**Randall Morin:** Good morning. My name is Randall Morin, and we are here in Nashville, Tennessee at the 50th meeting of the American Biological Safety Association, and I have with me this morning three distinguished guests, uh, each of which represents many years of service to the profession and to their respective governments. Emmett Barkley, Mary Ellen Kennedy and Jonathan Richmond. I’d like to allow them each an opportunity to, uh, respond to some questions and hopefully we’ll have, uh, an interesting discussion this morning.

First of all, I’d like to ask, uh, all of you, as you think back on your careers, uh, primarily in the government, uh, do you have, uh, any events or, uh, experiences that you felt are the most significant in your particular career, or events that, uh, you would say, are hallmarks in the field of biosafety?

**Emmett Barkley:** I might start.

**Randall Morin:** Sure

**Emmett Barkley:** I, uh, joined the National Cancer Institute in 1963 at a time that the, uh, National Cancer Institute was beginning to develop a major program of, for the, uh, search for a human cancer virus. And, the first priority that the director placed on that program was to develop a safety program that would assure the safety of the investigators who were undertaking this new task. And, I was fortunate enough to, uh uh, be introduced to Dr. Wedum, the person we consider the father of biological safety, uh, about a year later when he was invited to serve as a, uh, the chair of the advisory committee to the Cancer Institute on laboratory safety. And to me, as a very young person, it was a wonderful opportunity to be mentored by someone who had already established such greatness in the field. It was also fortunate that another member of that committee was, uh, Professor Bond from the University of Minnesota who became my doctorate advisor, uh, three years later, uh, where I decided to switch from engineering to micro-biology and environmental health. Uh, that was, uh, to me, uh, the most wonderful opportunity to pursue a new field.

**Randall Morin:** So, your career, uh, you actually started out as an engineer and once introduced to Dr. Wedum and others in the field of the biological sciences and safety, you made the decision to make a career change from engineering to biomedical research.

**Emmett Barkley:** That’s right. And, I found that, uh, exciting because, uh, being an engineer you knew how to plan and do something and, uh, know that you would succeed in building it. I found scientists were always looking for something that they did not know anything about and wanted to pursue it. And, it was a whole different change for me, and I was really, uh, impressed with their commitment to, uh, pursue basic research. So, I’ve, um, I’ve was guided by that

early on, thinking that safety, uh, had to be, uh, a program that was, uh, integral to the work that people who were at risk were carried out and that kind of marked my my whole future, and it was perhaps most, uh, uh, challenged and made so valuable, uh, when I joined with, uh, Dr., uh, John Richardson at the Centers for Disease Control, uh, in, uh, leading the effort to, uh, create the, uh, biomedical and macro biological, uh biosafety manual BNVL, uh, if that’s not the right set up. And, we were, uh, that was developed as a, a collaborative venture, uh, with the scientists who were most knowledgeable in the area of handling, uh, pathogens safely. And, I think that was probably one of the most, uh, exciting, uh, tasks, uh, that I had, and I’m, uh, pleased that it’s, um, it’s added to the foundation that Dr. Wedum established, uh, years ago.

**Randall Morin:** Right….Mary Ellen, uh, your career in Canada, uh, do you feel that the the Americans and the Canadians have always been together or did the Canadians, uh, go their own way, so to speak, uh, in the early days of bio safety?

**Mary Ellen Kennedy:** Well, I started my career as a micro-biologist with the Provincial, uh, Laboratory Services, which is the equivalent to your State diagnostic labs. And I spent, um, quite a number of years there, uh, in a diagnostic laboratory setting doing whatever you do in a diagnostic lab. And, um, at that time, the Provincial Laboratory Service in Ontario had thirteen labs and approximately 500 staff. Uh, laboratory safety was in it’s infancy at that time. Um, some places were good. Some places were bad. Some were non-existent. And, um, my director at the time said that our central facility, which was in Toronto, had decided to do something about lab safety and wanted someone appointed in each facility to be the lab safety officer. So, I got the job [laughs]. Along with the rest of my duties [coughs] excuse me, as a micro-biologist. And, um, before long, um, they set up a central, uh laboratory safety advisory committee in Toronto and, um, I was appointed to that. And, at that point, we were, um, mandated to, um, try to provide uniform safety standards for all thirteen facilities and I became quite interested in the whole process. So, I stayed with that for a while and, um, suddenly, after a number of years, um, there became an opening in the Federal Government. At that time it was the Lab Center for Disease Control in Ottawa, which is where I lived.

**Randall Morin:** And, that would be the equivalent to the American CDC…

**Mary Ellen Kennedy:** The equivalent of the American CDC. Uh, it has since been changed to the Public Health Agency of Canada, but it still exists. And, um, the, um, Lab Center for Disease Control was the central facility in the country which responded to the requests of Provincial Laboratory directors for various aspects, like, we need new testing facilities or we need to look at hepatitis at that particular period of time, or whatever, and one of the things the Provincial Laboratories felt that they needed was some direction in terms of lab safety and lab design. And, they were also concerned about, um, the incidents of hospital acquired infections. So, the Provinces of Canada asked the Federal Government to create a new bureau of infection control. That was the name of it at the time. And, uh, it was divided into two sections. One was laboratory safety, the other one was infection control. And, they, uh, put up a position for competition and I won that competition and became the first Director of Lab Safety, uh, in The Lab Center for Disease Control with, you know, across the Country responsibility.

**Randall Morin:** And then you, you were that office then was responsible for promulgating guidance and regulations that would then apply throughout the whole country?

**Mary Ellen Kennedy:** That’s correct. Uh, not long after that we renamed it because I [laughs] suddenly realized the scope of lab safety. And, uh, being a micro-biologist and not a chemist, um, I said yeah, I can’t cope with radiation safety and chemical safety and micro-biological safety and whatever, whatever, so, um, we changed the name of it to The Office of Biosafety and, um, we then directed our focus to, uh, microbiology and infectious disease facilities.

Um, my Director General was, uh, very interested in International collaboration. Um, he recognized the need for some kind of a guideline in the Country, uh, and at the time, the only thing that we had as documentation at the Federal level was a recombinant DNA guideline, which was produced in 1979, I think. And, I set out to, uh, write the first draft of the Canadian Laboratory Biosafety Guidelines for handling infectious agents. And, of course, the American document was very front and foremost in those considerations because, you know, we already had yours, but, um, it was very guiding. Um, some concepts we didn’t really agree with and I can remember many [laughs] many interesting discussions with John Richardson [laughs] when HIV came on the, uh, scene as to whether we should be doing that at Level 2 or Level 3. And, um, we chose to go our own way on that one. And, uh, we looked at, of course, British guidelines and Australian guidelines and whatever, and, uh, we were able to publish the first Canadian guideline in, um, 1992, I think it was. And, uh, it’s now in its third publication. So, in terms of my career, um, that was certainly my most significant, uh, step was moving from a Provincial State sort of setting to a Federal, uh, very broad scope, and it was very interesting. I met a lot of good people.

**Randall Morin:** Very good. Jonathan, I note that your career, after completing your, uh, doctoral work, I think in genetics, your first job was actually where the rubber meets the road as the Biosafety Officer at the Plum Island Facility, so I, I’m I’m assuming an animal biosafety was one of the first areas that you had to become very familiar with.

**Jonathan Richmond:** Well, you’ve just jumped twelve years into my history of Plum Island. I started as a Post-Doc, and spent ten more years as a bench scientist working on foot and mouth disease virus. In 1977, for some strange reason, this little nefarious virus found its way out of the laboratory and infected animals that were held in quarantine on the island. After the Congressional investigation that ensued, the Director of Plum Island came to me and he said, “I’d like you to be my Biosafety Officer.” And I said, “What’s that?” And this was just shortly after the NIH had published its recombinant DNA guidelines anointing people to be Biosafety Officers as a result of the Alsilomar Conference and everything that followed from that.

**Randall Morin:** So, was that the first time that the term Biosafety Officer had been used in a Federal document was in the recombinant DNA guidelines or was that term used before that?

**Jonathan Richmond:** I think it may have been used, uh, earlier than that, but there were very few Biosafety Officers as, as we’ve been discussing this week, um, the the, uh, Biological Safety Conference had begun in 1984 and included just a handful of people, mostly Federal, uh uh, people who were responsible for safety in their institutions. And that gradually grew over the years and after I had done about five years of work at Plum Island as a Biosafety Officer, uh, and attended some of those, uh meeting in the late ‘70’s, I remember, uh, an evening that Emmett Barkley came to me at a conference and said, “Would you be interested in coming to NIH? We’re reforming our safety program down there and I think it would be fun to have you there.” It took a little bit of persuading; I had four young children in the school system. But, uh, we made the leap and I went and had, um, not only a chance to work at NIH, so I moved from working with the animal, uh, particularly the exotic animal pathogens, to, uh, getting, uh, into the HIV discussions, uh, as I moved to NIH and had some some great times, um, there. But it was also at that time that ABSA was being formed. And I think a lot of credit there goes to Emmett for, uh, funding some of the initial efforts that, that allowed for, uh, the organize, the people, the organizers…I think there were six of us originally? There were two from Government, two from Academia and two from Industry who formed a steering committee and we worked for a couple of years to get this thing up and running.

Um, so I remained at NIH, uh, until 1990 when I moved to CDC. So, I then moved from the animals to the humans and then more into public health and a broad spectrum of what that is with the international involvement and so forth, so. Those, those were some of the key steps along the way.

**Randall Morin:** Right. You mentioned the, uh, early stages, the infancy of what we now know as ABSA. My first, uh, exposure to what is now ABSA happened when I was a graduate student at UNC with Jerry Tullis and I can remember coming in his office one day and he said, uh, “Come on, I want to show you something,” and he began to show me diagrams. They were debating what the ABSA logo would look like and there was a debate going on about how much Latin versus how much English. Uh, the logo, as it exists today, can you recall how they actually came up with the logo? The history behind that? Were you involved with that discussion, any of you?

**Mary Ellen Kennedy:** No

**Emmett Barkley:** Well, I think Dick Cruz was the, uh, the person who, who saw, uh, the emblem and, uh, as a very, very important statement for the association. Uh, and he was, uh, he was the only one who really looked at the, uh, language [laughs] that had been selected. And, I, as I recall, uh, it ended with just keeping it the way it was.

**Randall Morin:** I see.

**Jonathan Richmond:** I think we were about three years into using it at that point and the powers that be simply decided, well, we’ve got too much in text already and we’ll just keep it this way.

**Mary Ellen Kennedy:** I remember quite a controversy, though about the quality of the Latin.

**Jonathan Richmond:** [talks over Mary Ellen] Oh yes. Yes. That’s for sure.

**Emmett Barkley:** Well, that’s, uh, that was always a rich discussion. I agree.

**[Agreements all around]**

**Randall Morin:** I think that’s what Jerry was debating was the, the Latin, apparently, was not proper.

**Mary Ellen Kennedy:** Yes.

**Randall Morin:** Um, now the, the biohazards symbol itself, do you recall when that became officially recognized as, I guess, the international symbol for biohazards?

**Jonathan Richmond:** Yeah. Emmett can probably touch that one.

**Emmett Barkley:** Yeah, actually [clears throat]. That was, uh, developed as a part of the, uh, uh, biosafety program with the Cancer Institute, when it was dealing with, uh, its task of looking at, uh, cancer virus risks to humans. It was recognized, it was the only, uh, uh, material within a research community that did not have some, uh, symbol indicating that it was hazardous and they needed to draw attention to the importance of following good practices. So, it was actually developed by a contractor that, uh, we had with, uh, a Dow chemical, their, uh, group in Indianapolis, uh, whose name I can’t recall right now. Had a very excellent team that decided to really try to evaluate what type of symbol might be appropriate, and it was, uh, an absolutely wonderful study, and I won’t take the time to describe it, but I think it was the, it was absolutely a perfect study, and….

**Mary Ellen Kennedy:** Emmett, was there not some, um, background, as I remember Manny Barbeito telling me, that they took the radiation symbol and then kind of used that… yeah, morphed it. I mean, they took that as a sort of basis and then they worked around it?

**Emmett Barkley:** They actually took, uh, all of the safety symbols…

**Mary Ellen Kennedy:** Oh yeah.

**Emmett Barkley:**  …together as a guide post and, if you look at all of them, they all have that type of orientation, but yes, the radiation symbol was, uh, was the dominant one and what they, what they wanted to do was to make sure that there was no, uh, uh, that the symbol did not relate back to anything else.

**Mary Ellen Kennedy:** Right.

**Emmett Barkley:** Because they wanted to get a…

**Mary Ellen Kennedy:** Completely unique.

**Emmett Barkley:** …symbol that people could, uh, would not recognize as being something that, when they were doing this study, but remember that unrecognized symbol, uh, in their evaluations. And, this one came out as that no one knew any association with it, but everybody recalled it, remembered it after they had been exposed to it initially, so that was, uh, that basis of it, uh, it was the Pittman Moore Division of, uh, Dow Chemical. So [clears throat] the, uh, the Cancer Institute then just proceeded with, uh, developing it as a national standard. Uh, and I think it was in 1969 that it, uh, uh, maybe in the early ‘70’s, it was recognized as a Nancy standard. And, unfortunately people found the design so, uh, attractive that they were changing colors with it, uh, and the standard very clearly defines that particular color and basically indicates its particular use, and so I, the, it’s recognized around the world but it’s still used on T-shirts [laughs] and everything else you can think of. But, it was, uh, it was a part of that, uh, early effort at the Cancer Institute.

**Mary Ellen Kennedy:** Emmett, was there not a specific color? Was there not a biosafety orange?

**Emmett Barkley:** This was the genesis of biosafety orange.

**Mary Ellen Kennedy:** Right. And that is why, when we published the first edition of the WHL, the World Health Organization guidelines, we chose to put the color, the cover, of the document in biosafety orange.

**Emmett Barkley:** That’s right. The world followed the law, ok, so [laughs].

**Mary Ellen Kennedy:** Yes.

**Randall Morin:** It appears to be about the same hue as the Coast-Guard life preservers, so I don’t know if there’s any, uh relationship….

**Mary Ellen Kennedy:** Yeah. But, it’s kind of gone red.

**Randall Morin:** Yeah, it’s a little bit redder now than originally.

**Mary Ellen Kennedy:** Yes.

**Randall Morin:** Uh, so, you know, working at Ft. Dietrich, when I look back at some of the old photographs and a few of the remaining buildings from the, uh, biological warfare days, I saw no evidence that there was any symbol. The Army just chose to use the traditional white sign with black letterings saying, you know, “Danger. Keep Out” or “Biological Materials Present” or whatever. The term Bio-hazard itself, was that coined at about same time that the, uh, emblem became known?

**Mary Ellen Kennedy:** Must have been.

**Emmett Barkley:** Probably.

**Randall Morin:** Combining those two words together…

**Emmett Barkley:** Yeah, I thought…

**Randall Morin…**as you know, the term bio-hazard.

**Emmett Barkley:** I remember writing it a lot [laughs].

**Randall Morin:** And that would have been in the ‘60’s?

**Emmett Barkley:** That would be in the ‘60’s.

**Randall Morin:** Ok. So the legacy of Biosafety, I guess everyone considers, of course, Ft. Dietrich to be the, the birthplace, and it, then it gradually transitioned to the, the NCI of the NIH and then, and then the NIH, uh, took on the roll of having overall responsibility through the division of safety, so prior to the creation of the division of safety at NIH, there was no over-arching office to, that….

**Emmett Barkley:** There was an office, uh, uh, an Environmental Health and Safety Office in the, uh, service organization, of Division Research Services. Uh, it had probably been there for twenty years, dealing with issues of laboratory safety.

**Randall Morin:** Traditional safety.

**Emmett Barkley:** Traditional safety issues. It was only, uh, and I don’t know that they had a unit on infectious diseases, uh, at that time, uh, but it was really, uh, I think the Cancer Institute was the first where there was a focus on biosafety as an entity and it really….

**Randall Morin:** That came out in concern for the, uh, oncongenic virus issue? The unknown nature of….

**Emmett Barkley:** That’s right. There was clear evidence that, uh, uh, there were leukemia viruses in mice, uh, the causative agent of leukemia, and the, the focus of the early cancer program was, uh, childhood leukemia, and it was really called the, uh, the viral oncology leukemia program, uh, uh, and that was, that kind of brought it together the, the interesting time, being in the mid and late ‘60’s, was also the time that the Federal Government was, uh, really getting very, very serious about, uh, uh, prohibiting, uh, uh, bio warfare activities, uh, even, uh, work to, uh, the biological work that was done at Ft. Dietrich which was defensive bio-defense, uh, work, and it, um, uh, President Nixon, uh, basically in 1969, indicated that there would be no more Federal work on biological defence work and closed Ft. Dietrich for that function. This was, um, uh, at the, we were very fortunate in the Cancer Institute because the biological safety program for cancer viruses, uh, to, uh, gain Dr. Wedum’s entire group, uh, as far as this transition, so we made, uh, a very strong argument that that resource was so valuable that it could be of great help to the, uh, biomedical research community. And, so, uh, Dr. Wedum became an advisor to the Cancer Institute, uh, as did his deputy, uh, Dr. Briggs Phillips, and the staff of his program, part of the staff came to The National Cancer Institute. Uh, I got the gold piece, which was Manny Barbeito, and, uh, the other staff became part of a, uh, Litton company that had then got a contract to, uh, carry on the cancer program at Ft. Dietrich. So, the group stayed intact, uh, which was which was…

**Randall Morin:** That was very fortunate all those years expertise were not lost when they shut down the offensive program at Ft. Dietrich. They were able to find jobs in the field, so to speak.

**Emmett Barkley:** It was, it was absolutely, uh, a wonderful opportunity for, uh, for the Federal Government and, as you know, the recombinant DNA, uh, era was in the process of its, uh, uh, development in the late ‘60’s and early ‘70’s, so, uh, Dr. Wedum and Manny Barbeito and all these people were available to, uh, uh, work with NIH, uh, and, uh, uh, in developing the physical containment guidelines which were very significant part of the guidelines.

**Randall Morin:** Speaking of the Federal Government and it’s role, uh, the three of you, obviously, were Federal employees for much of your career, how do you feel, uh, now in terms of what you think is the best role for the Federal Government in terms of trying to regulate and control, to some degree, what, um, research is conducted in your particular country? Um, are you satisfied that the role is about what it should be now? Do you feel like they’ve gone too far or they haven’t gone far enough?

**Jonathan Richmond:** I don’t think that we need anymore regulation. Um, I remember a quote from Maxine Singer who said, uh, “Rules as rules are lousy ideas. What we really need is common sense.” And, I think this is, there certainly is an attitude in our country at the moment that things are out of control, that things are not there, and I would reflect back on, on two things at this point. Number one, you had mentioned some of the staff that you were able to capture at NIH. Back when we had, following the problems at Plum Island, the release of the virus, one of the, one of the salient things that occurred was the requirement that we have an external, outside biosafety review every year. And, the people that were appointed to that review were Manny Barbeito, Everett Hanel and John Richardson. And, my experiences working with them over the next five years were incredible, as a learning tool. But, I think one of the things that we have missed in, um, as we go forward, particularly with our containment facilities, as I’m not sure all of them are using external reviews, um, in the way that could be very helpful to them. And, the second point that I remember, and I was talking with Emmett about this earlier, is Carl Johnson, who is one of the, the first people working in the, um, Level 4 labs at CDC, um, said at a, at a meeting, gosh it could be almost 30 years ago now, that one of the things that the biosafety community really needed to be doing was collecting, uh, data on near misses and on lab accidents and laboratory acquired infections, and challenge the government to figure out a way to do that. And, uh, that has not happened. And, for a number of regulatory reasons, I know the Federal Government can’t seek out certain kinds of information. But that, that is really the basis for a lot of the development of the agent summary statements in the BNBL is being able to evaluate lab acquired infections, and then, just as, as Dr. Wedum did, dissect that, find out what the root cause was and how can we prevent that. And, we, we just don’t have a mechanism for clearly looking at these. It’s one thing to have a, let’s say, a needle stick injury is going to happen sooner or later. If you’re playing with needles, sooner or later, somebody’s going to get a needle stick. Um, that’s one kind of accident, and there’s, there’s some things you might use through engineering controls to prevent that, some you can’t do. But, if you can look at patterns, or if you can look at systemic problems that may be occurring, either in multiple locations in your own institution, or even across institutions, then you can say, wait a minute, we have a problem we have to deal with. And, right now, we don’t have that ability to do that.

**Randall Morin:** Emmett, I think it was you that mentioned, uh, your experience, uh, at the Alsilomar Conference during the early days of the debate about the potential hazards of the new recombinant DNA technology. Uh, thinking back on that, uh, now knowing what we know about recombinant DNA, and its become very commonplace and, uh, you know, conducted at the High School level, do you have any thoughts about how that experience went, and uh, the debates that raged, I’m sure?

**Emmett Barkley:** I think it was one of the finest moments of the scientific community to take responsibility for addressing an issue of potential risk. Uh, it was, uh, it was an invigorating experience. And, yes, there were Nobel Laureates on both sides of the picture. It was, uh, it was just absolutely wonderful to observe and to participate in. And, [clears throat] it, um, interestingly began at the first Alsilomar Conference, which a lot of people don’t realize existed, uh, where the primary issue that raised the concern of scientists of, of, of working with, uh, a human pathogen then, uh, uh, introducing a gene into e-coli to replicate, uh, genes that may be a causative factors in disease, uh, came about. Um, uh [clears throat], that conference raised the issue of, of, of potential risks, uh, in many, many ways and was the pre-cursor to the Alsilomar Conference in ’74, I guess, where they actually looked specifically at recombinant DNA. The, um, several members of the science press were invited. Uh, they were asked not to report until the, um, the end of the conference where the guidance might, could be addressed. And, there were a group of, uh, ethicists that were invited to the conference, uh, and it always struck me as of interest that, uh, the, the transparency they wanted to really convey, they really wanted to talk about their responsibilities and the ethicists were, uh, very, very, uh, influential in the, uh, in their thinking, and I can always remember that the, um, the most contentious argument, uh, in that whole, uh, the discussion and debate, was over the question of whether the guidelines should prohibit malth pipetting [laughs] or not. The same issue that had been alive for almost a century, and, and it was, uh, it was really a surprise to me because the, uh, organism that they wanted to insert the genes into was e-coli, and the only way e-coli was going to be of a hazard to anybody was if you were to make it hazardous and, uh, ingest it [laughs]. So, the compromise, and it took hours, uh, one night to work out, was that, um, there would be a strong recommendation that pipetting aides would be made. Uh, and that was, uh, basically for that low level of risk. The, the intermediate levels it was prohibited, but, uh, then the first revision of the guidelines that came two yeas after the first ones were issued in 1976, prohibited it at the, uh, the lowest levels. So, it’s the, uh, the kind of history of wanting to not, uh, uh, do away with a habit that one learned from their, uh, uh, professors and uh, uh, laboratory aides in, in college. It took a while to change, but….

**Randall Morin:** The practice of malth pipetting, um, it’s interesting you mentioned that because, um, my understanding of the definition of the containment levels that came out of the Alsilomar, the P1 through P4, actually focused more on the physical containment aspects of the laboratory rather than the practices and procedures in the laboratory, um, so it’s interesting you would, you would remember that the malth pipetting issue, so that was a, uh, did they also discuss the, the, the aspects of the various levels of physical containment that would be required in the types of laboratories?

**Emmett Barkley:** Yes, and they, they basically patterned that after the Cancer Institutes’, uh, three levels of, uh, of containment.

**Randall Morin:** So, the P1 through P4, uh, levels were already defined pre-Alsilomar.

**Emmett Barkley:** No. The, uh, it’s, uh, the scientists are very ingenious and at the conference, there was a consideration that, um, if, if we’re able to manipulate, uh, the genetic information of cells, uh, we aught to be able to, uh, do it in a way that we can make a cell safer. And so, what the, their, the reason I think for the strong debate on malth pipetting is that, uh, one of the, one investigator had been studying how you could, you could, uh, alter e-coli so that it would, when it, when it was out of its, uh innate environment, it would die almost immediately. And, so that it wouldn’t, it would not be capable of replication if it were to escape the, uh, nutrients in the lab. And, so they, they created the, uh, containment, the bio-containment, biological containment and they called it EK1, EK2 and EK3, and they used the P for physical, so that’s why we had P1, P2, P3 and P4. P4 was what was being done at Dietrich in the, their high-containment laboratories and P1, P2 and P3 were kind of similar to the Cancer Institute….

**Randall Morin:**  I see.

**Emmett Barkley…**standard. And, it was really kind of exciting to see all of that, that come together and…

**Jonathan Richmond:** You, you were talking about, um, malth pipetting as an issue and, um, this really came to a head, uh, in the, uh, late ‘70’s, early ‘80’s when the guidelines were coming out. At that time, that was also, um, when we were introducing the first biological safety cabinets at Plum Island. Prior to that, we had used a lot of the old Blickman 1 cabinets. But, we were bringing in the Class 2 cabinets, and the struggle that our people went through trying to figure out how they were going to do pipetting, getting inside the cabinet to malth pipette or to do something else, and that really was a physical barrier that led them to wanting some kind of pipetting devices, uh, that, that helped us, uh, stop the malth pipetting. Although, it took many years to teach people, uh, proper ways to use the cabinets. Um, I remember one day walking through the lab, uh, and seeing a veterinarian – uh, I love veterinarians – but, seeing a veterinarian, um, dissecting a pig that was laid out on the floor and he had raised up the, the cabinet, biosafety cabinet glass, thinking that was going to provide the protection to him. So, we had to have a little, uh, discussion there as to, uh, how the cabinets worked, etc. It was one of those teaching moments.

**Mary Ellen Kennedy:** I have a malth pipetting story I have to share with you. And, [clears throat] when I first began to work with the Provincial, uh, microbiological lab, um, I rotated through the facility, so I learned all of the various procedures. And, I worked for some time in the syphilis serology unit. We did large volumes of work, uh, syphilis serology. And, the lady that was the head of that particular unit [clears throat] was very strict - very strict lady. And, at that time, we had, everything was glass. Glass pipettes, glass Petri dishes, everything, and she used to meticulously was these pipettes and everything. But, she was very fussy about how many pipettes you used in a day. She was also very fussy on who made up the Kohlmer saline. So, every morning she would take a flask and she would make the Kohlmer saline and she would put one pipette in it. And all the technicians had to use the same pipette. So, we’d, you’d have to fill hundreds and hundreds of little tubes, you know, to do your serology. And, [clears throat] you know, you’d use the pipette and the bottle of Kohlmer saline and you’d pass it to the next guy. [laughs] And, she would not allow more than one pipette. And, I used to think this was so gross because my Mother taught me to never share my toothbrush. So, we went, that went on for a long time until one of the technicians came down with active Tuberculosis, that shared the pipettes.

**Randall Morin:** Interesting.

**Emmett Barkley:** It’s like using one syringe to inoculate, vaccinate a thousand people.

**Mary Ellen Kennedy:** Uh huh. Uh huh. And, eventually we were able to stop that, but, uh, I still remember it to this day.

**Emmett Barkley:** But, one of the, uh, you have to also recognize that the, uh, pipetting aides that existed in the ‘60’s were exceedingly difficult to use.

**Mary Ellen Kennedy:** Oh yeah.

**Emmett Barkley:** And, they probably caused more injury to scientists and technicians than much of the material that they were pipetting. Uh, they, they would not be, uh, on anybody’s program of an ergonomic piece of equipment.

**Randall Morin:** Right.

**Emmett Barkley:** And, if you look today, uh, at the pipettes, uh, the pipetting aides that are available, they, they are wonderful pieces of equipment for scientists to use because they are, their precision is specific, uh, their deliveries are specific, they’ve been designed with ergonomic standards, they, and, part of safety and part of our responsibilities as biological safety officers is really to, uh, help develop the means by which people can, uh, uh, enhance their safety, improve their work. And, that was one of the very unique things that was happening at Ft. Dietrich, uh, in the time of, of Dr. Wedum. Their safety people worked hand and glove with the scientists and with the engineers and they were able to, um, build equipment to meet the needs of scientists and we see very little applied research in the field of biological safety today. And, the people who were really, uh, uh, demanding the changes and getting ideas out are scientists themselves, uh, and the collaboration between, uh, manufacturers of equipment and scientists is probably a lot stronger than it is between biological safety officers and the scientists. And, we need to, we need to change that. We need to really be complete partners, uh, and not, uh, uh, always compliance oriented. But, it’s, um, it’s a good field to get into.

**Randall Morin:** Yeah, it concerns me as well that there really are few, if any, programs, at least in the United States, that are dedicated to the field of, what I would call, biological safety research. Um, there are few training programs out there, but they primarily are oriented to train people how to practice the field of biosafety, not research, uh, as was evident at Ft. Dietrich, um, and that’s unfortunate. The, the research funding, I guess, is becoming more and more difficult and, um, the program that we had at Ft. Dietrich, at one time, has now been completely shut down. The safety department no longer has any money dedicated to research, and that’s unfortunate.

**Jonathan Richmond:** I remember going to many, many ASM meetings and enjoying them, um, because of all the exhibits. Uh, this was before ABSA started to have exhibitors. But, I went, went around to every single exhibitor and looked at what they were marketing, what they were trying to sell, from a safety perspective. And, if you go repeatedly year after year, and you challenge people as to how they’re doing things, it was really great to see how they took up that challenge and would come back and make the modifications, um, for that it was, it was interesting, um, a paper was given this morning, somebody who’s been looking at, uh, some of the risks or potential risks associated with the, um, uh, cell sorters. And, I remember twenty years ago that, that, uh, we did some work for you, um, uh, on trying to evaluate any safety hazards with cell sorters, and that was a paper that was eventually given at some meeting. Uh, so, there are some people who are trying to do that, but some of this richness of the, of that work was never captured in a publication anywhere that people could reference.

**Randall Morin:**  Right. One last area I’d like to just throw out before we, uh, conclude the session is, um, you mentioned the early days of recombinant DNA technology and it started with, uh, e-coli and, uh, I note, noted in the paper, the day before yesterday, that uh, the three winners of the Nobel Prize this year, uh, was for work done with transgenic, uh, animals, specifically mice, uh, that have now been engineered to carry a number of different genes. They’ve knocked out a lot of the, uh, genes to make these mice more susceptible to various diseases, which, uh, obviously is a great aide in research. Um, how do you see the future of the, the field of, of the use of transgenic animals and, are you at all concerned, uh, that this is another area that, that the biosafety officer is going to have to become very familiar with, uh, in terms of potential hazards associated with animals that, uh, are capable of, of, uh, harboring infectious agents and incorporate, uh, human genes within their genome?

**Jonathan Richmond:** Personally, I think that, uh, just like with some of the recombinant work, the, the risks don’t change just because you have a different host. You’re still looking at the risk associated with the infectious disease. Um, so, I, I don’t really see a major, major shift. Um, I don’t know how you feel about it.

**Mary Ellen Kennedy:** No, I don’t think so either, and I think, I think that, uh, it’s being [clears throat] it’s being looked after in terms of the guidelines and recommendations that we have now. I don’t see a great change.

**Randall Morin:** Good.

**Emmett Barkley:**  I agree with that. I, I would like to return, just a moment, to, uh, Alsilomar because I, I think the, perhaps the most important thing that, uh, related to that was the decision of scientists to prohibit the conduct of recombinant DNA experiments that involved materials that were considered potentially dangerous until the community could really wrestle with the whole problem of risk. That, that, and that, uh, that actually happened. For two years, science was stopped in moving towards, uh, experiments that, uh, were planned to be carried out, uh, where, uh, a cancer virus gene was going to be inserted into, uh, uh, e-coli. Uh, an experiment that was eventually done, uh, at NIH under a P4 level of containment. But, the scientists recognized that they were not, um, that they were moving into a new era of research, uh, an exciting era, but they, they were not sure about the risks. And, so I, I think that is a, uh, it’s not only exciting for us in the laboratory safety field, I think it’s, uh, it’s, uh, also a lesson that scientists will probably replicate in the future when things that….

**Randall Morin:** So, you’re a believer in the basic premise of self-regulation and the scientists appear review process that the scientists can come up with safe and reasonable rules to control the hazards.

**Emmett Barkley:** I, I do to certain, certain limits, certainly. I, I think the recombinant DNA, uh, era, demonstrated that scientists could do that.

**Randall Morin:** Right.

**Emmett Barkley:** And, uh, the guidelines are, uh, uh, guidelines from NIH. They are conditions under which, uh, they, uh, govern that work, to a degree. But, had they been regulations, I think the, um, the great progress that has been made in the field of, uh, of research today would not have accelerated as it has been done. And, I think, uh, I think we need to be exceedingly careful about what we regulate and what we choose to lie upon federal agencies that provide resources for work and, uh, defining responsibilities of those who, uh, take on that work. I think we need to be very careful about that, what we do that, how we handle that in the future.

**Randall Morin:** And, Mary Ellen, is the Canadian model similar to the U.S. model in terms of the, the way that your guidelines are…

**Mary Ellen Kennedy:** Yes. Very much so. Um, we have a national research council that oversees recombinant work and they’re very closely attached to our guidelines and, uh, I think it’s a very similar process.

**Randall Morin:** And, when you think about the, the, the broad field of biosafety, uh, I think I’m accurate in saying that, uh, except for the OSHA standard on blood-borne pathogens and the fairly recently enacted select agent laws, there really are few regulations governing the research. Um, it, it is focused more on a reasonable approach in allowing the scientific community to, uh, self-regulate itself, to a large degree.

**Emmett Barkley:** And, and I think that’s an excellent model that the government aught to follow as well. I think it was absolutely appropriate for OSHA to come out with a regulation on blood-borne pathogens because it was a major, uh, source of, uh, uh, disease among people in the healthcare industry.

**Randall Morin:** Right.

**Emmett Barkley:** Uh, the nursing community, and, and they drew upon the guidance of the BNBL, and, and so, with, with, uh, standards that, uh, scientists and safety people have put together voluntarily. And so, and to me, that really makes a lot of sense. That’s a good, uh, collaboration among the scientific community, the safety community, uh, federal agencies, and, and the regulatory agencies as well.

**Jonathan Richmond:** Just as a follow on, um, and I totally agree on principle, and I admire the stature of the scientists in the mid ‘70’s at El Alsilomar who basically said, “Time out. We have to figure out, uh, what’s right, what’s wrong, what’s safe,” as you mentioned the ethicists and so forth. What bothers me today is that we have a number of kinds of experiments that have been proposed and indeed have been done and have been published, it’s probably infringing upon that same arena that says should there be a time out. Should there be responsible scientists saying, “You know, we really need to think through some of these kinds of experiments.” Um, and we had, we’ve had some pretty heated debate about this the other day, uh, from the floor. Um, and, and I still that, that guidance is the direction to go. But, I think that there’s the counterpart to that which says that the people doing the work need to be, perhaps, thinking more in the same vain as the Alsilomar scientists were. Is this the right thing to do – Is this the safe thing to do, rather than just saying, we can do it.

**Mary Ellen Kennedy:** The one thing that’s come up in the last couple of years that really concerns me is the re-construct of the 1918 flu. And, um, I, I [clears throat] when I read that, I was really concerned because it makes you question a whole bunch of areas relative to the facilities that work with (51:33 – unintelligible word). What are they doing with it? How are they storing it, etc.? And, I don’t think some of the people appreciate what that 1918 flu was really like.

**Randall Morin:** Yeah, I read the other day that, um, (51:46 – unintelligible word) is that in a few years, probably less than ten, uh, they’re talking about the creation of life through the technologies that we now have at our disposal, so.

Well, in closing, um, do you have any thoughts about the future of biosafety, either as a profession, or as a field of, of, of research? Do you have any thoughts on, uh, challenges that would, that really do need to be addressed? Or, um, anything else that you’d like to comment on?

**Jonathan Richmond:** I’ve, I’ve become concerned over the last few years as we look at the, um, particularly at the growth of our containment laboratories, that we do not have a really robust program for training biosafety officers. Um, the, the program that, that you were part of at, uh, in North Carolina, um, was a great program to bring out people with Masters Degrees and Doctorate Degrees in biosafety science. We simply don’t have that kind of program. And, if you look at some of the laboratories that are being built today, uh, and I’m not necessarily talking just about the biosafety officers, but the people who work in these facilities. Uh, we have a, um, very large facility being built at Ft. Dietrich, uh, that will be focused on huge numbers of non-human primates in Level 4 containment. I think the number of people, the animal care personnel themselves, that have to populate that facility, uh, exceeds all of the people who have experience working with non-human primates in Level 4 anywhere in the world. We have engineers that are going to have to run a facility that don’t have that experience. I’ve spent a lot of time over the last few years trying to bring the facilities engineers into the biosafety training programs that I do because of that marriage that has to occur. You talk about that relationship between the engineers and scientists.

And then, the whole issue of, do we have enough biosafety people trained and experienced at a high enough level, who really are experienced at Level 3 or Level 4. I just don’t see them out there.

**Mary Ellen Kennedy:** I think the situation in Canada is even worse. Um, [clears throat] we’re behind, you know, by a number of years, relative to the progression of safety in the United States. I mean, it wasn’t until 1990 we had our first set of guidelines even. And, we have no formal training programs. We have no university programs. And, my experience with talking to people, certainly the, the, so-called biosafety officers, these young people coming along said they’ve been pretty well thrown into the position. And, in many cases, these are in the university settings. They haven’t got the financial backing to send them down to the States for some kind of post-graduate training. And, so we’ve got the same proliferation of containment facilities coming along. I mean, it’s absolutely amazing what’s happened in the last five, six years. And, I’m very concerned about the staffing of those facilities. And, additionally, when we go back to the comment on regulations, the only regulations we have in Canada relative to Level 3 and Level 4 are tied in with the importation of human pathogens regulations. And, [clears throat] what that means is if you’re going to import a human pathogen of a particular, uh, risk group, such as your select agents, then, um, the facilities have to be built in accordance with our guidelines and they have to be inspected by federal agencies. Other than that, without the importation regulations tied in, we have no regulations that control these facilities. And, we have no inspection program, unless it’s a voluntary thing where they say, ok, we’d like someone to come in and look at them. So, I think that that’s, that’s, to me that’s quite a concern in our Country. And, I don’t know how they’re going to staff them either.

**Randall Morin:** Well, absent of formal, uh, training program, uh, one option that I think, perhaps, we should look at is using folks like you to help mentor these new folks that are now coming along, they’re being appointed as the biosafety officer, uh, similar to your situation, you were a micro-biologist and you were given the job. Well, that’s one thing in, in your typical Level 2 diagnostic laboratory. It’s a completely different animal if you’re talking about a Level 4 facility that’s housing infected non-human primates, so I would agree that that’s something that, that we really do need to take a hard look at before we get in too deep and these facilities are open, the scientists are coming in, and, suddenly, we’re faced with this complete void in safety experience.

**Mary Ellen Kennedy:** And a two and three day training course is not sufficient.

**Randall Morin:** Right. Yeah.

**Mary Ellen Kennedy:** At all.

**Emmett Barkley:** I certainly agree that training is the most, uh, is the greatest challenge that we have in the future. Uh, I’ve always saw, uh, saw safety as the most important element of safety is how organisms are handled in the course of research. And, the next is the equipment that they use to contain things, uh, what we call primary barriers in the facility, so that the facility is the third level of deterrence. And, but the, we get more attention to the, the physical part of the facility and I’m less concerned about the risks that, uh, that those facilities present because of the rigorous procedures people have to go at just to get in and to use it. I’m more concerned with the BSL2 and BSL3 laboratories and, um, I think they’re, we know that there’s going to be a lot of resources available, we think, uh, to conduct research in these areas with pathogens. That means that there are a lot of scientists and technical people that are going to be drawn into this area, most of whom have not had experience in handling pathogens at all. So, training is, is essential. The mentoring that is really needed and, and, I agree that mentoring of biological safety officers is very important, but the mentoring that is really needed needs to come from within the scientific community. Uh, particularly the scientists, uh, who are proficient in the handling of infectious agents. We need to capture some program there that can bring about the, uh, the competency levels that are really essential for this work.

**Jonathan Richmond:** And, and I think too, as we have moved, we the science, has moved more and more into the molecular biology side of things, people tend to either forget or ignore the source of some of the agents. They aren’t necessarily trained, uh, in understanding the infectious nature of some of the, what would be the starting materials, or things that they may be injecting into animals.