ANALYST'S NOTEBOOK

SPRING 1993

California Water Pollution Control Association-Laboratory Training Committee

FEATURE ARTICLE

LEGAL DEFENSIBILITY: SERVING YOUR CLIENT'S NEEDS

by Diane Lawver

The following article is an excerpt from a presentation given at the San Francisco Bay Section Quality Assurance Committee meeting March 17th by Ms. Lawver of Sequoia Analytical, 415-364-9600.

I would like to make clear that the focus of this talk will be general. Even though I am from a commercial laboratory, the ideas presented here are applicable to internal wastewater laboratories as well as to those organizations who use data from a commercial laboratory.

Finally, I would like to give a personal opinion about generating legally defensible data. The way to prove your data is defensible is by being able to assemble data packages that document raw data and summarize all your measures. You must prepare for generating data packages much the same as you would prepare for a fire, earthquake or any natural disaster. It takes pre-planning and practice to assure success.

The process for preparation is basically the following:

Step 1 EVALUATION/AUDIT
FOR SYSTEMS THAT WILL PRODUCE LEGALLY DEFENSIBLE DATA SUCH AS INTERNAL AND COMMERCIAL LABORATORIES.

Step 2 CORRECTIVE ACTION
IN THIS PHASE YOU EVALUATE THE DEFICIENCIES AND DEVISE SYSTEMS THAT WILL OVERCOME THOSE DEFICIENCIES AND IMPLEMENT THOSE SYSTEMS.

Step 3 DATA PACKAGE DEVELOPMENT
ATTEMPT TO PRODUCE DATA PACKAGES ON SELECTED METHODS FOR BOTH INTERNAL AND COMMERCIAL LABORATORIES.

Step 4 DATA VALIDATION
HAVE PACKAGES FROM YOUR INTERNAL LABORATORY AND COMMERCIAL LABORATORY VALIDATED.

Step 5 CORRECTIVE ACTION
EVALUATE DEFICIENCIES FROM THE VALIDATION REPORTS AND IMPLEMENT CORRECTIVE ACTION.

continued on page 3...

OPERATIONS AND LABORATORY

DELTA DIABLO'S LAB TRAINING FOR OPERATORS

by Ricardo Cruz

Delta Diablo Sanitation District has developed a training program for plant operators related to test procedures used for process control and NPDES monitoring with emphasis on quality assurance and control (QA/QC) and safety.

The original program was developed for two major reasons: to comply with federal law (Laboratory Standards: Chemical Hygiene Plan) requiring employers to implement measures to protect laboratory workers from exposure to hazardous/toxic chemicals and to promote sound QA/QC practices among laboratory workers as prescribed in the State Department of Health Services Environmental Laboratory Accreditation Program (ELAP).

Both criteria are incepted into the standard operating procedures (SOP) for the operators by putting a section in the procedure on safety whenever there is a potential hazard involved in performing a test or an activity such as sample collection. Part of the training is a review of the MSDS's for all chemicals used in the test. During the review, the hazardous chemical is identified, safety precautions and personnel protective equipment (PPE) emphasized, and, in case of exposure, course of action defined.

After satisfactory completion of each step of training, both trainer and trainee sign a checklist. Upon completion of the four-day program, the trainee receives a certificate of completion from the District Board of Directors. To date, eight operators have successfully completed the program.

Cleo Hartman of the State Water Resources Control Board's Office of Operator Certification evaluated our training program and awarded 3.2 education points for wastewater treatment plant operator certification to each person who successfully completes the training.

SAFETY SPOTLIGHT

CHEMICAL SAFETY IN A NUTSHELL

THE RIGHT ATTITUDE
Commitment from every single member of the laboratory is essential to making chemical safety management work.

KNOW YOUR OPERATION
Know the hazards of the materials you work with and of your equipment. Identify safety requirements and existing capabilities and weaknesses. Correct the problems and implement appropriate procedures and practices.

REDUCE YOUR HAZARDS
Find ways to make your operation safer. You could reduce your inventory of hazardous substances, find less hazardous substitutes, or change your processes.

PEOPLE ARE THE KEY
Train your lab personnel in proper procedures and practices, develop task requirements for employees and contractors, and update training to keep up with changes.

TAKE CHARGE OF CHANGE
Any change in one part of your operation may affect other parts. Plan accordingly.

PROTECT YOURSELF
Keep equipment in top shape, inspect and maintain it faithfully, conduct regular safety reviews, and have a working emergency action plan and appropriate emergency equipment available.

LEARN FROM MISTAKES
Investigate accidents and near-accidents, determine the causes, and make whatever changes are necessary to prevent them from happening again.

ONCE IS NOT ENOUGH
Managing chemical safety is a continuing process. It's not a document on a shelf; it's an everyday part of running your laboratory successfully.

(from EPA's "Managing Chemicals Safely")

FOOTNOTES

WHAT does "USEPA-Approved" MEAN?

Instruments: With regard to instruments, this phrase means that the instrument can be used for testing when results are to be reported. It does not mean the USEPA approves or disapproves specific laboratory or on-line instruments.

However, the USEPA may establish minimum instrument design and performance criteria. For example, for turbidity measurements, minimum instrument specifications for turbidimeters are detailed in USEPA Method 180.1, paragraph 5.5. All turbidimeters meeting this criteria can be used for reporting purposes.

Methods: With regard to test methods, "USEPA-Approved" means the procedure meets all the requirements of the applicable USEPA approved method or has been approved as

continued on page 6...

KEYS TO SUCCESSFUL LABORATORY PLANNING

Know yourself. Understand what your needs are (such as space, storage, electrical) in each laboratory section.

Include lab personnel in planning. No one knows what they need for success more than the individual lab analysts.

Design in "flexibility". Determine which areas may need changes, evaluate the extent of the changes, and build-in flexibility in important areas.

Request a "Basis of Design" report. A lab has so many design parameters (such as equipment power requirements) that they should be documented prior to the detail design phase.

Keep maintenance in mind. Plan for easy access to major building systems for inspection, calibration, maintenance, and repair.

Design for people. A laboratory's success depends on people. The building should serve them, not vice versa.

Plan for expansion. Make sure the lab service system (such as water, air handling, and electrical) are sufficient to meet reasonable future demand increases. It's cheaper to add capacity in the beginning than later.

(from "A Laboratory Designed for Efficiency and Comfort Too! by Roger F. Newill, WEF Operations Forum, February 1993)

Legal Defensibility
...continued from page 1

Step 6 MAINTENANCE OF SYSTEMS

Let's start first with Step 1, the EVALUATION/AUDIT phase of this process.

There are two documents that will assist you in this process. The American Association of Laboratory Accreditation (A2LA) Auditors checklist will help you audit any laboratory because it addresses QA systems as well as actual methods. The A2LA organization is working very closely with the EPA to develop a national certification program and their audits are very detailed.

The other document is a handbook called the Guide to Environmental Analytical Methods that is an excellent reference book for organic and metals methods. Basically it compares different methodologies in a very concise way. There is the possibility that in the future a guide such as this will be available for wet chemistry.

My advise is to allow at least a day for a commercial laboratory audit and to make sure that you talk to the analysts as well as upper management to assure a complete understanding of the program. The best way to check data is to randomly pick a laboratory number of a project you have done with either a commercial laboratory or your internal laboratory and see how the QA system was applied to the data set selected. Warn the group about what projects you want so they can have the time to pull all the records.

Now I'd like to point you towards some areas that I feel are very important. From my experience, the three most likely areas for data to be thrown out of court will be from doubt cast about practices in Field Sampling, Sample Control, and Sample Preparation. Let's address some of these areas:

a. Field Sampling Issues

- Date of Sampling
- Time of Sampling
- Line out blank spaces on the Chain of Custody (COC), no white out, errors are lined out with a single line with a date and initials.
- Watch time between sampling and log in.
- Anyone who handles the samples must be on the COC.
- May want custody seals if you feel the data may go to court.
- Holding time issues
- Blue ice and thermometer
- Jot down temperature on the COC when samples are relinquished.
- Standard Operation Procedures (SOP's) for sampling practices + sign off
- SOP's for bottle preparation + sign off

b. Sample Control Issues

- Correct sample descriptions that match container and COC
- Good/bad condition is noted (Absence of notation means it wasn't looked at).
- Custody seal notations (Present, Intact, Broken)
- Storage conditions are documented.
- Daily temps and NBS annual (calibrated thermometers)
- Locked refrigerator
- Internal chain of custody
- SOP's for practices + sign off
- Documentation system for problem samples and action.

c. Sample Preparation

- Methods are appropriate and available.
- SOP's are available (Discuss documentation of clarifications vs exceptions as opposed to re–writing SOP's. You must say there are no exceptions if there are none).
- Standards for spiking are traceable from manufacturer through preparation to laboratory.
- Reagent Lot numbers are documented.
- You must document temps of Ovens and Baths with calibrated thermometers (annual).
- Calculations must be clearly documented for preparing standards.
- Recipes for preparing standards with calculations are available.
- Hold times must be met.
- Corrective actions or Laboratory Narratives are written when there are problems and reviewed by supervisors and a QA person.
- All blank spaces are "Z"d out, no white out is used, records are in ink, errors are initialed, dated and a single line through that does not eradicate the deletion.
- Balances are checked with S class weights and P class weights are used for each day of use.
- Training records are available and signed off (Still in the early stages for commercial laboratories)

d. Actual Analysis

- There is conformance to the methods with any deviations documented.
- Method exceptions or SOP's must be reviewed annually and signed off as such.
- QA manuals are available and have been signed off by all personnel that they have been read and will be adhered to.
- Training records are available and signed off
- There is conformance to the method required QC for blanks, initial calibration, continuing calibration, duplicates, and matrix spikes. Go into analyst run logs and count up the frequency. You can get this information from the Guide to Environmental Analytical Methods.
- Calibration records are absolutely traceable to the analysis date. Pull that from the run logs.
- Raw data should be in a package with all the QC measures that were made to accept the results. All criteria should be met and corrective action reports or laboratory narratives written for any situations that may appear to deviate.
- There must be equipment maintenance logs that link an

Legal Defensibility
...continued from page 3

instrument I.D. to the log for retrieval in the future.
- Overall water quality issues are addressed per Standard Methods up to the 17th edition for wastewater.

Step 2. CORRECTIVE ACTION PHASE

– DEVELOP DAY TO DAY PROGRAM THAT ADDRESSES DEFICIENCIES

– REAUDIT INTERNAL FUNCTION TO ASSURE MAINTENANCE OF THE CORRECTIVE ACTIONS.

– REQUIRE FORMAL RESPONSE FROM THE COMMERCIAL LABORATORY ON SIGNIFICANT ISSUES.

Step 3. DATA PACKAGE DEVELOPMENT

The next phase of this program is to select a couple analytical groups to develop data packages to see if your systems will produce legally defensible data. Mainly the data will go onto summary forms with the raw data attached to the back. I would suggest having the commercial laboratory do it first so you can see what the forms look like. You can get blank copies of these forms from your commercial laboratory or develop them yourself from what you get from your commercial laboratory.

From your own operation pick metals, one or two inorganic tests, and a GC test for one or two samples. With a commercial laboratory you can pick a typical project to see what type of data package will be assembled. A commercial laboratory will charge a surcharge for assembling a data package of 20 to 30% of the analytical costs and it takes about 30 calendar days to get one assembled.

There are two very good guidance documents that can be used to help you assemble data packages for your internal laboratories if you've never done it before.

One of the documents is "LABORATORY DOCUMENTATION REQUIREMENTS FOR DATA VALIDATION" written in 1990 for non–contract laboratory data.

What does non–contract laboratory mean?

The EPA has a program called the Contract Laboratory Program (CLP) where they select laboratories that they use to perform work on locations that have been designated as superfund sites. The CLP program has its own protocols or methods that are similar to those seen in SW–846, but deal with heavily contaminated samples. The CLP protocols require an enormous amount of documentation. I've been involved in developing data packages using these procedures and 20 samples will generate about 2000 pages of documentation.

The document "Laboratory Documentation Requirements For Data Validation" was written to guide people in assembling data packages for other than CLP work and it is enormously useful in helping you to know what documentation is required and in what order.

The other document is written by actLABS which is a group of commercial laboratories that have collaborated on Industry practices. actLABS stands for the Association of California Testing Laboratories and the document was written by the QA committee. Ten to twelve QA Officers from major laboratories get together every other month to discuss QA issues and this was the culmination of about one year's worth of work. The document is called: "INDUSTRY–WIDE STANDARD PRACTICES" and gives even more information than was provided in the previous document I mentioned. It should prove very useful because it also has been tested with different laboratories to see if data packages can be put together using it and the results were very good.

Step 4. THIRD PARTY REVIEW AND VALIDATION

Once you have assembled these data packages from both the commercial laboratory and your internal laboratory, I suggest you have professional validators write a report on the quality of the data. Basically, they will make recommendations as to whether the data can be used in its entirety, whether it can only be used for estimation, or whether it is invalid.

You can instruct these groups to evaluate the data against requirements to validate the wastewater methods and they'll charge about $20 to $25 per sample per test but you should get an estimate.

Step 5. CORRECTIVE ACTION FOR BOTH COMMERCIAL LABORATORY AND INTERNAL LABORATORY SUBMISSION

Once you receive the reports from the validation company, they need to be evaluated for the problems and corrective action plans developed to address the issues. Don't be surprised if issues come up because it is difficult to produce perfect data. The goal is being able to have a system that allows people to evaluate the quality of the data to make appropriate decisions.

Step 6. MAINTENANCE

Depending on the extent of the problems, you may just choose to go directly to the maintenance of systems with the corrective actions rather than endure another round of data validation. That depends on your resources of time and money.

I would like to bring up one other important issue about the maintenance process. Once you have guided the organi-

continued on page 6...

ANALYST'S PUZZLE

by Bev Franza

How many of the words shown below can you find in the box to the right?

The words may be listed horizontally, vertically or diagonally, forward and backward.

Good Luck!

D	I	S	S	O	L	V	E	D	O	X	Y	G	E	N	K	N	L
S	R	M	E	O	I	O	E	R	L	Y	R	L	C	C	O	O	I
M	X	E	T	R	T	L	T	E	U	C	U	U	H	I	O	I	M
O	N	E	T	T	E	U	A	Z	S	A	C	C	L	R	B	T	S
N	O	V	L	E	R	M	R	I	O	R	R	O	O	T	E	A	D
T	I	A	E	P	M	E	T	D	D	U	E	S	R	E	T	C	O
H	S	L	A	S	R	O	I	I	I	C	M	E	I	M	O	I	H
L	I	C	B	D	U	A	T	X	U	C	H	C	N	E	N	F	T
Y	C	O	L	S	T	M	E	O	M	A	I	I	E	N	S	I	E
R	E	T	E	M	O	M	R	E	H	T	O	X	I	E	T	T	M
E	R	U	M	W	X	O	U	E	Y	P	E	T	I	L	Y	R	D
P	P	A	A	I	I	N	B	I	D	C	O	L	F	Y	L	E	R
O	H	I	T	N	C	I	O	N	R	I	W	R	O	T	A	C	A
R	I	M	T	K	D	A	E	R	O	H	R	P	T	E	N	C	D
T	D	H	E	L	I	U	M	I	X	I	L	O	C	C	A	E	N
T	A	O	R	E	U	T	S	P	I	K	E	S	L	A	E	R	A
E	T	F	H	R	E	L	H	A	D	L	E	J	K	H	X	P	T
M	A	F	E	S	E	R	P	S	E	D	P	N	P	W	C	Z	S

ACETYLENE
ACCURACY
AMMONIA
ANALYSTS NOTEBOOK
AUTOCLAVE
BURET
CERTIFICATION
CHLORIDE
CHLORINE
CWPCA
DATA
DISSOLVED OXYGEN
DOHS
GLUCOSE
HELIUM
IMHOFF
KJELDAHL
LIMS
LITER
MERCURY
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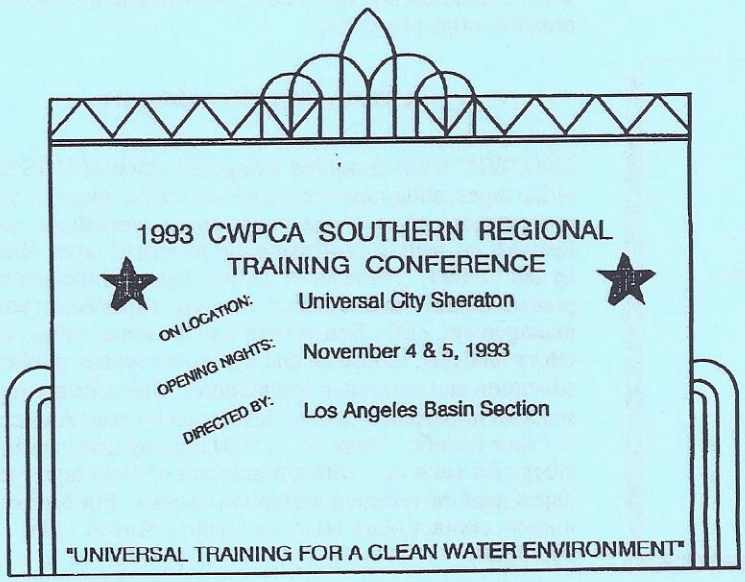
MONTHLY REPORT
MSDS
NPDES
OXIDIZER
PRECISION
SETTLEABLE MATTER
SODIUM HYDROXIDE
SPECTROPHOTOMETER
SPIKES
STANDARD METHODS
THERMOMETER
TITRATE
TOXIC
VOLUME
WINKLER



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Legal Defensibility
...continued from page 4

zations to be able to generate legally defensible data, the systems MUST be monitored for problems that require corrective action.

An example of why monitoring must be done was given in the last speaker's presentation. In David Gann's talk, he told us about a railroad company that had to prove it did not allow a shipment of perishables to spoil. They maintained records of the amount of ice used to keep cars cold. When there was a question as to how the contents of a railway car were stored, records showed at one point in the trip, an unusually high amount of ice had to be added which implied that there were problems with maintaining low temperatures. Ultimately, the data the railroad company generated was used against them and they lost the case because the records showed that temperatures had not been maintained.

This example may have given the impression that good records can cause you a lot more problems than if you had none at all. In actuality, the message is that records that have been developed to produce validatable data must be monitored for abnormal results and CORRECTIVE ACTION made when there are problems. In the case of the railroad company, losing the case was due to not taking action about the problems indicated by the Quality Assurance Program.

This process can be done with very little money that requires a purchase order. If you have packages developed on work that is already performed on a routine basis, you will probably add another $200 to $300 as a one–time cost on a $1,000 invoice. For validation, I would estimate $500. Where it gets expensive is in finding the time to go through this process. But I highly recommend making the effort because it could potentially save you from unknown damages in the future.

Chemistry

All the people died who wrote it.
All the people died who believed it.
All the people die who learn it.
Bless the death!
They surely earn it!

anonymous
ca. 1900

Footnotes
...continued from page 2

an alternate test procedure (ATP).

What are alternate test procedures?

An ATP is a method which differs from the approved method. Before an ATP can be approved for regulatory reporting, an extensive comparability study must be completed. If the results indicate the ATP method provides results statistically comparable to an approved method, the ATP also may be approved and may be used for reporting. Notice of approval of an ATP is published in the Federal Register.

USEPA APPROVES CEM'S MICROWAVE DIGESTION PROCEDURE FOR WASTEWATER SAMPLES

The USEPA has approved closed-vessel microwave digestion as an alternate procedure to open-beaker hot plate digestion of wastewater samples for metal determination. The final rule was published in the Federal Register on Friday, September 11, 1992.

The approved procedure specifically applies to the preparation of domestic and industrial wastewater for elemental determination of thirteen elements by ICP/AES, eleven by AAS and ten elements by DCP/AES.

While this rule is specific to the CEM procedure, other microwave system manufacturers may apply for approval for their systems pursuant to 40 CFR 136.4. EPA will consider proposing a more generic microwave digestion procedure when validation and data becomes available to support a broader scope procedure.

CWPCA VIDEO LIBRARY

The CWPCA has compiled a large selection of VHS format video tapes, slide/tape programs, and audio tapes of selected presentations given at past conferences, workshops and film festivals, as well as professionally produced tapes obtained by the Library. These tapes include topics in the areas of process control, maintenance, training, supervision and management, collection system maintenance, safety, laboratory analysis, industrial and hazardous waste, public education and computer applications. This Library represents an important resource developed by your Association for your benefit. There is a $ 5.00 mailing and handling charge for each tape with a maximum of three tapes per loan. Tapes must be returned within two weeks. For further information, contact Mark Niver or Cynthia Kuo at (408) 945-5300.

EDITOR'S NOTES

If you are planning to submit an article for publication, please send your article to the editor on a 3.5 inch disk. (We can convert 5.25 inch disks if need be.) If you do not have a word processor, just send your document on paper and we will input it for you! Label disks with the author's name, date, the names of the files, and the program (and version) used to create them. All 3.5 inch disks should be marked MAC or IBM. The document should be saved in text (ASCII) format if possible. Our system can interpret WordPerfect, MacWrite, Microsoft Word, WriteNow and several other wordprocessing file formats. Be sure to let us know how to contact you in case we have difficulty reading your disk. We will return your disk to you if requested.

MARK YOUR CALENDAR

- ✔ **CWPCA ANNUAL CONFERENCE:** April 20-24, 1993 in San Diego, CA. at the Convention Center.
- ✔ **TCP APPLICATION DEADLINE:** April 30, 1993.
- ✔ **TCP CERTIFICATION EXAM:** July 24, 1993.
- ✔ **CHALLENGES FACING ENVIRONMENTAL LABORATORIES-METHODS, QUALITY, MEDIA AND LIABILITY:** will be presented August 8-11, 1993, in Santa Clara, CA by the Water Environment Federation's Laboratory Practices Committee. For further information, contact Robert K. Wyeth, Conference Chairperson (716) 691-2600.
- ✔ **66th ANNUAL WATER ENVIRONMENT FEDERATION'S CONFERENCE AND EXPOSITION:** October 3-7, 1993 in Anaheim, CA.

Analyst's Notebook

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