing. As -- as applicable to forensic testing as they are to pharmaceutical testing, as they are to testing dog food.

But in this case rather than relying on those kinds of international testing standards that have been accepted in the analytical community, FDLE has opted to try to develop and promulgate their own. And so my basis for comparison is to the international quality standards -- national and international quality standards and compare FDLE's to those.

Q Laboratory standards?

A Yes.

Q All right.

A These are laboratory testing standards.

Q Now, was this -- you talked near the end of your -- well, during the beginning of your testimony you talked about mulligans?

A Yes.

Q And -- and do overs.

A Yes.

Q And you can't have that.

Now, at the end when you began to discuss a handful of the documents in Exhibit 105, you were talking about, well, the problem with these people is they just kept going. Whereas what I would do is I would stop and start over, correct?

A Yes. Yes.

Q All right. In fact...

A Stop, fix the problem and start over.

Q So if the problem, for example, was that you had a leak on your simulatory -- in other words it was not, in fact, holding pressure and some of the vapor was escaping out, the fix for that problem would be to tighten the leak and then start over?

A Possibly, yes.

Q Well, what other fix would there be if that was the problem?

A You don't get to start -- you're -- you're assuming that you get to start over in the middle of the analytical sequence. You have to start back over at the very beginning again.

It's a failed run. That entire batch is then over. And so when it fails, you investigate, do corrective action and then start over.

Q What is the agency inspection protocol for the FDLE? Can you tell the -- can you walk the panel through it?

A I've -- I've read it a number of times. But if you would let me see those -- it's one of the rule forms. I -- I don't want to miss a step.

Q Okay.

A Thank you.

(Pause)

This is a '97 one. There's a more current one.

I'm sorry, it doesn't appear to be in here.

Q While we're looking for the rules here...

MR. HYMAN: That's Exhibit 83.

THE WITNESS: Thank you.

(Pause)

BY MR. WOOTEN:

A Okay. These are the department inspection procedures that are applicable to the kinds of materials that I reviewed.

You essentially start by warming up your instrumentations is the first step. They specify as the second step, only use of distilled or ice water.

Is this the level of review that you want me to go through?

Q Um-hum.

A The third step says that we only want you to use approved and within their current shelf life, reference standards.

Q Why would -- why would that be in a rule?

A That's a very essential component of ensuring the tracablity and acceptability of the referenced standards.

Q All right. So that would be good?

A That's a good thing.

Q Okay.

A There -- there are other problems with the reference standards but that particular one is a good one.

Q Okay.

A Let's see, approved -- four. Okay. Then you press escape twice, you access the main menu. So they are essentially mixing up sort of work instruction level press gears with -- with high level kinds of requirements.

You enter your name as to who the user is, enter your password, scroll to maintenance, enter --- let's see, that looks like it for that one.

The next is the result must be 0.000 for each air blank. The instruments will check the inspection process if the air blank result is not 0 -- will abort the air inspection process if the air blank result is not 0.000 except for the diagnostic check. If a check or test is out of compliance, the instrument will prompt the department inspector to repeat the check or test. Each check or test may only be repeated once. That's the reference -- the explicit reference to they allow one -- one repeat analysis.

If a check or test must be repeated, the reason must be entered when prompted and recorded in the remarks section, and that's why indicated an appreciable

amount of the time they enter no such reason. They simply accept the default parameter that notes the existence of the out of control.

Q Appreciable sign -- amount of time, what percentage?

A I'm sorry, what appreciable amount of time?

Q You said -- you told the panel an appreciable amount of occasions there was no entry as to what that is.

A Oh, as I said, I didn't attempt to review the many thousands of pages that were there. They were not in any searchable format. So just for that small packet that I pulled at random for the first link there are -- there are multiple examples in that small packet.

Q So there were thousands of available records that you could have reviewed?

A Yes.

Q And you chose not to review them?

A Because the scope of my review listed the adequacy of this program. That was my own just personal curiosity when I realized that the records were available so I could see sort of the next step to what extent do they even follow their own rules, which doesn't speak to the sufficiency of the rules.

Q All right. So, in fact, if there was individual cases of human error, that doesn't tell us about the rules at all, does it?

A No. But it does bring forth the fact that the rules do not require that kind of analysis systematically.

Q What -- what rule requires that there be no human error?

A Now, the purpose of a quality assurance program is that you collect the data so that when there is a human error you have a record and can assess the scope and magnitude and significance of that error.

Q All right. And making the data available so that not only can it be internally evaluated but it's open to external evaluation, that's good science; isn't it?

A That's very good science practice.

Q All right. And you don't have any personal knowledge as to how often these records are, in fact, reviewed by the program and what steps they actually take to follow up on these issues?

A No. Again, because they may be doing things essentially outside the scope of the rule, but all I was assessing was whether the rule in and of itself, if it was followed explicitly, would that be sufficient.

Q Okay. Now -- so now we're talking about program administration?

A No. I'm talking about scientific reviewing data quality assessment.

Q Okay. Continue on, please.

A Okay. We just did the mulligans. Let's see -- and a reason.

Verify the date is the next step. Adjust if necessary. That actually is a pretty troubling requirement for analytical instrumentation simply because it allows people to time travel and time travel can be a problem in our world when they have monthly requirements. This would enable them to go back and alter the date if they were not meeting their monthly requirements. It's a very, very bad practice in analytical chemistry.

Minimum sample volume check, press enter. When provide sample now is displayed, provide a breath sample volume of less than 1.1 liters as shown on the display.

And this is where they only have a minimum sample volume check. They don't have any maximum check.

The next is a barometric pressure sensor check, the displayed pressure on the instrument to that of a barometric pressure gauge. That's cute. I don't -- any old

pressure gauge will presumably do and as long as they degree within one percent, then it's okay.

When these kinds of measurements -- this is something that's like a temperature measurement. It's two a gauge. That's in calibration with respect to a NIST traceable standard.

Diagnostic check, press enter. The result must be okay for each diagnostic check. If any result is not okay, the instrument will abort the inspection process.

Do you want me to keep going?

Q Yes, please.

A When there are simulators used, enter the number of the simulators used during the inspection. Next is an alcohol-free subject mouth alcohol test. When provided sample now is displayed they introduce an alcohol-free breath sample into the instrument and the rest -- result must be 0.000. Rinse mouth with mouth alcohol solution. When the sample is again displayed, introduce a breath sample and the result must be sloped down and met in order to be compliant.

Q All right. You would agree that that would be scientifically good for the purpose of this instrument?

A In its use as a screening device, yes. I would submit that because of the testimony that you've already heard in -- in ample quantities this morning, that in -- in and of itself is insufficient.

Q Not from your area of expertise, you just happened to sit here and you've heard other people say why they think that might not be good?

A Yeah. And I guess it's important to understand that as a -- as a quality assurance person and as an analytic chemist with pretty diverse analytical background, I have a lot of understanding of the kinds of variables that matter. I've done a lot of gas

analysis myself. I've done a lot of gas manipulation in handling. So I understand sort of the basic principles that are important. But I do rely on experts for essentially confirmation of what are the variables that matter and what are the variables that need to be controlled.

Q Okay. Why would total volume need to be controlled?

A It's -- it's the volume of the analytical sample. It's not total volume. And frankly I'm -- I'll be really interested in seeing how the -- how the source code actually integrates against given the -- my understanding of this particular analytical scheme.

Q It might not be a variable that has much influence at all.

A Oh, I doubt that in a gas measurement.

Q Okay. Total volume?

A Excuse me?

Total -- is -- was there a question in there somewhere? I'm sorry, I missed it.

Q You're saying that you think total volume would be important in the ultimate measurement on this instrument?

A It depends on how the instrument is integrating.

Q Okay. You don't have any practical experience in breath testing results, right?

A No. But what I'm telling you is that it's -- it's a red light special here for an auditor to look and see that there are -- there's an explicit requirement for minimum sample volume. No idea how that is -- is actually insured, but there's nothing for maximum.

Q Okay. And if maximum turns out to be a variable that matters, that would concern you?

A Yes.

Q And if it's not...

A Then it's not.

Q Then it's not a problem either.

A That's true.

Q Okay.

A And I just want to see the data to support that.

Q All right. Now, again, you indicated that you looked at some of the samples and the question I was going to back to is, so you didn't -- in fact, in your words, you didn't do a rigorous study of all of the agency inspections and how people are doing them?

A No.

Q Okay. And, in fact, your notes on many of -- you have no notes on some of these, correct?

A Yeah, that's correct.

Q And others you have very brief notes?

A Yes.

Q Okay.

A I think I did -- I think I did most of my scribbled notes on the plane so if they're not legible that may be part of it.

Q You spent a great deal of time talking about the -- this issue of if your -- if your ultimate is the blood-alcohol-level testing to ensure that you get back to that point, you're -- do you remember that line of testimony?

A Yes.

Q In fact, you were concerned, because the rules dropped a requirement there

would be a blood-breath correlation, correct?

A Yes.

Q All right. Were you aware that Florida Law changed so that there would no longer be a requirement to have any type of relation of breath results back to blood alcohol?

A The origin of my concern is that essentially the same decision is being made.

Q So...

A And from a quality assurance perspective the level of quality assurance -- the protections that you need to put in place are driven in large measure by the importance of the decision that's being made.

If I'm only deciding whether or not I dump something down the drain or -- or put it a different waste receptacle, the consequences are not as serious as having -- of making a wrong decision as they are of having a wrong decision in a case like this.

So because there is such important consequences for the decision, that would imply at least as much rigor as -- and quality assurance components, quality control and quality assessment as exist for the blood-alcohol program. Anything less would imply that the results are less -- have less importance in terms of their impact on the decision.

Q So you weren't aware that the statute changed, which was actually the question that I asked you?

A No. But from my perspective...

Q Okay.

A ...it doesn't matter.

Q Okay.

(Pause)

You're not the director of the alcohol testing program, are you?

A No, sir.

Q All right. Nor any other alcohol testing program?

A No.

Q All right.

(Pause)

Are you aware of something conceptional called functionality testing?

A Sure.

Q What's functionality testing?

A Well, it depends on how it's used and I've heard it used in a variety of different ways. So if you can give me a clue of what you're interested in, I can maybe give the relevant definition.

Q Okay. In reference to scientific testing equipment?

A It's basically -- the way I've heard it used in -- in the past is, evaluating an instrument for a particular scope of -- of applicability. So -- and for example, if you took one of these breath alcohol instruments and you put it in a laboratory, it could potentially find use in the laboratory as a screening device to limit the load on the gas chromatographs.

So I'm not sure what you're after, but I'll -- if you help me, I'll try to get there.

Q Well, functionality testing is determining how -- whether an instrument can perform a particular function by having simulated the activity and see whether it's capable of properly detecting or measuring whatever is in question.

A An example is taking a gas chromatograph to the field and actually

operating a gas chromatograph in the field as a field instrument. That would be an example of functionality testing.

Q All right. You would give it a series of tests and you would determine whether it could properly determine whatever it's evaluating?

A Yeah. Yeah. It's a little -- in -- in that particular example, it's a little more complicated than the kinds of testing you do in laboratories simply because you don't control the environment as much, so you're trying to get an idea of what are the environmental controls that might be an issue.

Q All right. That's an effective way to determine whether an instrument can perform a particular function, correct?

A It can be.

Q Yes. All right. It's generally accepted by scientists as a way to determine whether an instrument can perform something?

A That's a pretty -- pretty blanket statement but it can be, yes.

Q Okay. And one of the things you would want to do is you would want to introduce a standard, for example, correct -- a known standard and determine can this instrument meet the -- meet reliability or accuracy or precision?

A Yeah. Reference standards are control samples, positive controls of a fundamental way of evaluating instrument performance.

Q And reference standards are things that are produced by scientific laboratories; is that correct?

A Generally they're manufacturing facilities that have labs and support.

Q All right. And then distributed to laboratories for their use in various types of testing?

A Yes.

Q Like gas chromatographs, for example, have standards, don't they?

A Yes.

Q So that when you're measuring -- if you're doing -- evaluating drugs, for example -- have you ever done that?

A Yes.

Q All right. You've got a standard in there that you use as part of that evaluation, correct?

A Yes.

Q And that comes from one of these providers?

A Yes.

Q All right. And it comes with certificates of assurance; is that correct?

A Yes. It's generally called a certificate of analysis.

Q All right. And in a laboratory setting, what do you do when you get that standard in before you put it in your gas chromatograph to use it as a standard?

A I'm not sure I understand the question. There -- generally the certificate of analysis will specify explicit storage conditions so it will say that these -- for example, these sealed vials need to be stored under refrigeration and then the shelf life changes once they've been opened. I -- what particular...

Q Okay. So it comes in and you store it properly?

A Yes.

Q Now, it's time to put that standard in gas chromatograph, what do you do?

A You get it out, you check it and you use it. I'm not...

Q What do you mean you check it?

A What do you mean you check it?

Q You said it. What do you mean when you say you check it?

A If -- it -- it depends on its source and origin. If it's a primary reference material or if it's a prepared solution, but essentially you validate or verify the acceptability of materials prior to their use on unknown samples.

Q How do you validate them?

A Against another source.

Q Well -- okay. So now...

A Because a lot of the bias that is introduced analytically can have its problem in that one solution, so you check things against a second source solution.

Q Another product from one of these producers?

A A different lot, a different manufacturer, different instrumentation.

Q And what do you mean you check it?

A You test it as if it was a sample.

Q Okay. So testing a standard would be good science, correct?

A Yeah. Most quality assurance programs require that they be evaluated periodically.

Q All right. Before you let that standard go out and be used?

A And during use.

Q Okay.

(Pause)

The purpose of having an operators manual in schematics would be to assist you when you're performing an approval or an evaluation, correct?

A Under the -- under the FDLE program, yes. That certainly would not be the only use out in the world and in operating practice.

Q Okay. Certainly. If you had a question about how to do something, you would want to refer back to the...

A Yes.

Q But the point is, you would look at those things if you had questions about how the instrument performed, but you wouldn't just look at those things and say, gosh, this is great documentation and send it out the door, correct?

A Well, no.

Q You would want to test it?

A Yeah.

Q Because they could put anything they want in the manual potentially and the instrument might not live up to the expectations.

A Most laboratories have a very explicit requirement that instrument performance be empirically evaluated upon receipt before you even pay for the instrument that there be such an objective analysis.

Q And such an objective analysis would involve using such things as known standards and testing the instrument to determine if it was capable of doing the analysis that it needed to do?

A Yes. Yes.

Q That would be good science work?

A That is good science, yes.

Q And if you had an instrument that used software, correct, and you got some new software for the instrument, you would want to test it to make sure it doesn't affect the performance -- the functionality of that instrument, correct?

A That's correct.

Q And the way that you would do that is you would use known standards to determine, okay, has the software change affected the ability of this...

A That's -- that's one of the ways. That's essentially the most straightforward

condition. But, yes, that's one of the ways.

Q Okay. Scientifically acceptable way.

A To do part of it, yes. The problem is that some of -- depending on the nature of the software changes, it may affect not the plain vanilla testing but the more complex scenarios and so those would also need to be evaluated, depending on the nature of the change.

Q And would also depend on the nature of the instrument and the nature of the testing, correct?

A Yes. Yes.

Q Okay. Some instruments are much more complex, engage in multiple functions. Others are not as complex and are more straightforward?

A Yes, that's correct.

Q The greater the number of different uses for the instrument and different scenarios for the instrument to be used, you start adding lots and lots more variables in there?

A It's not really the uses that makes them more complex, it's really the underlying scientific principles.

Q Okay.

A Sort of, you know, half million dollar instrument and they only have one discrete use.

Q Okay.

A So it's -- that's not the correlation.

Q All right. But -- well, because it only has one use?

A That was your example. That if it only had one simple use -- one use, then it was necessarily more simple.

Q Well, its testing might be more effective versus an instrument that had a whole bunch of -- a broad range of uses?

A What you're calling functionality testing, I'm going to call validation of that technique.

Q Okay.

A That's the more accepted term.

Q So it's not approval, it's not a evaluation, it's validation, that's the term...

A Not the validation has a very specific discrete meaning in the scientific community. And it is determining through a collection of empirical evidence that a given method is appropriate for its intended use, whatever that use is.

Q And -- all right. That would include the types of things done in an approval of an instrument?

A Yeah. It would certainly include that, yes.

Q And that type of testing could also be a description of what's taken place in the agency inspections in this case?

A It would include that type of testing, yes.

Q So there's constant method of evaluation?

A Verification, yes. Verification that you're still essentially meeting your original expectations.

Q All right. And the more of that verification or validation you do, the greater comfort you have with your initial assessment?

A I'm not sure I understand your question.

Q If you did a validation test twice and then you did it 98 more times, when you got to test 100, would you feel more comfortable if you were seeing consistent results all the way through than if you just stopped at two?

A If you did a good job of validating your method in the first place, it's not necessary to go back and validate the unchanged method periodically. You don't need to essentially revalidate an unchanged method. There's an ongoing process of verification. But you 've -- validation is when you control everything and you don't change anything from that point on. It's when you make changes that you go back and revalidate.

Q And you make changes to the method is what you just said?

A Yes.

Q So if you make changes that don't affect the method, you wouldn't need to revalidate it at all?

A Yeah. Like you said, if you change the color of the box, we don't care.

Q If you don't change the method, you don't need to go back and revalidate.

A That's correct.

MR. WOOTEN: Thank you.

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REDIRECT EXAMINATION

BY MR. HYMAN:

Q I'm showing you what's in evidence as Defense's Exhibit 70. I'm representing to you that every one of those pages shows a dry gas standard that was out of control. Does that cause you some concern?

A Yes, it does. What period of time is this for?

Q Over years, since the Intoxilyzer has been on line -- 8000. Since May.

MR. WOOTEN: Which one is she...

BY MR. HYMAN:

A Well, as I'm scrolling through, they're all from 2007.

Yeah, that would -- that would trouble me a great deal. Because frankly, of

everything that this instrument does, the dry gas analysis ought to be like the easiest thing it does. That's not as complicated a measurement.

Q Well, why -- why -- if the dry gas standard is supposed to be pure and it's supposed to be certified, why would those controls be reading out of tolerance?

A There are any number of reasons and that's the kind of thing they should be investigating. But, you know, when you just retry it and go again, you lose that scientific inquisitiveness to figure out what's really going on.

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REDIRECT EXAMINATION

BY MR. JAEGER:

Q We've got one question. Ma'am, he asked you about gas chromatograph. You're familiar with that, right?

A I am.

Q And you know how they operate?

A I've bought them, used them and reviewed them.

Q Okay. They only operate one way.

A Well...

Q I mean, as far as doing an analysis on it basically, they're basically one way, correct?

MR. WOOTEN: She's -- objecting. Interrupting his own witness.

THE WITNESS: No. I just can't hear over you actually.

I'm sorry, try me again.

BY MR. JAEGER:

Q So during an analysis they only work basically one way?

A Yes, that's correct.

Q Okay. And he kind of tricked you into saying that by using a simulator, that that would be sufficient for doing...

A Oh, a simulator -- I -- if that question was asked, I didn't hear it.

Q Okay.

A A simulator is a whole different ball game.

Q Have you ever operated this 8000 breath test?

A No, I've not.

Q Did you know that on the 8000 breath test machine there's four separate ways to operate it -- four ways; air blank, simulate, dry gas and breath. And when you do it those four different ways, the air is actually channeled into different channels.

A Well, see, that's why I would want to see the schematics and the instrument operating conditions.

Q When you use a simulator, you don't even get the volume. When you use a dry gas, you don't get volume, and when they do all these testings he's talking about constantly, they don't use breath, they use a simulator or a dry gas standard. And it goes through a different hose and through a different path...

A Well, the saving grace for that is -- the saving grace for that is because the number of variables in -- in these things, that can help you track down problems. So those -- those dry gas samples that you gave me, that would help me track down the origins of that problem. Doesn't help me analytically in terms of the reliability and validity of the results, but it does help you to solve problems.

Q So if you want to test the machine, you should test it with human subjects to make it...

A If you're going to use it on human subjects; yes, sir.

MR. JAEGER: Thank you very much.

MR. HYMAN: No further questions.

THE COURT: You are finished. Thank you.

THE WITNESS: Thank you. That's beyond the call of duty.

THE COURT: We love it.

So we're at the 6 o'clock hour. I guess we're quitting.

MR. HYMAN: We would -- we have one more witness we would like to call.

THE COURT: Well, you've got three minutes.

MR. HYMAN: Okay. We'll do the three-minute drill.

THE COURT: Actually, you have a minute and a half, because the State has a minute and a half.

(Pause)

MR. WOOTEN: The only question I have is, am I starting Monday morning.

MR. HYMAN: My question is, has his testimony changed from the last time he testified?

THE COURT: All right. You can ask that one question or can we stipulate the answer as no? Is that what...

MR. HYMAN: Yeah, his feelings about those documents that are in Evidence are the same.

THE COURT: We all agree on that or do you want to cross-examine him on that?

MR. WOOTEN: Well, which part?

THE COURT: Any part.

MR. WOOTEN: How long did he testify last time?

THE COURT: I don't know.

JUDGE MILLER: What does that have to do with anything?

MR. HYMAN: Well, the Rules of Evidence is relaxed. We'll introduce the transcripts.

JUDGE MILLER: That's why I asked the question before. So you-all have a nice weekend.

THE COURT: Yes, we are starting Monday. Now, you've got to have everything you want to put into Evidence marked, all your curriculum vitaes and present it to the Defense when you arrive.

MR. WOOTEN: Okay.

WHEREUPON: These proceedings were concluded at 6:00 p.m.

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C E R T I F I C A T E

STATE OF FLORIDA:

COUNTY OF ORANGE:

I, DIANE S. HEBEL, being a Digital Court Reporter as authorized by Rule 2.070(c), Florida Rules of Court and Administrative Order of the Ninth Judicial Circuit numbered 07-98-43, certify that the foregoing transcription is true and correct.

Dated this 11th day of February 2009, in the City of Orlando, County of Orange, State of Florida.

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DIANE S. HEBEL
Digital Court Reporter