County Court, Jefferson County, State of Colorado Jefferson Combined Court 100 Jefferson County Parkway Golden, CO 80401-6002 THE PEOPLE OF THE STATE OF COLORADO, Plaintiff, v. XXXXX XXXXX, Defendant.	COURT USE ONLY
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OFFER OF PROOF IN ADVANCE OF AUGUST 10 DISCOVERY HEARING	

Defendant, XXXXX XXXXX, provides this offer of proof in advance of the August 10, 2012 discovery hearing.

1. Defendant has filed a Motion to Compel Discovery or, In the Alternative, to Dismiss the Charges and a Brief in Support of the Motion (collectively "Motions").

2. This Court scheduled a hearing for August 10, 2012 to address Defendant's Motions.

3. The defense has endorsed Janine S. Arvizu as an expert witness in this case. Ms. Arvizu is a chemist and laboratory quality expert who will testify at the hearing about why the requested materials should be provided to the defense in light of the problems at the Colorado Department of Public Health and Environment ("CDPHE") lab.

4. Defendant's Motions request items in Paragraphs 1 through 51. *See* Request for Specific Discovery. Ms. Arvizu will testify about the significance of the requested materials. By way of an offer of proof, Ms. Arvizu explains the importance of some of the items in this Offer of Proof.

During the hearing, she will testify about the significance of each item and why it should be provided to the defense in light of the problems at the CDPHE lab:

1. Produce a copy of the validation study for the blood alcohol method used to analyze evidence in the subject case. Produce a copy of the complete validation file, including scope and approach of the empirical design, assumptions, raw and processed data, results, statistical analysis of data, conclusions, and uncertainty. If the laboratory relies on external method validation, produce a copy of all relevant references, and a copy of the laboratory's internal verification records documenting the empirically determined performance characteristics for the method.

Ms. Arvizu: *Scientists all over the world agree that before a laboratory method is used to test unknown samples, the scientists MUST test the method so that they understand whether the method will give them the answers that they need. When a scientist tests a method to figure out whether the method can be used to analyze particular samples, it is called "method validation." If a scientist wants to analyze blood samples to find out how much ethanol is in them, then the scientist has to use a method that has been validated.*

To validate a method, scientists go into the laboratory and run a whole bunch of tests using blood samples that have had known amounts of ethanol added to them. They are trying to figure out how well the method works, and what kind of things cause problems for the method (if a method has interferences, the scientist needs to know about it so those interferences can be avoided). At the end of a validation study, the laboratory should have a whole bunch of data that describes the performance and the error rate of their method. Then, and only then, a laboratory can use the method to analyze an unknown sample.

All over the world, scientists require methods to be validated before they are used to analyze unknown samples. Method validation isn't optional; it is required in both national and international standards. The scientific community believes that method validation is required for scientifically valid results.

2. Produce a copy of the validation and verification records of any laboratory-prepared or laboratory-revised software, or any data processing applications (e.g., Excel templates) used to process, summarize, or report blood alcohol data.

Ms. Arvizu: *Sometimes, laboratories use computer applications to process the data that they get from an instrument during the analysis of samples.*

3. Produce a copy of the laboratory's approved blood alcohol Standard Operating Procedure that was in effect at the time the subject casework was performed, as well as a copy of the procedure that was superseded by the approved version used to perform the subject casework. If any aspect of the blood alcohol testing method was addressed in separate procedures (e.g., sample preparation, instrument calibration, quality control), produce copies of those procedures.

Ms. Arvizu: *Scientists know that they have to write everything down. When a lab runs the same method over and over again, it would be a real nuisance to have to write the same steps over and over again. Instead of developing writer's cramp, laboratories use written procedures, called Standard Operating Procedures (SOPs). These SOPs are like the recipe for a laboratory's method. An SOP describes all the steps in the test, and it includes instructions for all the little tips that the scientists have learned to make the method work well. The SOP explains what should happen when the method works right, and it explains how to tell when the method has failed, and the results should not be used.*

Written procedures that have been formally approved by a laboratory's managers are not optional; they are required by quality standards. In order to be accredited, a laboratory must have written procedures so that the laboratory's work can be reviewed.

4. Produce a copy of the laboratory's Quality Manual (however named) that was in effect at the time the subject casework was performed.

Ms. Arvizu: *If a procedure is like the recipe for an analytical method, then the laboratory's Quality Manual is like the kitchen rules. The Quality Manual describes policies and practices for everything that goes on in the laboratory. It describes how the laboratory makes sure that the people who work there are qualified, how the laboratory itself is operated and maintained, how purchases of important materials are made, how the laboratory equipment is operated and maintained, and how results are reported.*

5. Produce a copy of the blood alcohol laboratory's nonconformance reports, however named, documented during the period 2010-2012.

Ms. Arvizu: *Even at the very best laboratories, things don't always work smoothly. Sometimes people make mistakes. Sometimes, for a variety of reasons, an analysis doesn't work the way it should. As part of a quality system, scientists in laboratories write down a description of these problems, or nonconformances (they get called a lot of different names; for example: excursion reports, event logs, or nonconformance reports). Sometimes it takes a long time, and a lot of nonconformances, before a lab can figure out what was really going on with a problem, and what was causing it.*

6. Produce the laboratory's internal audit schedule for the five year period ending with the year in which the subject testing was performed, along with the scope of each scheduled audit.

Ms. Arvizu: *Every year, laboratories are supposed to carefully inspect everything that they do to make sure that their results are technically correct, and to make sure that their work in the laboratory isn't causing any problems. These annual inspections are called "internal audits" and they are required by quality standards (and for accreditation).*

All the sections of the laboratory that participate in blood alcohol testing should be scheduled for annual internal audits. This would include: evidence management; toxicology; and standard

preparation.

7. Produce copies of all internal and external audit reports generated during the five year period ending with the year in which the subject testing was performed, along with documentation demonstrating the closure or status of each finding.

Ms. Arvizu: *A laboratory's internal audit records can paint a very accurate picture of how well a lab works. If a laboratory has a strong quality program, it shows in the audit report. And if a lab has a weak quality program, it shows in the audit report.*

It is important to look at audit reports over time, to see whether the laboratory doesn't just fix the problem, but is able to prevent a problem from happening again.

8. Produce a copy of the ASCLD-LAB standards that served as the basis for the laboratory's accreditation in effect at the time the subject testing was performed.

Ms. Arvizu: *When a laboratory is accredited to a particular written standard (such as ASCLD-LAB), the laboratory is committed to following all the rules that are described in the standard. Since the ASCLD-LAB standards aren't generally available (they are only provided to labs who are applying for accreditation), the lab needs to provide a copy of "their" standard if they expect to get credit for their accreditation to that standard.*

9. Produce a copy of the laboratory's original ASCLD-LAB application for accreditation, and copies of all subsequent correspondence between the lab and the accrediting agency or its inspectors; including: annual reports, formal or informal communication, email, and contemporaneous notes of meetings.

Ms. Arvizu: *One of the ways that a laboratory can demonstrate that their work is acceptable is by getting accredited by a third party agency. These accrediting agencies (like ASCLD-LAB) review materials and conduct an on-site audit to see whether the laboratory meets the requirements of their standard.*

10. Produce a copy of any accreditation or certification received by the laboratory or the responsible analyst from any independent agency or organization (other than ASCLD-LAB).

Ms. Arvizu: *If a laboratory has been accredited by an independent agency, or if the analyst has been certified as competent, the people who use the lab's results should know about it. This is a chance for the lab to spread the good news and get credit for their good work, if they have it.*

11. Produce any and all documentation with respect to any Quality Control or corrective action investigations of laboratory operations conducted by the crime lab itself, state agencies, certifying organizations, ASCLD-LAB, or any other entity or agency and the results thereof.

Ms. Arvizu: *Labs that perform poorly or that have ethical problems are often investigated. The investigation may be started by anyone who feels affected by the problems, but labs may not volunteer the fact that they've been investigated. People who use lab data shouldn't find out about an investigation by reading about it in the newspaper – the lab should voluntarily provide the information.*

12. Produce a drawn to scale floor plan of the entire laboratory facility, with areas of the laboratory relevant to blood alcohol testing identified (i.e., blood sample storage, blood sample preparation, headspace GC analysis, report preparation); include the actual staffing headcount assigned to the laboratory (numbers of technical, management, and support personnel) at the time the subject testing was performed.

Ms. Arvizu: *When you are trying to figure out whether a laboratory has problems with contamination of their samples, one of the things you need to look at is how the lab is laid out, which labs are located where, and what kind of work is done in different places. You need to know how people and samples move through the lab. For example, sometimes the floor plan means that a laboratory room functions like a hallway (e.g., the only way to get to a given room is to pass through another room. This can create interruptions (a very bad idea when placing a very small vial in the wrong very small hole means the results will be completely (and invisibly) wrong), and it can cause contamination (e.g., transporting solvents through a room where blood alcohol samples or standards are processed can be a problem).*

Ethanol is a volatile organic compound – that means it likes to be in the gas phase, and it moves through the air. And laboratories use a lot of volatile organic compounds. By seeing the laboratory's floor plan, it is possible to tell if work that could cause problems is performed in the area where blood alcohol samples are stored or prepared or tested.

If the lab doesn't have a floor plan, they can always provide a tour of the lab. A quick tour of the lab could be used instead of a floor plan.

13. Produce a description of the laboratory's HVAC (heating/ventilation/air conditioning) system, with emphasis on air flow directions, conditioning of intake air, identification of areas of positive and negative air pressure, and the total number and operating capacity of exhaust hoods.

Ms. Arvizu: *When you build a laboratory, more than half of the cost goes for the design and construction of the HVAC system. Unlike our houses and offices, laboratories have a lot of air moving through them. This is one of the ways that we keep the working air safe for the people who work in labs. But having all that air moving around means that it provides a route for moving airborne contaminants – and that can be a problem for a lab doing testing for volatile organics – like ethanol.*

14. Produce a copy of the laboratory's procurement and receipt records for gloves used by analysts during the period one year prior to performance of the subject testing.

Ms. Arvizu: *Laboratory analysts use gloves for two reasons. First, they use gloves to protect themselves from the chemicals and the samples that they use. Second, it is just as important for laboratory analysts to use gloves to protect the unknown samples that they are testing. This means that analysts have to change their gloves many times during the day. For example, to prevent contamination, an analyst should change gloves after they handle a high concentration sample (this helps avoid transferring a contaminant to a low level sample). One of the ways to tell whether analysts are changing their gloves when they need to is to watch them working in the lab (and of course, that would be a welcome option!!!). Another way to tell whether analysts are changing their gloves as often as they need to is to see whether the number of gloves they are using lines up with the number of analysts and the number of samples.*

15. Produce a copy of the laboratory's contamination control policies and procedures applicable to blood alcohol testing. If formal procedures are not available, produce a copy of any relevant guidelines, memoranda, instructional materials, or other documentation.

Ms. Arvizu: *Often, when they are asked to provide a copy of their contamination control policies and procedures, laboratories provide a copy of their health and safety plans. It is a good thing that they have safety plans, because that is how a laboratory protects its people. But a safety plan is NOT a contamination control plan. Contamination control policies and procedures describe how a laboratory protects its samples, so that the sample that gets analyzed has the same composition as the sample that was received. For blood alcohol samples, a contamination control plan should deal with things like: storing samples separately from standards; processing high concentration standards separately from samples; keeping samples and standards stored under refrigeration; requiring analysts to change gloves between handling standards and samples; and rules for disposing of empty standard bottles.*

16. Produce records documenting the scope, approach, and results for any environmental monitoring performed in the laboratory to assess volatile organic contaminants in the ambient air.

Ms. Arvizu: *Laboratories that are in the business of identifying volatile organics in unknown samples need to periodically check the air in their laboratory to see whether volatile organics are present. This kind of check should be done during normal working conditions, because that is when samples are processed, and that is when airborne contaminants could be introduced to the samples.*

17. Produce a copy of the laboratory's procedure or any available written instructions or guidelines for verification and use of externally purchased controls, calibrators, or internal standards for blood alcohol testing.

Ms. Arvizu: *Laboratories often buy standard reference materials from outside companies. These reference materials (they are solutions of known purity, that come with a certificate of analysis) are used to prepare the solutions that are used to calibrate the instruments (calibration*

standards), and to check the performance of the method (quality control solutions). Under quality standards (the rules for laboratory accreditation), laboratories are required to check these materials, and make sure that they are acceptable before they are used to analyze unknowns. Every lab should have a written procedure that describes the steps to verify these materials, and that sets the pass/fail grades that the materials have to meet before they are used.

18. Produce a copy of the laboratory's procedure or any available written instructions or guidelines for preparation and verification of internally prepared controls, calibrators, and internal standards, and samples for blood alcohol testing.

Ms. Arvizu: *Laboratories sometimes prepare their own reference materials. Just like externally purchased materials (see item cc)), these reference materials (solutions prepared in the lab from primary standard chemicals) are used to prepare the solutions that are used to calibrate instruments (calibration standards) and to check the performance of a method (quality control solutions). Under quality standards (the rules for laboratory accreditation), laboratories are required to check these materials, and make sure that they are acceptable before they are used to analyze unknowns. Every lab should have a written procedure that describes the steps to verify these materials, and that sets the pass/fail grades that the materials have to meet before they are used. If these materials aren't tested before they are used, the lab shouldn't rely on them to have the "right answer."*

19. Produce laboratory production data for blood alcohol testing: number of blood alcohol tests received per month the year the subject samples were tested, and the number of analysts qualified to perform blood alcohol testing during the same period.

Ms. Arvizu: *Some labs operate like scientific production lines, with lots of qualified analysts analyzing and reporting batches of results, each and every day. In other labs, one or two analysts might set up a single instrument to run blood alcohol tests every week or two. When it comes to consistently producing high quality results, each of these extreme situations has its own challenges.*

20. Produce a list of gas chromatograph instruments (manufacturer/model/serial number/software version) and accessories (headspace autosampler) in use for blood alcohol testing at the time the subject testing was performed.

Ms. Arvizu: *When we review data, we need to know specifically what instrument was used to generate the results. This is because different instruments perform differently (e.g., a Volkswagon and a Ferrari are both vehicles, but they perform dramatically differently). So we need to know the serial number for each instrument to be able to know which results came from which instrument. And which maintenance was performed on which instrument.*

21. Produce resumes for each of the individuals responsible for receipt, storage, preparation, testing, or technical review of blood alcohol samples in the subject case.

Ms. Arvizu: *Everyone in a laboratory who touches a sample needs to be qualified to do their job. That is because every single person who touches a sample can do their work right, or they can cause problems. And problems in handling or storing, or analyzing a sample can mean that the results are not reliable.*

22. Produce a copy of the original and each succeeding analyst permit or certification issued pursuant to state regulations; include documentation as to whether or not the responsible analyst has ever had his or her permit or certification suspended, canceled, or revoked.

Ms. Arvizu: *Just like you have to have a driver's license to drive a car, in most states, you have to have a permit or a certificate to show that you are allowed to analyze a blood alcohol sample. The person who analyzes a forensic blood alcohol sample must have a valid permit when they test a sample. And just like a driver's license can be revoked, an analyst's permit can be revoked. If an analyst's permit isn't current and valid, their work isn't allowed.*

23. Produce records demonstrating the qualifications of the responsible analyst and technical reviewer in the subject case; include a copy of employment applications, academic transcripts, disciplinary files, training records, and personnel files. Redaction of personal information from the requested public records is acceptable.

Ms. Arvizu: *Some of the people who test blood alcohol samples aren't really scientists. They may have learned how to push the buttons to operate the GC instrument, but they don't have the scientific training and experience to understand how the method works. Often, particularly for people who majored in something other than chemistry (e.g., there are a LOT of biology majors trying to do chemistry in forensic labs, and you can get a biology degree without taking more than an introductory chemistry class) they may never have even seen a GC instrument during their college studies, much less learned the theory behind chromatography. And some of the people working in forensic labs did poorly in college.*

Laboratory auditors look at whether there is evidence that the people who work in a lab are qualified for the work they are doing. One of the important ways of doing this is to look at their personnel records. Some lab workers have lied about having a degree. Some lab workers have been disciplined for poor performance or unethical behavior. Some lab workers have not completed required training.

Unless the records prove that an analyst is qualified, the fact that they were hired to do the job doesn't prove anything. A lab coat and gloves don't make you a scientist.

24. Produce a copy of all internal and external proficiency records from the five year period ending with the year in which the subject testing was performed for the responsible analyst and technical reviewer in the subject case; include sponsoring agency(ies), date(s) performed, procedure used, true values, reported results, raw data, scores, all related correspondence, and corrective action records, as appropriate.

Ms. Arvizu: *The people who analyze blood alcohol samples are required to analyze proficiency*

samples every year. These proficiency samples are prepared by someone else in the lab (internal proficiency samples) or they are purchased from an outside company (external proficiency samples). In either case, the people who made the samples know how much ethanol is in them, but the analyst who has to run them doesn't know the right answer (this is called "blind" samples; the right answer is "blind" to the analyst). The analyst isn't supposed to do anything special to improve their chances of getting the right answer (say, running the sample on two different instruments); they are supposed to run these proficiency samples the same way they run the everyday blood samples.

If an analyst always gets the right answer on proficiency samples, it can show that they are capable of getting the right answer.

However, labs do better on tests than they do on real world samples. When a lab knows that a sample is a proficiency sample, and not just a regular old blood sample, their work is better. There have been lots of studies that have shown that labs do worse on proficiency samples if the samples are "double blind." In double blind studies, the proficiency samples come into the lab just like their regular samples, and neither the lab nor the analyst knows that they are anything except a normal sample. When a lab doesn't know they are being tested, their results are worse.

Even if an analyst has failed a proficiency sample, you wouldn't necessarily know it if the lab only reports a summary of overall performance. This is because under many proficiency schemes and state-run programs, an analyst's first proficiency failure doesn't count. This is why you need ALL the proficiency records to understand how an analyst has really performed.

25. Produce evidence intake and control records, including: evidence receipt log (documenting sample volume, labeling, and security); field-to-lab custody transfers; intra-laboratory custody records for evidence and derived analytical samples; initial assignment of laboratory identifiers (written and/or electronic); storage locations; and documentation of temperature in sample storage locations.

Ms. Arvizu: *A laboratory can only analyze what is in the sample tube that it receives. And the laboratory's results are only reliable if what is in the tube is the very same as the sample that was collected someplace else. Laboratories that run blood alcohol samples are like science on a production lab – they receive and run a lot of samples. This means that it is extremely important that the laboratory have very good systems for keeping track of exactly what they receive, and for making sure that each and every sample is labeled the right way, and each and every sample is stored the right way (in a refrigerator separate from standard solutions). There can't be any guesswork, and we can't simply assume that a sample with a smeared label "must be the one I think it is." The lab has to have records to prove that the sample that they analyzed was absolutely positively the same sample that was collected in the field, and nothing happened to that sample that could have mixed it up or let it get too hot.*

26. Produce documentation of the disposition of tested case samples; include documentation of the interim storage condition and current status of any untested case samples.

Ms. Arvizu: *Every lab should have records that describe everything that ever happened to a*

sample. This is called "cradle-to-grave" documentation. The lab should have records that tell everything that has happened to every sample they have ever received. If two tubes of blood were collected from someone, and only one of the tubes was tested, there should still be an unopened tube of blood. And they should have records to tell whether it has been stored in a refrigerator (and could still be tested), or whether it has been stored at room temperature (remember the rule for sample quality: low temperature is good and high temperature is bad).

27. Produce copies of all internal and external communication regarding the subject case, including telephone logs, facsimiles, e-mails, records of conversation, and any other record documenting the parties to and substance of communication regarding the subject case.

Ms. Arvizu: *People who analyze blood alcohol samples sometimes make their decisions about how or when to analyze a certain sample after they get advice or requests from a law enforcement officer involved in a case. Any communication that influences the analyst is part of the complete picture of what happened to the sample, and why it happened.*

Analysts who have problems when they are running samples sometimes contact their supervisor to ask for advice. Sometimes, this kind of a record is the only hint that the first time they ran a sample, it didn't work.

28. Produce copies of bench notes, log books, and any other records pertaining to case samples, instruments used during testing, or methods used to analyze case samples.

Ms. Arvizu: *Every lab collects and records information in different ways; forms to collect the same kind of information are called something different in different laboratories (e.g., these could all be the same thing: receiving record; inventory logsheet; laboratory worksheet; analyst log; batch preparation form; and so on and so on). This request is an effort to obtain any information about the work done on a client's sample, whether or not it fits in any of the other categories.*

29. Produce source, preparation and usage records documenting the traceability and shelf life of standard materials and solutions used for calibration and quality control in the subject case, including: unique identification of stock, parent, and working solutions; external source of purchased materials; records documenting composition, preparation, concentration and origins of internally prepared solutions, including solutions prepared from purchased standards and stock; records documenting dates of use of purchased and prepared materials; certifications provided by suppliers; storage conditions of standards and controls; and shelf life of purchased and prepared solutions (provide the empirical basis for determination of shelf life for prepared solutions). Produce traceability documentation for the thermometers in the refrigerator(s) used to store samples and standards.

Ms. Arvizu: *This is a list of items that describe the details of the day-to-day workings of an analytical laboratory. Basically, these items are used to prove whether the calibrators (the solutions that are used to calibrate the instrument) and the controls (the quality control solutions that are used to check whether or not the method is working) were OK when they were used.*

For ethanol calibrators and controls, it can be tricky to be sure that these solutions are good when you use them. Even if you buy the highest quality standard solutions, the lab still has to prove (with traceability records) that they stored them the right way (in the dark and at 4 degrees Centigrade), used them within their shelf life (just like we rely on the expiration date to avoid drinking spoiled milk, we rely on the manufacturer's shelf life to avoid using spoiled standards), and prepared them the right way (making very careful dilutions using calibrated volumetric glassware).

And a word about the word: traceability. It simply means that the lab has the records to prove, in detail, that everything they used was proper when they used it. Traceability isn't something that a lab can choose to ignore. It is required by quality standards and accrediting agencies.

When you hear on the news that they recalled a batch of ground beef or a bunch of lettuce, you might wonder how they know which states got all the tainted groceries. Their manufacturing is traceable, by lot. If a big lot, or batch of hamburger is tested and found to have E. Coli in it, then they can use the lot number to know all the affected packages. In much the same way, if a reference material is found to be a problem, we can trace it through its lot number.

30. Produce documentation of the laboratory's storage conditions for the standards and controls used in the subject casework, for the period from the initial date of receipt through the date of the subject analysis; provide a procedure describing practices for storing standards and controls (if available); provide a description of the materials that are co-located under refrigerated conditions with standards and with unknown samples.

Ms. Arvizu: *During analysis of a typical blood alcohol sample, a laboratory uses a large number of standards and controls. These solutions contain ethanol at different concentrations, and these solutions MUST be of known purity in order for their analysis to be reliable. Ethanol in solution isn't stable. This means that we have to be very careful to store and use these solutions under carefully controlled conditions. If a container is open to the air, ethanol will evaporate, and vaporize into the air, leaving the solution with a lower ethanol concentration. Or microbes can get into the sample (the same way they get into soy milk after you open the carton) and cause fermentation. And after a shelf life has expired, we should not use a solution. Just like we should not feed our children milk that is past its expiration date.*

The manufacturers of reference materials specify their storage and use conditions. They set conditions for temperature (stored under refrigeration), storage conditions (protect from exposure to light), and shelf life (the unopened containers are given an expiration date). Because the standards and controls are so critically important to the reliability of results, we shouldn't just assume that a lab stored and used them the way they were supposed to.

If the lab didn't store these solutions properly, their concentrations aren't reliable, and the results of the analyses that used them aren't reliable. To calibrate the instrument, a lab may use

three to five solutions of ethanol, with each solution having a different concentration. And a lab may use three to six different controls samples during an analysis. A lab should be able to prove that each and every one of these solutions was properly stored during the entire time it was in the lab, and they should be able to prove that each and every solution was used within its shelf life.

31. Produce copies of product inserts provided by manufacturers for purchased standards and controls used in the subject casework.

Ms. Arvizu: *When a lab uses purchased standards and controls, the true value of the ethanol concentration of those solutions is provided by the manufacturer, along with the manufacturer's instructions for the storage and use of the solution. In order to tell whether a lab followed the rules, we need to see a copy of the manufacturer's documentation that sets the rules.*

32. Produce contemporaneous records documenting preparation of all solutions, standards, and controls used in the batch in which the subject case samples were tested.

Ms. Arvizu: *Laboratories often prepare dilute solutions from concentrated standards. The details of how they made their dilution should always be documented. For example, it should describe how 250 microliters of a 1000 mg/l stock solution was pipetted into a 1.00 liter volumetric flask and diluted to volume. When a lab writes this down, it is like showing your work in a math class. Just like showing your work helps you find problems, this makes it possible to tell when a lab made a calculation error.*

33. Produce records documenting the verification of the standards and controls used in the batch in which the subject case samples were tested; for both purchased and prepared solutions, provide verification data for testing performed prior to use.

Ms. Arvizu: *Before you use a new lot of a reference material, quality standards (the national consensus rules for laboratories) say that you must test the reference material to be sure it is acceptable. This is because reference materials are so important to the reliability of results, that we have to be sure that they are correct before we use them. We should never just assume that the reference material is OK; if we test it then the verification data can prove that it was OK.*

34. Produce all GC calibration records relevant to the subject case (*e.g.*, as prepared, and as determined values for initial and continuing calibrations applicable to case samples; as prepared and as determined values for second source calibration check samples; empirical data for verification of internal standard solution).

Ms. Arvizu: *Calibration is the way that scientists teach a gas chromatograph (GC) instrument how much ethanol gives how much of a peak. There are a lot of ways to calibrate an instrument, and the lab has to explain how they did it so other scientists can tell whether their work is reliable.*

There are a lot of rules about calibration, and the lab has to provide their calibration records in order to tell whether they followed the rules. Without an accurate calibration, it is impossible for the instrument to tell how much ethanol is in a sample.

35. Produce pipettor/diluter calibration and verification records for the instrument used to prepare samples, calibrators, and controls for the analytical batch that included the subject samples; if calibration verification is performed at least monthly, provide all calibration records for the two year period that includes the subject testing; if calibration is performed less frequently than monthly, provide all calibration records for the instrument from the time the instrument was placed in service.

Ms. Arvizu: *GC methods that analyze blood for the presence of alcohol usually use what is called an internal standard technique to figure out how much ethanol is in a sample. In this technique, an identical amount of an internal standard (like n-propanol) is added to each and every sample in the batch – even to the blanks and the control samples. When we run the samples and get the chromatograms, we can compare the size of the ethanol peak to the size of the internal standard peak to calculate the concentration of ethanol. It's a pretty handy technique to use, but it absolutely positively depends on the assumption that you added EXACTLY the same amount of internal standard to each and every sample. If you measured out a different volume of internal standard into some of the samples, the results will not be accurate.*

When you use the internal standard technique to figure out how much of something is present, it is essential that you know how precisely you are able to measure out the internal standard and the sample. Most forensic labs use a piece of equipment called a pipettor-dilutor to measure the samples and internal standards. This means that they have to be able to prove that their pipettor-dilutor was performing properly.

36. Produce instrument maintenance and repair logs and records for the instruments (e.g., gas chromatograph and pipettor/diluter) used to perform the subject testing, for the two year period ending with the date of the subject testing.

Ms. Arvizu: *If you are going to buy a used car for a road trip, it would be a good idea to check its maintenance records, to see whether it is a lemon. Lab equipment is kind of like that. If you are going to rely on the results generated using a particular piece of equipment, you want to know whether it was a reliable performer, or whether it had frequent and/or serious problems.*

37. Produce all balance calibration verification and quality control records relevant to any balance used in support of blood alcohol testing (e.g. preparation of standards) for the two year period ending with the date of the subject testing; include records for calibrated weights, documenting their ASTM class and traceability.

Ms. Arvizu: *Just like we have to be sure that our instruments were working properly, and our standard solutions were of acceptable quality, we need to be sure that the equipment that was used was calibrated, and performing properly when our work was done. In a laboratory,*

analytical balances (basically, these are very fancy scales that allow us to weigh very small amounts) may be used to weigh out the materials to prepare standard solutions (calibrators or controls), and they may be used to check the performance of other equipment (such as a pipettor-diluter).

Analytical balances are capable of great accuracy and precision, but they are also subject to a long list of complications. Among many other things, their performance can be affected by temperature changes, changes in humidity, being even a tiny bit off-level, or any movement or bump against the counter that they sit on. Labs need to periodically have their balances calibrated, and they need to check the performance of a balance before they use it to make careful mass measurements.

38. Produce instrument or equipment run logs (sometimes called injection logs or load lists) for the instrument(s) used on case samples on each day(s) case samples were tested, including identification of all unknown samples and controls.

Ms. Arvizu: *Laboratories generally don't analyze samples one at a time; it's just not practical. Instead, labs will group a bunch of samples together in something called a batch. For a GC run of blood alcohol samples, all the samples in a batch are prepared and placed on the tray of a robotic autosampler. The samples are loaded on this tray in a particular order. It will usually start with the calibration samples. If the calibration results are acceptable, then the rest of the samples can be analyzed. Often this happens automatically, after the analyst has left work for the day. The samples in the batch will include quality control samples (samples that the analyst prepared that have a known concentration of ethanol) and unknown subject samples (the forensic samples). The run log describes every sample in the batch, as well as the order in which the samples were analyzed.*

The run log helps us understand whether the lab used the right number and type of quality control samples, and whether the order that samples were analyzed was appropriate.

39. Produce raw and processed data for each analytical batch run that included samples from the subject case; include sample and instrument specifications, and chromatograms for all calibration, quality control, and unknown samples, <u>including</u> all data excluded or not reported by analyst. NOTE: names of sample donors may be redacted, as long as the subject's sample(s) is(are) explicitly identified.

Ms. Arvizu: *Raw data are the data generated by the instrument for the entire analytical batch. And this should include a detailed description of the instrument operating conditions (things like how hot was the oven, how much sample was injected, and how much gas was flowing through the instrument).* <u>*Without being able to see the raw data, there is absolutely no way of knowing where in the world a laboratory got its results.*</u>

Sometimes, labs don't want to provide the data for <u>*all*</u> *the samples in a batch. Scientifically, this doesn't make any sense. When we batch samples together, we are taking advantage of the fact that the performance of the method on known samples from the batch should be similar to the performance of the method on unknown samples. This is because as much as possible, all the*

samples in the batch are processed using the same methods, and the same reagents, by the same analyst, using the same instrument, operating under the same conditions. If there are problems with one of the samples in the batch, we have to review the data carefully to see whether the other samples were also affected. This is why within the lab, data reviews are done for the entire batch. And this is why a lab should provide ALL the data from the batch for review.

40. Produce an electronic copy of the raw and processed data for the batch(es) that included the subject case, along with the specific version of instrument software used to process the data.

Ms. Arvizu: *Electronic data files with GC raw data can be manually edited by an analyst. This is scientifically appropriate and entirely reasonable for qualified analysts (these analysts document what they did and why they did it). However, analysts have been known to manually edit electronic data files in a way that is not scientifically reasonable, just to make their work look better than it is. And some analysts have edited electronic data to make it look like they had results for a sample, when it was never tested.*

By getting a copy of the electronic data file for a batch, we can tell whether the data were manually edited by the analyst.

41. Defendant also requests the items in Paragraphs 41 through 51 in its Motion, which will be discussed during the hearing.

Respectfully submitted,

Dated: September 6, 2012

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CERTIFICATE OF MAILING

I certify that on 08/01/2012 the above-titled Offer of Proof was filed with the Court by [X] mail using the United States Postal Service or [ ] personal delivery to the below address; and a true and accurate copy was served on the First Judicial District Attorney's Office by mail using the United States Postal Service to: 500 Jefferson County Pkwy., Golden, CO 80401.

Jefferson County Court
Division B
100 Jefferson County Pkwy.
Golden, CO 80401

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