Scientific Ethics: What Are Our Responsibilities As Facility Managers? M&M 2001 Expert's Session on Core Facility Management

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This article is the second of a series transcribed from the discussion taped during the Core Facility Management session. Bulleted paragraphs indicate comments by individuals attending the session.

D. Sherman: The next topic was suggested based on the discussion at last year's Core Facility Management session. Those of you who have not been involved in formal discussions on scientific ethics probably are going to have your eyes opened a bit. There is no such thing as a quick answer when it comes to ethics. What was initially brought up last year was the question of what are our responsibilities as facility managers when we see things going on that are perhaps not exactly appropriate as far as interpretation of data and such. With that in mind I asked Dr. Michael Kalichman to participate in this session. Michael is an active researcher in the Division of Neuropathology in the Department of Pathology at UCSD (University of California-San Diego). He is also Director of the UCSD Research Ethics program and has taught courses related to Scientific Ethics for over a dozen years. He offers various seminars at UCSD to help students and staff understand the many aspects of ethics such as: Survival Skills in Academia, Scientific Ethics, Scientific Integrity, Scientific Communication, and such. I will not take the time to go into a lot of additional details of Michael's extensive resume but will say that he is an active speaker and presenter at Bioethics conferences throughout the country and I welcome him to this particular session.

M. Kalichman: Good Morning. First of all I would like to point out that one of the nice things about giving an ethics talk and maybe one of the bad things is that everyone who is unethical leaves. So those of you who are unethical can leave anytime you want (laughter). We are left with just the ethical people so it makes it a little easier to run the discussion. This is the topic that Debby asked me to cover...what are our responsibilities as Facility Managers. However, at the very beginning we have those two terms together...scientific and ethics. I want to point out that what you see in front of you is actually something fairly unusual. Even though, hopefully, most scientists operate in an ethical fashion you don't very often hear scientists talk about ethics. There are several problems that come out of this and I hope we will get into these as I go through some of the discussion today. Let's focus now on that word ethics. The problem is that many of us, when we were high school students or undergraduates read in one course or another some of the philosophers such as Kant or Hegel or Spinoza and we really saw no relationship between that philosophy, that ethical theory, and what we do now as scientists. The result is that when you hear the word ethics you think, "That is not what we need to worry about. We just need to worry about doing the right thing." That is what Ethics is about. In a very brief time, I want to give you sort of a landscape for discussion about data, data management, and ethics issues. Then we'll follow with some discussion that will not just involve an individual spouting specific opinions, but instead, some back-and-forth discussion about ways to deal with specific situations.

When we think about ethics there are several different ways you can approach the question about "what is the right thing to do." What are the rules? What tells us what we can and cannot do according to the law? It is wrong to kill somebody for his or her data. That is pretty clear because there are laws against doing that. But, as it turns out, there are very few laws that govern most of what we have to do when we deal with data in particular, especially the kinds of data with which most of you are dealing. And also, unfortunately, most scientists do not know about the few laws that do exist that are relevant to this, so that is not how we make our decisions about what is right to do.

The second area is guidelines. Professional societies, institutions, and journals often have guidelines about expectations of the way you should handle data. Guidelines are not binding in the sense that you will be jailed if you violate them, but they are at least a standard by which people can begin their discussion. Interestingly relatively few scientists know about guidelines either. So the place that people usually look to decide what is acceptable, what is right and what is wrong, is standards and common practice. Standards is what somebody, usually more senior to you, tells you as you are developing as a scientist such as someone working in electron microscopy or some other area. They tell you what is the correct way to do things. So you have heard from somebody the way to do things and then maybe you operate in the same fashion. More likely we worry about the "Do as I say not as I do" problem. We might look at common practice and see what people actually do as opposed to what we are told they do.

These are the two ways we might operate. Either or both of them would probably be fine if everyone had the same idea of what is acceptable. But in almost every arena you can think of such as image work... I am in a pathology department and we do some image work...different people will have standards about what quality of a micrograph you can publish or at what point you can say you have really found something of interest in a particular sample. Is it okay to put that arrow over the artifact in your picture so that people won't see that there was a little bit of dirt rather than going and getting a better picture. Those are issues that I am not prepared to tell you that one way is wrong and the other way is absolutely right. But we do have a problem because different groups have different approaches and don't talk about them. Which leaves us then with the situation where we have rules, guidelines, and standards of common practice as ways people might decide what is ethical. This leads us to that question of "How do we make an ethical decision?" How do we decide what is right? So we come to that initial basic question: what are the responsibilities of facility personnel when it comes to the use and misuse of scientific data generated in their facility?

I have selected a few principles that we might think about as starting points.These three principles are:

First: Integrity of research depends on the integrity of the data. That is obvious but think about the implications. If somebody wants to know whether research misconduct has occurred on a study, this is what they have to look at to find out whether some work was actually done or not. They must determine whether the work was done as described as having been done.

Second: Integrity of the data is a shared responsibility. This presages my final message for today that will be that it is all of our responsibility. It is not something that you can get away with by saying, "I am only the facility manager and someone else is doing this." At this point it is a good time to say if you did buy that $2,500,000 SEM you would not want to risk that machine on

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someone who is poorly trained because they might mess up that machine. Is that machine more valuable than your reputation or your facility's reputation? The answer is of course not. That machine is only one part of a larger picture and just in dollars. Your reputation is much more valuable and you don't want to risk it. So you do have a responsibility that we will come back to in a moment.

Third: This is a little different kind of principle but one that most people don't realize has many implications. Data that are generated, no matter what form they are in, whether they are micrographs or numbers, those data belong almost always to the institution, not to the investigator. We like to think that we are scientists and, as such, we are doing science and are somewhat different than somebody working in a factory or in some other business that generated things that belong to that business. But what we do and the products we generate belong to our institution. There are many implications that follow from that fact.

Based on these principles, I have divided the issue of responsible data management into seven different areas as an overview for our discussion. I will briefly describe examples of issues that we have to face from an ethics point of view. The first step is preparing for data collection, followed by data collection and record keeping itself. Once you have collected the data, the information or images or whatever you are working on, you must do the analysis and selection of data. How do you analyze that so as to find when something statistically interesting has happened? How do you decide which data you are going to use and which data you are not going to use? Who actually owns or has the rights to use the data? How long does data need to be retained and by whom? Who should be able to see or share the data and at what point? So let's look at each of those areas.

Preparing for data collection: Before you even start an experiment of any type, and this is presumably in the purview of most if not all of you, decisions are made involving experimental design and statistical methods. How are you are going to decide whether you have something real, especially in biology, out of what you are getting from the results that you are presented? These are issues that need to be approached before the study is done, not after, because of the risks of false positives? I hope all of you are familiar with the statistical question of false positives -- if not, that is another lecture. You need a clear plan of responsibilities. Who will be doing what? Without that clear plan you can have somebody thinking somebody else is taking care of things that need to be done. Many biological studies involve either human or animal studies. Who got approval to use those subjects and who will get in trouble without the approval of how the experiment is being conducted?

Data collection: Once you have planned for the experiment, what are some of the issues that you face? We think of data collection as being fairly mundane and automatic but in fact it isn't. Today's session began with a question about training people. Is the training sufficient for those who are actually doing the data collection so they will be able to do the necessary job? Is the experimental design set up so that you are going to eliminate, or at least minimize, any bias that may occur in the study? Are procedures in place to deal with problems that are likely to arise? If you have a study where an instrument needs to be calibrated on a regular basis so that you know what numbers you are getting out of it and what the meaning of them are, does the person using the instrument know how to calibrate it and know whether it is calibrated or not? It is likely problems will occur if people aren't trained in those things.

Record keeping: Are the records there to permit future verification of what was done by whom and when? Good record keeping seems essential but many laboratories in science still operate on the assumption that paper towels are sufficient. They aren't! You need to be using a bound lab notebook with numbered pages and entries written in ink so that someone can come back and find out who did what and when.

The following are all examples of things that are "mechanical" scientific things to do. I hope they all seem like good things to do. But they are ethical problems in the sense that if they aren't done right we damage the integrity of a study and we damage the integrity of science at the same time.

Analysis and Selection of Data: Once you have done the experiment you still have more issues to worry about. How do you decide what you are going to include in your final study or final report? Selection of data should be based on objective criteria not on after-the-fact decisions that are made without deference to variation with which you may be dealing. You should not violate assumptions of statistical analysis methods. If there is no statistician in your immediate research group, then you might need to find that expertise. You need clear documentation relating to the process of reporting what you have found. This includes how the data were obtained and what were the criteria for data selection and exclusion, methods of data analysis, location of data used for analysis and potential sources of bias. All these are your responsibility from an ethical point of view.

Ownership of Data: This is a serious problem and there are many aspects that are fundamental. However we don't have any rules or guidelines sometimes to help us deal with them. We do know that the institution owns the data. That is the one thing we do know. But, in the absence of other agreements, the PI has the right and responsibility to make all decisions about the collection, use, and sharing of the data. We also know that original research records should be kept and maintained in the laboratory in which they were created. That is part of the institutional ownership aspect. But what happens when somebody leaves a group or a facility? What happens when two collaborators have worked together to generate data but then have a falling out and one wants to use the data and the other doesn't? Researchers leaving one laboratory for another normally are entitled to take copies of their research records with them. But that doesn't always happen. If there are reasons that this doesn't happen such as regulatory reasons or proprietary reasons, confidentiality reasons, or maybe other issues that precludes taking copies of their research records, then the PI is responsible for making this clear at the beginning. This is part of their responsibility.

Retention of Data: How long do you have to keep data? There are federal guidelines for grant purposes that tend to be 3-5 years after the final financial report. For some purposes, regulations or guidelines may require that data be retained for longer periods. The quality of the data is moot if it is not accessible and it is usually the responsibility of the PI to ensure records are stored in a secure, but accessible, fashion.

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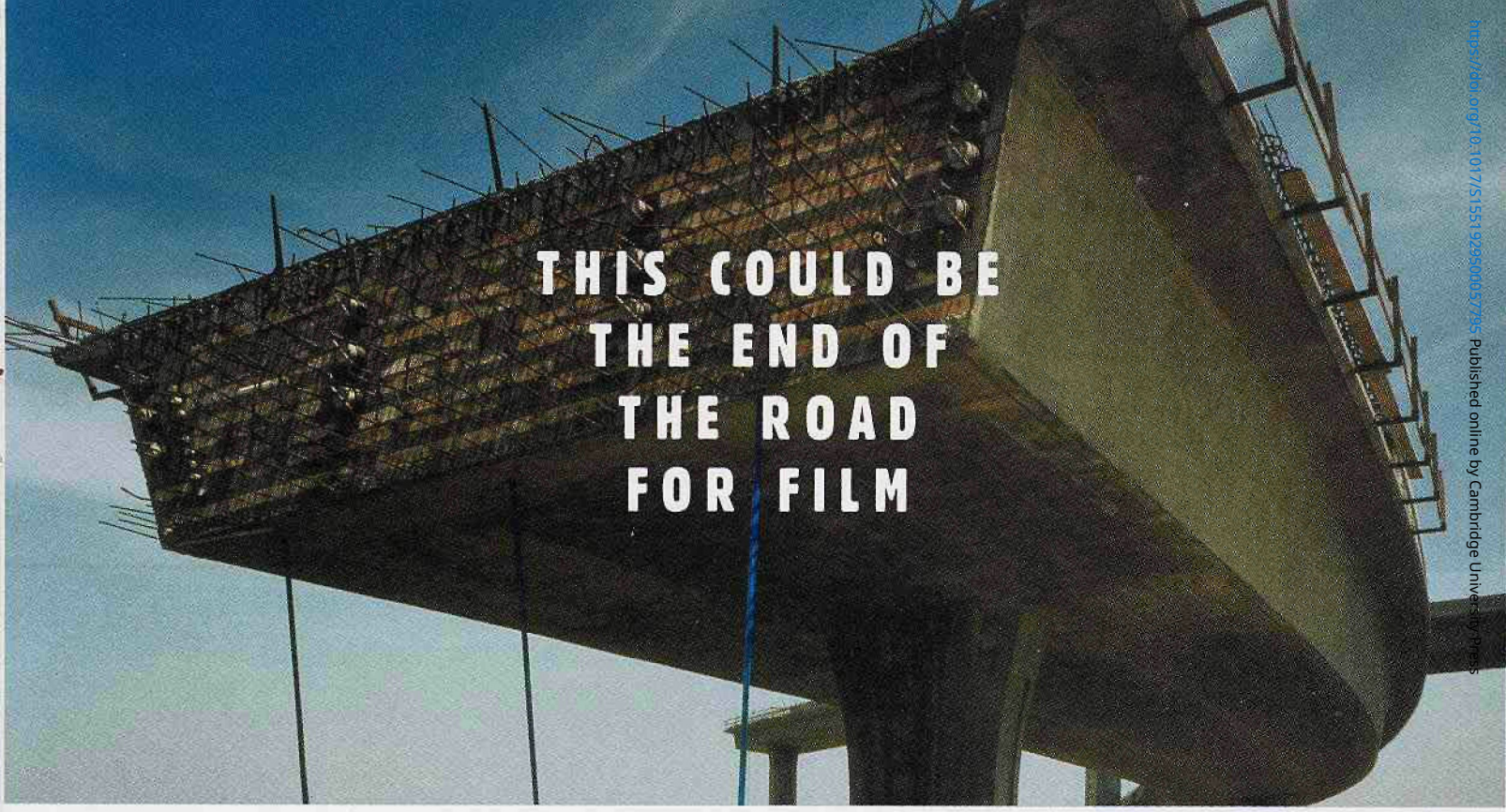

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Sharing of data: The progress of science is best served by sharing of data so that we don't duplicate what someone has already done. We can learn from the mistakes other people have made. This can be done before publication by attempting to maintain an open data policy. Having said that, you need to do this with caution. Many of us have had the misfortune of being burned by another investigator who steals essentially what we are doing and runs with it before we get a chance to publish. After publication the PI must be prepared to grant reasonable access to the raw data. Some institutions and some federal agencies have guidelines that require you do this. Reasonable access brings up its own problems. What does reasonable access mean? I argue that reasonable access should be defined to include any request that is in the best interest of scientific inquiry, can be accomplished without extraordinary expense, and can be completed in a timeframe that is not burdensome to either the researcher or the requestor. These are elements of reasonable access to data that are part of sharing of data that we would like to see happen. So if sharing of data is in the best interest of science but you cannot get access to the data, such as if two investigators are fighting over the data, then a mutually agreeable arrangement needs to be made. That might be accomplished through mediation or arbitration using a third party who is mutually respected.

For the sake of time I have gone through this survey quickly to leave time for some discussion. I am now going to be asking you some questions. I am going to begin by asking the question of what are data? Data can be defined as measurements, observations, or any other primary products associated with the research activity. Hopefully we think of them as a factual basis so that someone can figure out how we made our conclusions and what we put into our publications. We think of them as research products necessary to validate our published or reported work. So under those circumstances, what are the data that each of you is producing?

- We produce an awful lot of images.

- We do a lot of image analysis and generating numbers from various images including using morphometric techniques.

M. Kalichman: Part of what I would like to get across even though some of you may not be thinking of it is that, sometimes, there are aspects of what you do that are in a sense data, even though you may not have thought of them as data that someone else might need to access. It is not just measurements. It might be computer files, gels, DNA sequences, antibodies, etc. acquired in conjunction with the study. These start to sound like things that might not be written down in your notebook. However, they might be needed to verify the integrity of your work. So in that sense they are data. Someone who is doing image analysis might have developed some custom software to be able to do the recognition necessary to extract some numbers from an image. It may be necessary for somebody to have access to that software to verify that you have truthfully and fully reported what you are doing.

Some questions to consider in any discussion are: who owns the data, who has the rights regarding access to the data, and who has responsibility for the data? Do you need to worry about whether there was appropriate approval if someone comes to you with a sample from a human subject or is that only their problem? What about research misconduct? Do you need to worry about whether the person receiving the data is proceeding appropriately? Do you need to worry about sloppiness or ignorance that may lead to misinterpretation of the work?

How many of you have bound lab notebooks that record all the work done in your facility?

- We do a lot of digital imaging, so we do it through archiving on CD-R disks and doing the documentation on the disks.

- We do the same with images. We archive them on CD-R. We also maintain computer records of protocols for individual researchers. We do not have bound lab notebooks but rather written notes that are filed under the individual researcher's names regarding times, dates, protocols, etc.

M. Kalichman: I have mixed feelings about how to do this. I am personally trying in our own research group to emphasize using bound lab notebooks. My wife, a biochemist, has a history of using 3-ring binders. As experiments are done they are posted in the binders. How many of you have been involved in a research misconduct investigation? Let me tell you what can happen, to emphasize the advantages of a bound lab notebook. There is a very well known case of Imanishi-Kari and David Baltimore that lasted over a period of 10 years. There were accusations by a postdoc, Margot O'Toole, of research misconduct on the part of Imanishi-Kari. The secret service was eventually called in to examine lab notebooks from her Kari's laboratory in order to verify what had or had not occurred. They checked the different inks and dates to see if things were in the right order and whether they were done when they were supposed to be done. One could argue that if you have electronic records as you do and I often do, dates could easily be changed after the fact. So if you were trying to prove your integrity it is going to be harder with the electronic record or the loose-leaf pages than with a bound notebook written in ink and with numbered and dated pages. What I encourage people to do is keep a lab notebook even by an electron microscope that has a record of users, images taken, etc as a permanent record.

- That sounds great unless you are working with about 25 users as I am, who are all doing different things. I found the most practical way to deal with it is to have a folder for each PI. I date the pages and put them in the folder. If I had a bound lab notebook I would never be able to go back and figure out when I did something for somebody that I wanted to do again. So in a practical sense, if you are working with a multi-user facility and processing tissue using different protocols that need to be recorded, it works much better to have individual folders.

M. Kalichman: That is a good point and I can see that it would be hard.

- On the TEM we can do it really easily since we still use film. There are always the counters. On the SEM it is digital and users bring their ZIP disk to copy their images and just sign off on time. So I have no idea what goes out on their ZIP disk...how many pictures or what they do with them. That is going to be a little harder to control.

- As far as the bound notebook, I have the same problem working with several different PIs and projects. I have created an index at the back of the book to try and keep my notes straight.

- We have solved that problem of bound notebooks. We use

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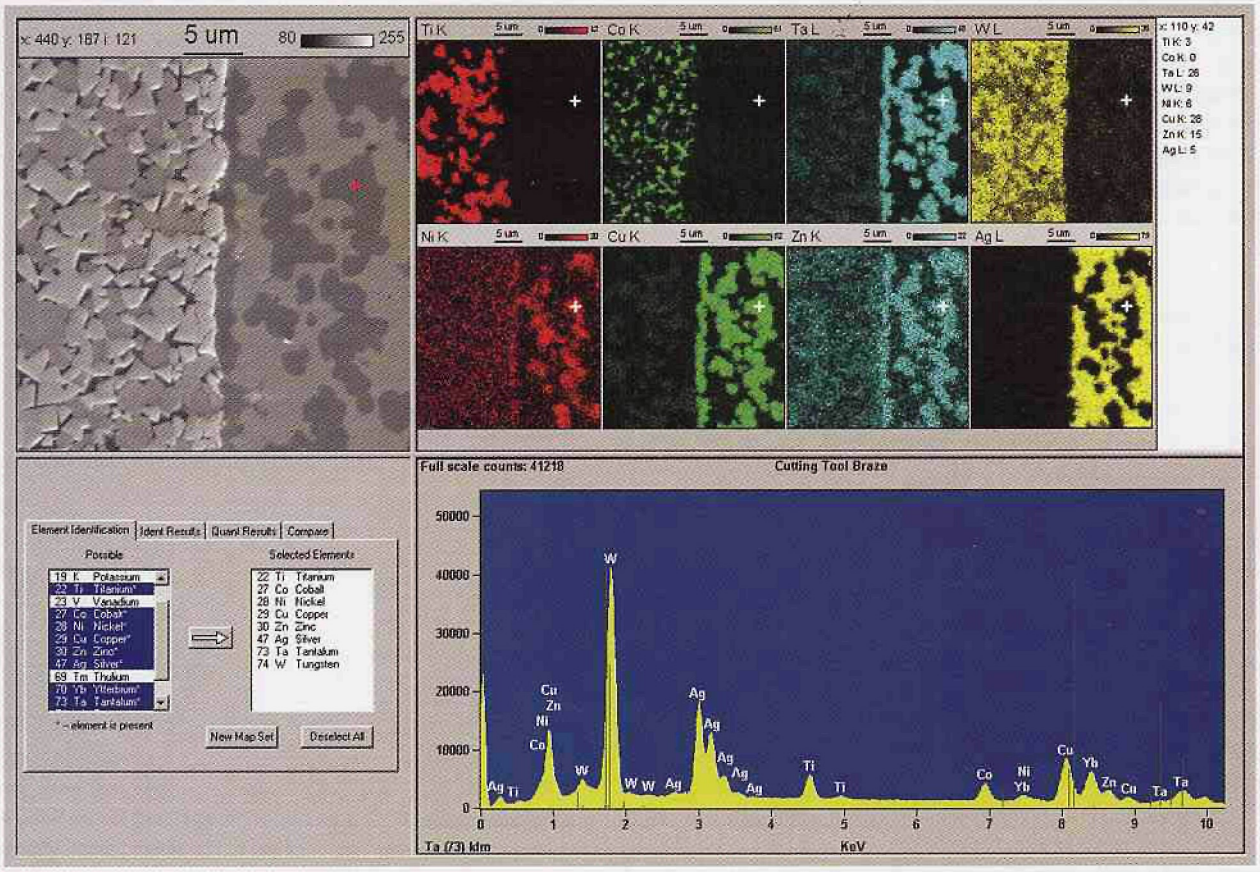

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the carbonless copy so that one copy goes into the investigator's file and one copy stays in the bound notebook. Each of the techs in the lab has their own bound notebook. A copy goes into the investigator's file and then an additional copy may go somewhere else such as a central record for the laboratory. We have multiple ways of tracking what is going on. It is possible to keep things going that way because at one point we were going to try to become a GMP facility so we thought about those things in advance.

● This is a new idea for me. What is my responsibility if I have a user come in and I train him to use my electron microscope? Am I then responsible for the images that he takes? Is a car rental place responsible if a customer has a drink and then goes driving? You have to have insurance but I don't think the car rental place is responsible if you screw up and go drinking and driving and crash.

M. Kalichman: There are two aspects here. If your facility is simply providing a resource the same way a car rental agency is and somebody using your facility commits research misconduct, it is not you who will be in trouble directly. However, the record that you have at your facility may be important to somebody investigating that allegation of research misconduct. The other part is that even if you are only acting sort of as the car rental agency, you don't want to be the car rental agency that rents to all the drunk drivers. So you, hopefully, want to have some degree of control over what is being done. Think about how what you are providing is being used. I do not have a core facility that has a lot of users but we have a morphometric unit and some people come to us for help. A lot of people come to me for statistical help. I know that there are ways they could misuse what we are providing. I do not want my name associated with a study as an acknowledgement if I do not get to approve the final version of the manuscript. I certainly don't want to be an author on something like that. As facility some of you managers may automatically be tagged on as authors on papers or at least be acknowledged. If you are going to allow that to happen you should not allow it to happen if someone is showing the ignorance or sloppiness we talked about before that might cause data to be misunderstood or misinterpreted. That's your reputation.

● In a private laboratory setting as opposed to a university setting, there is an entirely different way of looking at some of these issues. We don't really want to have a bound notebook that could be opened in a court proceeding because that would be everyones' confidential information. So we have to keep it all separate. In a private laboratory setting you issue a report and you want it to be credible. You want it to be admitted in a federal court. On one hand, you could say if you put in the resumes of more of your PhD staff it looks more credible. On the other hand, they take on enormous legal exposure if they get asked what went on and they don't have the slightest idea. That is a fraudulent way of boosting up your credentials that would be seen as inappropriate. So you have to be very careful that if you are taking credit for the work you know what is really happening.

● One thing that some of us have to remember is that sometimes when we are working with graduate students or even post-docs in the facility setting, we may be one of the most influential people in getting them to be responsible for their data and thinking of liabilities and record keeping. They may not be exposed to it any other way.

M. Kalichman: Good point. Just by being here this morning I can picture a lot of different facility environments with which we are dealing. But if you have what you just described, you are training these people and giving them a sense of good record keeping and how to handle things.

This is one that gets a little more interesting or troubling. On what circumstances is it acceptable in your field to exclude an anomalous data point from analysis? If people are asking you to provide them with images, how do you decide what can be excluded? If data are excluded, how should your manuscript reflect that? Now what do I mean by excluding data? If you are taking images from a control group and an experimental group and you want to know the difference, how do you decide which images you are going to analyze? Are there going to be circumstances where you elect not to use one and how would you report that?

● I generally do it the opposite way. I ask what they want to see and we will go find it. Chances are that you can as long as you make everyone understand that you are looking at a few microns of a sample and it is impossible to make images really objective. They are all subjective. It is very difficult and you have got to say that this is just a tiny proportion of your whole sample. I had someone who had a particular type of knife and wanted to prove that it was better than surgical scalpels. Most of the blade was useless. We found a place that was nice and sharp, that was easy, so I just had to tell them that this was just one tiny bit of the whole thing.

M. Kalichman: But you found many parts of the blade that weren't sharp. How did you report that? What did you tell them?

● Outside of the lab it is their responsibility. I take the picture that they want to be taken.

M. Kalichman: Do you worry that later someone is going to say, "This is the lab that said this knife was this sharp."

● I don't say it. I just take the picture.

● I go beyond that. It is my integrity on the line too, and I will not search for something in a sample where I find it once and cannot find it reproducibly and then tell the people that this is their data. I just don't feel that that is right. I don't care if it is a service situation. I may not be able to stop them if they want to go and publish it. But there is going to be my protest on the record.

● I have been running into this issue just recently with researchers and graduate students in our facility. My general approach is either (A) blind...you give me the sample and I look at it and you don't tell me if this is experimental or control or anything else about it so I am not biased when I do my imaging or (B) I go and twiddle knobs until I get a random field and I image that. It is sort of a statistical process. Either you have some sort of rigorously laid out grid or sampling that you follow or pretend you are an ecologist out in the field and throw your sampling net over your shoulder and then count everything in the area it lands. I go to random fields and image that area. We collect data until it is sufficient to make a decision about whether the experiment worked or not. Even if it were my own experiment there is a sampling issue and you have to go after it randomly in some manner, such as a blind sampling, or you get all sorts of bias effects.

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M. Kalichman: How many of you receive studies as just described where there is a control and experimental and you are supposed to go through and look for things? (Many hands are raised). How many of you, when you do something like that, always have it blinded? (Few hands are raised). I have an ethics seminar series at UCSD, where I am from, that I do with a philosopher. Most of us think of philosophy as that soft discipline out there in the Humanities where they don't have much rigor. However, she comes over and sees how we do science and is just appalled at how we make decisions. I hope that all of you now know that for even the most objective measurements it is very, very hard to avoid unintentional bias. If you can be blinded you should be blinded so that you won't bias the findings you get. It is an ethical issue and it's a scientific issue. Try and change that practice if you can.

- I have one example that has something to do with this. This is one of the real-life types of examples that we run into all the time, especially in a service lab. I had an investigator who came to me with a sample and this is one of those investigators who think they know more than they actually do. They know how to put a sample into a microscope and take a picture but they haven't spent time learning the theory of the microscope to understand where it is possible to introduce artifact. This is an example where someone said to me, "I want you to image my sample with 2 kV and no coating for fast through-put." This was a biological sample that was not conductive. What do you run into with a non-conductive biological sample in an SEM? Right! Charging! This particular image series (Figure 1) was generated during a workshop at Lehigh University that I attended a number of years ago. It was a beautiful example of what happens with charging. The sample is of latex beads imaged with a field emission SEM. We were working at low kV, at about 1 kV, and we saw very nice latex beads. Look what happens at 1.5kV. All of a sudden we are starting to see what looks like frog's eyes as the center of the bead charges. At 2 kV we have something that does not look like latex beads at all. This kind of artifact is very easily introduced. What if you are dealing with an investigator who doesn't understand charging and doesn't understand what it can do? This particular investigator was looking at bumps on developing trichomes, the little hairs on leaves, and was going to extrapolate to the structural formation and development of the cytoskeletal structure underneath. This is a perfect example where charging can produce a bump when a bump is not actually there. And yet it was someone who was not receptive to learning theory or to listening to you explain about the possibilities of artifact. What do you do? And he isn't in the room with you. He just asks you or a student to take the pictures.

- What did you do?

- I tried to explain to the graduate student what was happening and why I was concerned about interpretation of that particular data. I only hope I sowed a sufficient seed of doubt for the student to question the data as it was applied to the basic problem, and maybe discuss this fully with the professor. I have my doubts since the student was rather meek and probably would not question the professor. I have not been involved further with that lab.

- We used to have a lot of cases in litigation. In any such case they are going to sue everyone involved. They are going to sue the lab, the analyst and everyone else not to get your money but to question your honesty. So who is responsible to make the faculty ethical is a difficult question. In this case it is because of misinformation. Does anyone remember the famous first image of a DNA molecule that came out of a California lab in the 60's? One of the graduate students decided that they wanted to see what they wanted to see so they manipulated a digital image. It made all the papers and was later shown to be fraudulent. If you have a user facility you can try to teach and educate and train the users, but you are going to get sued anyway because you are in the chain of litigation. Do you have a sheet where you have the PI sign off that you are not responsible for the ethical use of the data? Actually that may not be a bad idea in this age of litigation! Does any institution require that?

M. Kalichman: Personally I worry that nobody will take responsibility for anything and we don't want that to happen. But the converse can still be true. Put in your plan that this is what we do and this is what we are providing as opposed to saying this is what we are not providing.

- In the private laboratory community as part of loss prevention and risk analysis program, the philosophy is that you don't ever lose control of your data. So if someone came in and said "do this, do this, and do this", nothing goes out of the laboratory without a full report that discloses exactly what you did and why. The report will state if it is not being done according to accepted standards and forms. There is never any question. The courts also seem to hold professional people to a very high standard as to their conduct. It becomes very difficult to say that something was the responsibility of someone else.

- We had a case in southern Illinois where if you were director of a facility you were responsible…end of story!

M. Kalichman: Let me summarize by saying that it is our responsibility. It sounds like there are areas where each of us can do better. Find ways to maximize your control of the data. You could be in trouble if for no other reason than the data didn't come out well.

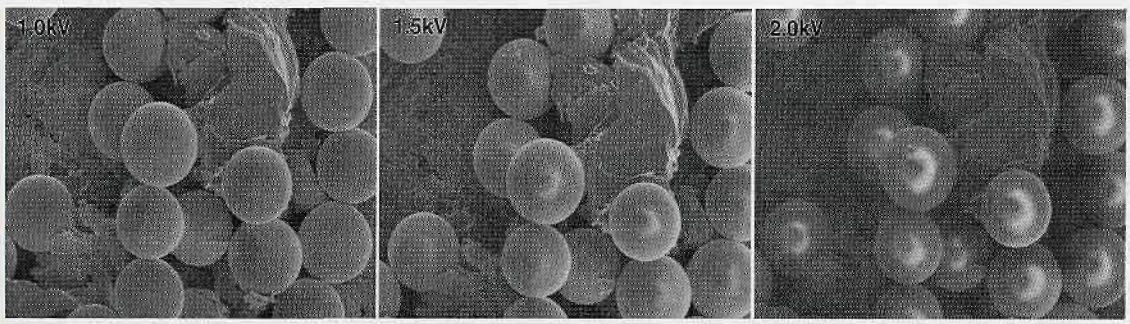

Figure 1: Latex beads imaged with a field emission SEM

D. Sherman: Thank you very much, Dr. Kalichman. APPLAUSE!!

Editors note: Scientific ethics will again be addressed during the Tech Forum Roundtable to be held at M&M 2002 in Quebec city. The discussion will on the legal and ethical issues of data ownership. ■

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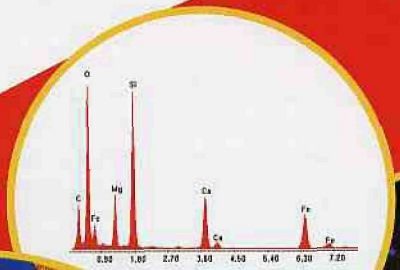

CHEMICAL ANALYSIS

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  GENESIS is the next generation of EDS analytical software on the Phoenix and Falcon platforms
- **Microcalorimetry in the SEM**
  Polaris sets a new resolution standard for elemental analysis

STRUCTURAL ANALYSIS

- **EBSD in the SEM**
  OIM provides crystal orientation mapping and texture analysis

  Delphi combines EBSD and EDS data for phase identification

INTEGRATED SOLUTIONS

- **Realize the next level of materials characterization with combined EBSD and EDS analysis**

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