History

of the

U.S. Food and Drug Administration

Interviewee: John C. Villforth

Interviewer: Donald R. Hamilton

Date: May 1, 1997

Place: Washington, DC

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

National Institutes of Health
National Library of Medicine
Bethesda, Maryland 20894

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John C. Villforth

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

CASSETTE NUMBERS

GENERAL TOPIC OF INTERVIEW: History of the Food and Drug Administration

DATE: May 1, 1997 PLACE| FDLI, Washington, DC LENGTH:

INTERVIEWEE:	INTERVIEWER(S):
NAME: John C. Villforth	NAME: Donald Hamilton
ADDRESS:	ADDRESS: Food and Drug Administration

FDA SERVICE DATES: FROM: 1961 TO: 1990

TITLE: Director, Bureau of Radiological Health and its current name, Center for Devices and Radiological Health

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DH: This is another in a series of interviews with the FDA Oral History Program. Today the interview is with Mr. John C. Villforth, former director of the Bureau of Radiological Health and its successor organization, the Center for Devices and Radiological Health in the Food and Drug Administration. The interview is being held at the headquarters of the Food and Drug Law Institute in Washington, D.C.; the date is May 1, 1997. Present in addition to Mr. Villforth is Donald Hamilton, the interviewer. The transcript of this interview will be placed in the National Library of Medicine, and will become part of FDA's Oral History Program.

John, to start the interview, we like to begin with a brief autobiography. Would you start with some of your early years, where you were born, raised, educated, include any work experiences you may have had prior to coming to FDA?

JV: OK. Let me get started. I'm John Villforth. I was born in December of 1930 in Reading, Pennsylvania. I consider myself a Pennsylvania Dutchman. I came from a long line of Pennsylvania German ancestry. I had all my early years in Reading, and after graduation from Reading High School in 1948, I went on to Penn State and received a bachelor's degree in 1952 and a master's degree in 1954 in what was called then sanitary engineering, which I guess today would be called environmental engineering. Obviously the thrust at that time was on water supply, waste disposal, and things, sewage disposal, and things like that.

But I had the opportunity to take a seminar in the program, in which there was a returning veteran from World War II who was very interested in the potential of ionizing radiation following the use of the atomic bomb in Hiroshima, Nagasaki, and he convinced a professor that we should have a whole special seminar on atomic theory and radiation because he thought that was the wave of the future. I took that seminar and was very much impressed with the potential of the subject, and I guess my early interest in radiation started at that particular point.

After graduating in January of 1954 with my master's, I had an opportunity for a direct commission into the United States Air Force as a sanitary and industrial hygiene engineer. These

engineers were assigned to the medical service as a part of the Medical Service Corps. After initial orientation at Gunter Air Force Base in Alabama, I was shipped up to Loring Air Force Base in the northern tip of Maine. It was a strategic air command base that flew B-36s.

In addition to the normal industrial hygiene – and I was the only industrial hygiene engineer on the base at the time – but in addition to the routine industrial hygiene work, such as being concerned about battery acids, jet fuel spills, work on the flight line, noise problems, et cetera, the B-36s from that base, as other bases around the country, were involved in nuclear weapons testing in the Pacific and in the Nevada area. These aircraft would fly around and through the clouds to give the – radioactive clouds from the detonations – to give the pilots experience with dealing with the atomic weapons at that time. These airplanes would return back to the base and would be contaminated, and there was always the concern of how to deal with that and how to set up methods of decontamination. So I was involved with some early radiation work at that time, as well as the large number of radioactive electron tubes that were used in the radar and all the electronic operations on the base. Many of these electron tubes, probably about five hundred different types of tubes, had small amounts of radioactive material in the tubes to increase the life and do things like pre-ignition, as they called it, of the tubes. When these tubes were worn out or expired, they had to be disposed of in a proper manner. So that was exciting trying to figure out how to do that.

The base also, in the fifties, as you can imagine, was concerned about the possibility of all-out war and the Russians with their capability of atomic weapons possibly targeting the base. So there was a big need to train the base personnel on how to deal with the effects of atomic radiation and the consequences of war. So I ended up being the training officer for the base on radiation protection.

I had an opportunity just about the end of my short, three-year tour there to go away for graduate training. I had applied to Reed College out in Oregon for radiation biology training, and when I received the approval from the headquarters, it indicated that I was going to Vanderbilt University in Nashville, Tennessee, to be a part of the Atomic Energy Commission's program.

This shocked me, because I couldn't imagine myself going to Tennessee. It just seemed like it was much more primitive than going to Portland, Oregon. But everyone assured me that the advantages of being close to the Grand Ole Opry compensated for any dislocation into a remote area.

Actually the Vanderbilt program had been going on for several years, and it was a part of the program that the old Atomic Energy Commission – which is now the Department of Energy and the Nuclear Regulatory Commission. The old Atomic Energy Commission supported programs around the country which were collaborations with universities and national laboratories. The Vanderbilt University program was collaboration in the physics department there and an opportunity for experience at Oak Ridge National Laboratory during the summer.

So I went off as an Air Force assignee, where all the rest of my classmates were recipients of an Atomic Energy Commission grant or scholarship. So I joined them and went through the program, went through the practical opportunity at Oak Ridge National Laboratory where we did all the things that radiation technicians do.

Then I had the opportunity to continue on to do some research in physics for my master's degree in physics. The work that I had, that I was involved in under the leadership of K.Z. or Karl Morgan and Bob Burkhoff and Harry Hubbell had to do with x-ray spectroscopy. The question was how can one characterize the spectrum coming out of a diagnostic or a therapeutic x-ray machine using the theory that had been developed – the theoretical approach – versus what really comes out. They developed a single-channel analyzer and a very primitive type of counting system to allow me to make the analysis of the actual spectrum and then compare that to the theoretical spectrum. So it was an interesting project. Today all that stuff is so obvious and so simple it can be done in seconds, but it took me months and months and months of collecting data to do what today would normally take seconds. But it was an exciting project, and it was exciting to be working with those people.

When I was finished with that tour of duty, the air force sent me to Wright-Patterson Air Force Base outside of Dayton, Ohio. Wright-Patterson Air Force Base was the headquarters of the organization which was at that time called the Air Matėriel Command (AMC). The Air Matėriel Command had a

series of three environmental laboratories around the country and was just establishing a fourth laboratory which was just devoted to ionizing radiation. The purpose of these three environmental labs and the fourth lab at Wright-Patterson on radiation was to…These labs were to receive samples and analyses of biological fluids, environmental samples, and so forth for radiochemical determination and for personnel dosimetry determinations for the entire Air Force.

So this was kind of a treat to be involved in the establishment of the laboratory to put in the Air Force's first whole-body counting system and to be responsible for the entire Air Force radiation film badge or radiation personnel dosimetry program. Then when overexposures occurred in any of the facilities, the medical facilities for example, we would send out a team from some of the other bases in the Air Matériel Command to investigate the cause of overexposure and try to correct the problem.

DH: John, this whole-body facility was out at Wright-Pat?

JV: Yes.

DH: OK. All right. I wasn't aware that they had a whole-body counter out there.

JV: They never really got it off the ground, I mean, it got started, but it never got completed. This was in the back of the laboratory. As far as I know, it really never ran through a lot of people. It got set up, and I got transferred out of there before it really got completed. But we laid out the design work for it, got it installed. The whole radiation laboratory function was transferred away down to Texas. The base mission changed, the headquarter's mission changed, and so forth. You know, I got involved in the beginning of this stuff, but the transition then changed the ultimate disposition of these laboratories.

But the Air Matériel Command was looked upon by all the rest of the commands—like the training, the tactical air command, the strategic air command, et cetera, all of those commands that had

problems in environmental issues or in this case radiation issues – they would use the consultation of Wright-Patterson and the engineers and health physicists and so forth.

I guess I was probably the first trained health physicist in the Air Force. There were about three people that were ahead of me but had not gone through the formal AEC training. They had been exposed, on-the-job training at places like Los Alamos and so forth. Most of them were, I think they were biologic, clinical laboratory officers who understood clinical laboratory work, and they were shipped away and did primarily bioassay work, radiochemistry work for urines and bloods and things like that. So, like I say, they were really probably the first radiation protection personnel, but I think I was the first one who had any formal training on the part of the Air Force in radiation protection.

We also did one other thing at Wright-Patterson, and that was establish what was known as the Air Force Radioisotopes Committee. As all users of byproduct and other radioactive materials had to be licensed by the Atomic Energy Commission, the Air Force decided that it was not practical or not wise to have each of its bases and each of its commands submit separate licenses to the Air Force. The approach was that all of these requests for use of radioactive materials… For example, exit markers in aircraft; the use of radioactive materials on I think it was a zinc, one of the zinc isotopes on twenty millimeter shells that could be used for determining the proximity of the projectile to a particular target. Obviously, if you're shooting at a target with a… In those days, it was on a… If it's towed behind an aircraft, the only way you could tell whether you got close to it was whether you put a hole in the target. But if you put a radioactive isotope on the projectile and you put a detector in the wind sock, or the sock that you're, the object you're towing, you could get some indication of how close the gunners actually came.

DH: It must be a pretty hot source.

JV: It was a fairly source, yes. It wasn't very practical because they were going to do it off the Gulf of Mexico, and there was a big question about what are you going to do with all of this radioactive zinc in the Gulf of Mexico and the fishing grounds and so forth. So it never got off the ground. But the idea of

working up the proposals for those materials, and working with the Atomic Energy Commission, and the licensing of it fell with me because I was the secretary of this committee. So I got my first taste of the regulatory process at that time. And I got to know quite a few of the folks in the Atomic Energy Commission quite well, and I think we had a good rapport.

But it was exciting whether the materials were radioactive tubes and electron tubes, or whether they were projectiles, or use of magnesium thorium alloy as counterweights on high-performance aircraft. How much thorium do you put in the magnesium, you know, with the magnesium before you get into a problem? That plus the laboratory work was very exciting to me.

So I did that from essentially the spring of 1958 until I joined the Public Health Service in the spring of 1961.

As my tour was ending, close to 1961, the typical military approach to things was to rotate people overseas. I had not had my tour overseas, so my next tour was going to be somewhere overseas. Unfortunately, there were no radiation billets overseas, which meant that I had to go back and do sanitary engineering. Or as I said, it's no fun, after you're working with radioactive materials in this high-tech area, to go back and design pit privies for troops and advances of posts for tactical aircraft somewhere in Europe. I was so excited about the radiation area, I wanted to stay in it, and there were just no opportunities there.

So I thought, well, my time is up, I'm going to look around. I had paid back my obligation for the schooling they gave me, and so it was an opportunity to make a change. So I started looking around. Since I was a member of the Health Physics Society, I remember putting my name on the bulletin board looking for a job at the Boston meeting of the Health Physics Society, and that was I guess in 1960 – probably the spring of 1960, it was.

Two gentlemen came up to me at the time and said, "Have you ever thought about the Public Health Service, the Commissioned Corps of the Public Health Service?" My reaction was, "What? Who? Never heard of them." So they explained to me that there was such a thing as a Commissioned Corps of the Public Health Service, and that if I were to transfer or … Actually one could not transfer. If I would

resign from the Air Force and then be reappointed to the Public Health Service, the Public Health Service would give me credit for my almost eight years of experience in the military; and since the Public Health Service had a twenty-year retirement, that mean in twelve years I was eligible for retirement from the Public Health Service.

Plus, they said they had a different system for calculating one's rank based on one's training and experience. Since I came into the Air Force with a master's degree and having essentially a year's more, a little more than a year's worth of experience than most people coming in at the bachelor's level, that would give me an additional benefit towards promotion, which they, although they couldn't guarantee me at the time, would probably give me the rank equivalent to a major. Well, I was still a captain in the Air Force, and so the idea of working in this new organization, the Division of Radiological Health in this to me unheard of Public Health Service, and they assured me I wouldn't really have to worry about a uniform, because hardly anybody ever wore a uniform. So I had all the benefits, and I would be working.

DH: Plus state-side service.

JV: Plus state-side service and this looked very, very attractive. So they gave me a hard sale, but what, I guess, convinced me was these two gentlemen said, "We had read your thesis, and we are doing work specifically on x-ray spectra, because what we're trying to do is work to reduce the radiation dose in medical radiation, specifically medical x-radiation. And we have developed a quick technique to check the quality of the dental x-ray's beam, the quality of the beam, by using pocket chambers and an aluminum sleeve – which they called CAP. By measuring the ratio of the CAP on and the CAP off – that is, using a dosimeter without the CAP, aluminum sleeve – making a reading, repeating the procedure with the CAP on and getting a different reading in the pocket chamber, one could get some idea of the quality of the beam, and this determine whether the filtration that is should be inherent in the x-ray beam was adequate or whether the patients were getting too much superficial low-level exposure because it was improperly filtered."

And it wasn't working well, and they were interested in someone who understands the spectroscopy, x-ray spectroscopy, and said, "So in addition to all these other things, we *really* would like you because you know something about x-ray spectroscopy."

Well, I started to salivate because, you know, they said all the right things. So I said, "Good, how do I join?" "Well, of course, it's very simple. You just have to resign from the Air Force, and then we'll recruit you the next day." So I thought, well, now wait a minute. If I resign, how do I know all this will happen? How can I trust the Public Health Service, because I don't trust the Air Force to let me go when I want to go, and how do I trust the Public Health Service?

So after a series of faltering bits of correspondence back and forth. Actually, the original suggestion was that I would get a conditional release from the Air Force, that is, the Air Force would allow me to terminate my commission under the condition that I would be picked up by the Public Health Service. They said, you know, "This has been done before, so you apply for this."

So I went to the Air Force, and they said, "A conditional what?" they'd never heard of this. I said, "Well, the Public Health Service says it can be done." They said, "No, I don't think we know what it is. Who are they?" So it became very apparent that the Air Force was not about to give me anything like a conditional release, and I don't know whether that ever happened or whether they just made it up.

They finally said, you know, "Pick a date, resign, and then we will try as best we can to get you into the Public Health Service the next day." Which to make a long story short, they did, and it happened and I did get in as the equivalent to a major or a lieutenant commander at that time.

I was ecstatic, and I was assigned to the – which they told me I would be – to the old DRH, the Division of Radiological Health, at 1901 Chapman in Rockville, Maryland, where the main activities of the Rad health program were taking place. My first assignments in 1961 from when I got on board – from I think May till September of 1961 – were to get acquainted and start work in x-ray spectroscopy. I'll explain what happened in 1961.

But maybe I better go back a little bit and just talk, if I may, about how the Division of Rad Health got started, because I think some of this becomes important to our tradition and to my direction, if you will.

The radiation program in the Public Health Service had a history that goes back at least to the 1920s when some of the industrial hygiene people were involved in measuring as best they could at the time radiation exposure in the 1920s at the old National Bureau of Standards, the NBS, laboratories for calibrating radium. Later on, they were involved in the investigation of the people who were the so-called radium dial painters following the recognition in the twenties and early thirties that those, primarily women, who worked on the assembly lines during the latter part of World War I painting radioactive luminous compounds, radium luminous compounds, on watches and dials and instruments used for the war picked up a lot of radioactivity by ingesting the material from this painting process, and many of them had very chronic, long-term consequences from the radium exposure. So the Public Health Service got involved there.

That sort of activity continued, the interest in radiation continued at the National Institutes of Health (NIH) with some early work on biological experiments to determine work on the consequences, genetic consequences with drosophila and other, and fruit flies, to support the fact that radiation does have a genetic consequence in that there is a long-term concern.

The NIH people were also involved with the use of radiation in therapy and were asked in the 1940s to follow up on the use of radium and x-rays at a reasonable number of leading radiation therapy facilities around the country. They observed some rather striking mishandling of radium and misuse of x-ray equipment at these facilities and suggested that there ought to be a radiation protection program. Now this was NIH, NIH does research, so there wasn't really much done to carry out the implementation of these suggestions.

Then, of course, following World War II was the concern of nuclear – or atomic at that time – radiation and all of its expectations for ultimately nuclear power and the continued concern for testing of weapons. The Public Health Service participated again through its environmental and occupational

programs to look at the consequences of run-off from uranium mining operations, to look at the consequences of radiation around some of the national laboratories and so forth, and also to participate indirectly on some of the atomic weapons testing in Nevada.

The world, I guess, at that time was becoming increasingly anxious about the long-term consequences of radiation, specifically genetic, and the concern over the increased amount of weapons testing, atomic weapons testing by the U.S. and Russia and possibly by other countries. The United Nations set up an organization called the United Nations Scientific Committee on the Effects of Atomic Radiation. That group was asked to study the consequences of increased testing and increased fallout throughout the whole world, that is, particularly the radioactive strontium, the long-term radioactive strontium's and cesium's, from all of this weapons testing would have an impact that was of concern. And the question was what is the magnitude of this? What might be the magnitude of this? And what is the level of concern?

So, the study, which was completed I guess in the middle fifties, identified that of all of the sources of radiation, that whereas fallout was of concern, the biggest source of radiation to the gene pool or to all of, or to the population was from medical radiation. Therefore, there needed to be more attention placed on reducing, as best one could, the consequences of medical and dental ionizing radiation to the population, because these radiations ubiquitous as a medical – you know, it was available as a medical tool – and it was becoming increasingly available, and thus the need to get started in doing something about that.

So the surgeon general in 1958 set up a committee to look at what the Public Health Service should be doing with this regard and what the consequences were. This committee, known as the National Advisory Committee on Radiation or NACOR, recommended among other things an increased commitment to consolidating all the radiation programs in the government, to making them public health issues, to making them a public health responsibility, to establish with the Public Health Service an entity which would be responsible for radiation protection. Out of this recommendation, in July of 1958, the Public Health Service formed the Division of Radiological Health which was formed as a unit within the

Bureau of State Services. The Bureau of State Services was the parent organization in the Public Health Service which supported state activities.

See, there was no regulatory authority, no legislative authority in radiation. The only way the Public Health Service could have any influence over this problem – the problem being medical radiation or fallout – was by working with the various state health departments and seeing if they could convince the state health departments and seeing if they could convince the state health departments to take action at the local level, because there was no federal authority to do anything other than the broad aspects of the Public Health Service Act which provide for technical assistance, to do research, and to provide states assistance. These were broad, very general legislative authorities to the Public Health Service. But nothing said that the Public Health Service had the right to inspect or fix x-ray machines or mandate any programs. So the program was born out of a cooperative relationship with the state programs which specifically could have the authority to develop regulations and do things at the local level, and that's what was slowly happening.

So the program focused in on the NACOR. NACOR recognized a concern that the United Nations Scientific Committee on the Effects of Atomic Radiation identified and encouraged the Public Health Service to be looking at medical uses of radiation and getting on with a program to bring that medical radiation under control. So that was the reason that the people in the old Division of Radiological Health were looking at ways and means of assessing and reducing medical x-ray exposure, and that's why the two gentlemen came to me and asked if I might want to join that group.

I sense I should point out those two gentlemen… I've lost track of one of them, but the other one is, I know very well, and I kid him about that or he teases me that the real reason he wanted to get me to come to the Public Health Service, to the Division of Radiological Health was that he had been promised an opportunity to go to the University of Virginia and get his doctoral degree in biophysics, but he was not allowed to unless he could find a replacement. So I always tease him that he went out of his way to trap me into coming into the Public Health Service so he could get his doctor degree.

DH: I'm blanking on who you're talking about.

JV: Well, the gentleman is David Janes, Sr., and, of course, I've gotten even with him because his son, David Janes, is now working for me here at the Food and Drug Law Institute as our computer expert. So I'm holding the old man hostage for his … Actually, in spite of whatever motive he had, I'm glad that it happened, because I think I made the right decision.

So we had that program when I came on board of trying to move ahead with the radiation in medicine, and I was in what was known as the Program Operations Branch of the Division of Radiological Health. The Program Operations Branch was mainly dealing with the state people. The old division had a training program; it had a technical operations unit which dealt with other agencies, like the Atomic Energy Commission or the Department of Defense; and the Program Operations Branch was primarily, as I said a state cooperative effort. We would do the research, the assessment, look at techniques and tools that the states could use for assessing radiation, and then try to figure out how to fix the problem.

One of the techniques for, rather a simple technique but effective technique in dentistry was a device called the Surpak, which was nothing more than a sheet of medical film on which was, with instructions printed on the outside of the film packet – it was like an eight by ten sheet, I guess – which suggested, which you then how to place the dental x-ray machine with respect to this film and make an exposure – told them how to make the exposure – and then the film was sent back to our laboratory for analysis.

By determining the diameter of the image on the film, one could determine whether the x-ray machine was properly collimated; that is, whether the x-rays coming out of the dental machine were, that they weren't unreasonably large and covered the thyroid, the head, and so forth, but rather stayed in the area of the dental film that was necessary. In other words, you don't want to irradiate something that is unnecessary. Then secondly by placing strips of aluminum on this Surpak, one could determine

something about the quality of the x-ray coming out and whether there was a need for additional filters to be added to the machine.

So the fix of this was by providing these files to the states, the Surpaks to the states, they would go around in their inspections to the state dental units, expose them, return them to us, we would do the analysis, and report to them whether the beam needed additional filtration, x-ray machine needed additional filtration, or whether it needed a collimator – a collimator in this case being a large lead washer that would be inserted in the front of the x-ray machine to limit the size of the beam to suggested or recommended levels at that time.

So this was how we cooperated with the state. We did the analysis, and we reported on the statistics for the various states. It worked very well, and again, it was a cooperative program. The states didn't have to do this, but they were interested and very supportive of it.

DH: John, did the facilities that actually did the exposure, did you report to them as well?

JV: No, the Public Health Service didn't report to the facilities. The Public Health Service only reported to the state. The state then would go around and make a follow-up visit to try to fix it.

So what we also did in the basement of Chapmen Avenue was to make these lead washers or these aluminum disks that would fit in the machine, knowing that there were, you know, I don't know how many numbers of dental x-ray machines there were. Therefore, we would have all different kinds of dyes that we would … We had people in the basement pounding sheets of lead to make these lead washers or pounding out sheets of aluminum to make disks, and then we'd put these in a packet and mail them back for Dr. X, Dr. Y, Dr. Z. The state health department would then follow up, place the filters, place the washers in the machines to make them less of a biological problem if they had this material in. So this was an example of the most elementary, the simplest type of a program.

DH: Did they then take another exposure to see whether the problem was corrected.

JV: Yes. I don't remember. I think that was the case to get follow up. I thought that the idea was very appropriate.

My career changed in September of '61, when all of a sudden the Russians started retesting nuclear weapons, and the U.S. started doing more testing. The Russians started atmospheric testing, and I can still dramatically remember in the middle of September 1961, after the Russians had tested one of their bigger bombs that the level of radioactivity swept across the country and we really ended up in quite a panic. This was the era of people building fallout shelters and a lot of anxiety. You remember, it was a year or so later that the Cuban missile crisis came about, and there was quite a bit of panic there, and the threat of war and the consequences was certainly in everybody's mind.

So the medical x-ray program got sort of pushed aside, and many of us got pulled into what was called the Radiation Surveillance Center. We had a command post down in the old Health, Education, and Welfare South Building (HEW), South – I forget the name of it now – but where we collected from all of the state health departments results of fallout levels on a daily basis.

The Public Health Service geared up a program to provide the states at least one and sometimes two or three air stations. These were air sampling devices that would consist of vacuum cleaner motors that were modified, and it would hold an industrial filter that was partially available. These were mounted on a tripod or some stand on the top of usually the state health department building. These units would run twenty-four hours a day.

In the morning, the health department people would take the filter out and put a new filter in. Take the older filter, put it in a glassine or a plastic envelope, put a Geiger counter in contact with it, get a reading, and telephone in the reading back to us in the downtown Washington, and we plotted these readings on a map. The filters were then mailed into us to get the reading probably about three days later. You would pick up natural radioactivity, the radon daughter products, in addition to the radioactive fallout. So that first reading was higher than it should have been because of the natural radioactivity; but when the fallout arrived, it clearly swamped the background of natural radioactivity, and it was a good

index and a quick index of what was happening. But the more complete data was determined after the filters were sent back to the laboratory.

In addition to this, we provided collecting devices for rain, and precipitation. So in addition to air monitoring, whenever it rained we got the fallout, precipitation data.

DH: Samples

JV: Yes, fallout samples.

The Atomic Energy Commission through its program was using so-called flypaper or sticky paper technique, which was independent of us. Throughout the country they had sticky paper laid out which would measure the particulate material that would stick to the paper, and you'd take it back and do an analysis. That was a separate type of program from us, and we would coordinate with them.

Obviously, since this radioactivity contained short-lived radioiodine, there was a lot of concern about what was getting into the milk supply because that was the most vulnerable. So milk samples were collected throughout the country based on some understanding of what the milk sheds were and the proportional, you know, where the herds were with regard to the particular shed, and what that milk shed provided to a particular population area. So we had an index, an immediate index – well, within several days – of what the consequences were of that radioactive iodine that was deposited initially. We also did, of course, radioactive strontium and radioactive cesium in those milk samples.

So that really focused attention to everybody, and as I said, in September the seventeenth or the eighteenth – there was an incredible high pressure area over the East coast. This cloud sat over there for several days, and the radiation levels which were, you know, less than ten up till that point, went to seven, eight hundred. The press gave a lot of attention to this, and the hysteria developed. I still have in my basement copies of all of the letters that were sent in by consumers to the Public health Service at that time, expressing fear. I always thought if I had the time I'd want to write this up as an example of mass

hysteria from the radioactive fallout. But today it just doesn't seem like like it ever happened. But at the time it was quite dramatic and a lot of anxiety.

Well, finally the treaties were signed, and the weapons testing in the atmosphere was stopped, and things sort of got back to normal, and that which I would call environmental or fallout program continued for some years, but became rather routine I had the opportunity to get back to what was originally the Program Operations Branch of the Division of Radiological Health and later became known as the States Assistance Branch, which was a better term. The States Assistance Branch, or SAB, really was designed to help the states, and …

DH: When you came back, when you came in as part of the Program Operations Group, what was the leadership?

JV: I should have pointed out the person who was the director of the Division of Radiological Health at that time was Francis Weber, M.D., and the deputy was Jim Terrill. Frank Weber was off on all sorts of assignments and Jim really ran things. Then Don Chadwick became the director. Don Chadwick was then almost immediately assigned to the Federal radiation council, and he wore two hats. The president established a Federal radiation council – I think it was 1959, '58 the purpose of which was to have representatives from the various government agencies that were involved: the Department of Defense, the Atomic Energy Commission, the Department of Health, Education, and Welfare, and I think U.S. Department of Agriculture (USDA), all involved with some aspects of radiation. That group, the Federal Radiation Council, was to develop consistent standards for the government. Obviously, in the case of radioactive fallout it would be disastrous if the U.S. Department of Agriculture, seeing the levels of radioactivity in the food supply, went off and made some recommendations of action.

(Interruption)

The Department of Health, Education, and Welfare went off with an entirely different direction. You know, how would the public deal with a USDA recommendation that might be inconsistent with a HEW recommendation? In order to prevent that, the Federal Radiation Council was to develop consistent recommendations for radiation.

Now that applied not only to radioactive fallout, but radiation occupational exposure – that is, what are the levels of exposure to individuals who were working with radiation? You could not have the Atomic Energy Commission have one set of exposure levels, the Department of Defense with another set of exposure levels, and other government agencies with another. There needed to be consistency. So the Federal Radiation council was charged to pull that together. The chairman of the council was the secretary of Health, Education, and Welfare, and he turned to the director of the Division of Radiological Health, Don Chadwick, to be the executive secretary. So Don, where he was in fact the head of the Division of Rad Health, was detailed on essentially a full-time basis to the Federal Radiation Council; and Jim Terrill, who was the deputy, really ran things, and we looked upon him as our boss because Don wasn't really available.

DH: So Chadwick replaced Weber?

JV: Yes. The person who headed up the Program Operations Branch and ultimately the States Assistance Branch was a physician by the name of Russell I. Pierce or "RIP" Pierce. Rip had been a long-time Public Health Service commissioned officer in the foreign quarantine program, he had worked in the tuberculosis program, and was in my way of thinking just a superb public health person that understood public health – all aspects of public health – and he was a big influence, I think, on me. He had an engineer as a deputy, Roscoe Goeke, who had been a long-time sanitary engineer in the Public Health Service, and Roscoe had had some experience in radiation. Rip had not been a radiation person other than perhaps in a tuberculosis program where they used radiation for photofluorographic determination of the TB in the chest. Roscoe had some experience.

But both these people were public health people and understood the role of collaboration and working with the states and how to get the states to get the job done, and had a lot of advisers to the program who came from the state activities. Now the state activities at that time were made up mostly of the state sanitary engineering people. These are the, I will say, the old-time traditional sanitary engineering programs. The radiation function – that is, whether it was fallout or whether medical x-ray – generally fell through these units in the state health department. And the younger engineers picked up the responsibility for actually doing the work in what would be a radiological health unit or a section or whatever the particular state may have called it. These people generally didn't have much training at all in radiation.

There weren't many places to go outside of the Atomic Energy Commission programs, and they didn't graduate enough people to rally fill the demand at the state level. Consequently, the old Division of Radiological Health had a training program that produced one-week, two-week training programs on everything you could think of in radiation protection. Maybe there would be a two-week course that would deal with the laboratory aspects of measuring radioactivity with radiochemistry and multi-channel analyzers or whatever at the time. There would be a course on monitoring in the environment, fallout monitoring, how to do all that. And there would be courses with the radiation biology and so forth.

So there was a whole battery of these courses, most of which were given at the training facility at Rockville, at 1901 Chapman Avenue, and at the other laboratories that the Public Health Service had throughout the country, such as the Robert A. Taft Sanitary Engineering Center in Cincinnati and the laboratory at Montgomery, Alabama, known as the Southeastern Radiological Health Laboratory. That was established in 1960. And then the laboratory in Las Vegas, Nevada, and later on the Northeastern Radiological Health Laboratory in Winchester, Massachusetts. So training went on at these particular centers, all of which was designed to try to help the state people understand the specifics of radiation.

Now separate from all of this, the Public Health Service had some monies for training grants and supported quite a few institutions around the country in offering graduate courses in radiological health, and these programs were quite effective and went on for quite a few years.

So the idea was that you would shore up the needs by sort-course training, and then try to prime the pump and supplement the Atomic Energy Commission's fellowship program, which was continuing to go along, by having more of the academic programs, usually at schools of public health, turn out people with a master's in radiological health. I think over time an awful lot of the leaders of today gained their experience in coming out of these radiological health programs. I didn't have anything to do with that, but it was an example of what the combined effort of the old Division of Radiological health, what it produced.

When the fallout craze or the concern sort of became moderated, I had an opportunity to go back into the States Assistance Branch and get started in a program of medical and occupational radiation, and I'll talk about that.

(Interruption)

DH: Talking about training grants.

JV: Yes. Are we running?

DH: Yes.

JV: I was just looking over my numbers here in terms of the training grants. I just see that we had something like thirty-some training grants from about 1963 until about 1971. It varied between thirty-one and thirty-five. Then it petered off to about 1975 when there were about twelve, only twelve training grants left, and it finally disappeared. At its peak, it was about a $2.5 million operation for these—per year—for these training grants. So there was some good work that came out of that at the time.

DH: These training grants were basically like, for example, a grant given to Johns Hopkins to support graduate students?

JV: Yes. Or the University of Pittsburgh School of Public Health. It was to provide the equipment and the facilities, as well as grants to students. So there was some equipment money that went in there for them to build the laboratories and support the program as well as the students. So it was pretty broad based. The whole program was given its boost in 1960. That program really came into effect in 1961.

(Interruption)

JV: After my experience with the Radiation Surveillance Center and the radioactive fallout and I got back into the States Assistance Branch, I had the opportunity to work with a group called the Radioactive Materials Program, which I eventually headed. The States Assistance Branch's effort around this time – now we're talking about the early, middle 1960's – was primarily to be concerned about how to fix the problem of x-ray, medical and dental x-ray exposure in the United States.

The concern was that those exposures were too high. The approach was that the radiation doses that were delivered in medical and dental diagnostic exposure were high because of three reasons. One, the equipment per se had some inadequacies which either caused the x-ray beam to be larger than was necessary to produce a good diagnostic picture, or wasn't of the proper quality, that is, it was not, as we would say, "filtered" to filter out the low-energy components which would deposit themselves, or which would be attenuated or stopped in the skin and not result in a diagnostic quality x-ray. So these were equipment kinds of problems.

There was a second component and that was the technique problem; that is, no matter how good the x-ray equipment was, if the technician or the dentist or whoever was taking the radiograph didn't use good techniques in the darkroom – because these were all done manually at that time – if they didn't use good techniques in the darkroom, then the film may be inadequately developed and processed, and the image might be degraded.

Or, as some people, some dental personnel did, they would deliberately overexpose the the dental x-ray film, by maybe several times more than it was needed, and then develop in the darkroom the film at less than the required time. This was overexposing and under developing the film. They would then look at the film as it was developing with a safelight in the darkroom, and when they thought it was about right, they would stop the process, fix it, and bring it out. Now this meant that the patient was getting multiple times what was necessary by this technique of overexposing and under developing, which was not an acceptable technique.

So no matter how good the equipment was, if the technique was not proper, there was a problem, and the same sorts of problems occurred in medical x-ray as in dental x-ray. It the technician who was to take the chest x-ray did not measure the thickness of the chest and guessed at what the thickness was and miss-set the x-ray machine, then the quality of the image wasn't very good. So these all would then contribute to unnecessary exposure to the patient.

The third element was what we used to call judgment. So we had the equipment problems, technique problems, and the third was judgment problems. The judgment problems were clinical problems; that is, was the x-ray necessary in the first place? So go back to dentistry. If a dentist had a procedure in the dental office that said every time I see a patient, every six months when I see the patient, I will take two- x-rays or two bitewing films of the patient, regardless of the condition of the patient's teeth, that kind of judgment would result in unnecessary exposure, because some people who may have excellent teeth didn't need to have an x-ray every six months.

So the American Dental Association would say that the dental x-ray should only be taken when the clinician, the dentist, examines the teeth and sees a need for it, rather than by the particular month of the year that the patient came in. And the same thing, again, happens in medical x-ray. If the state decides that everybody who is a food handler must have an x-ray every so often, then that's a requirement that, a judgment requirement that may not be appropriate in all cases. If skin testing were adequate at the time, then you don't need to have a chest x-ray each time.

So there were lots of procedures that developed that resulted in people getting exposed more than they needed to be. The States Assistance Branch goal – I was not directly involved with it at this time – was to see what they could do in the dental program to reduce the consequences of the population exposure.

Now there was a need to get some idea of how bad or how good population exposure was from dental and medical x-rays. In 1964, the division did a project with the Census Bureau whereby they went out and selected a certain number of the people who were give n a more detailed questionnaire about their experience with medical and dental x-rays. As a result of that information, they would then go back and try to determine, from the hospital or the private office where that exposure was taking place, some of the characteristics and some of the details of that exposure, and then try to construct what the dose may or may not have been to the patient and the consequences.

It was from that result which was known as the XES, or X-ray Exposure Study 1964 that they recognized that the genetically significant dose to the U.S. population from medical and dental x-rays was about fifty-five millirem per year. That number, that genetically significant dose was an averaged calculation based on the specific dose that the ovaries or testicles would have received and translated to the future reproductive ability of that individual. Obviously, a geriatric patient who receives a rather extensive amount of x-ray at near the end of their life is not going to pass on any radiation damage in the gene pool from those x-rays. So that dose thatt hose patients would have received, because of their age, didn't count as much as the dose to a child or a young adult who had the reproductive life ahead of them.

So this weighted average genetically significant dose became sort of an index of where the U.S. was vis-à-vis medical radiation. And from that number, it became apparent that the, perhaps one of the most important aspects of the genetically significant dose, was the fact that the x-ray beam was too large and was exposing the reproductive organs in many cases when that was not necessary.

The Public Health Service then said, "What we really need to do is develop ways of an educational program to limit the size of the x-ray beam to the area of the x-ray film so that the whole body was not exposed." We used to sort of call this wall-to-wall radiography if there was no way to

restrict the beam. Obviously if someone had a chest x-ray exposure and the beam was not collimated or restricted, it's quite possible that the reproductive organs would be directly exposed by the radiation. However, since a chest x-ray film only is of interest to the chest area, the x-rays that would strike the ovaries and the testicles would add noting to the diagnostic quality of the film and only could damage those organs. So that was the area that the x-ray people decided we really needed to focus on.

Now, while all this was going on – that is, this medical x-ray assessment, the medical x-ray corrective programs, the educational program, and so forth – I had the opportunity to see what I could do in the radioactive materials effort. We set up an organization called the Radioactive Materials Program which later became the Medical and Occupational Radiation Program (MORP). These were parallel efforts to the x-ray area in dealing with radioactive materials. It was of concern to us, because as the state people were becoming more involved in the x-ray area. Again, there were no federal or no departmental regulations or authority. The Division of Rad Health had to try to convince the state people that they should do something about this medical and dental x-ray exposure.

As the fallout situation subsided and the tension that went with it subsided, a lot of the state programs which were starting to get some adequate funding because of fallout directed those efforts to the medical and dental programs. So the dental programs were being picked up by the states. The states were enabling legislation which would allow them to regulate medical radiation. They had the training they were receiving from us through the grant program at the universities or from short-course training. So they knew what they. . . And we had provided equipment and techniques and procedures for doing surveys and collecting data. So the states were out measuring, and assessing, and trying to fix the medical program. As they got into hospitals and they got into private offices, it became apparent that there was an area here that needed attention that was being overlooked, and that was the use of radioactive materials that were not under the jurisdiction of the Atomic Energy Commission.

Now the Atomic Energy Commission, under its Atomic Energy act of 1954, set up a process for licensing all users. I mentioned when I was in the Air Force this was one of the things that I was involved with as the secretary of the Air Force Radioisotope Committee. Well, all users of radioisotopes in

medicine and industry at that time that were byproduct materials – that is, the materials that were byproducts of the nuclear process – were regulated by the Atomic Energy Commission, and the users had to have a license, and the manufacturers also had to have a license to produce these materials.

But there were some materials that were exempted from that, exempted from the Atomic Energy Act, and those were primarily the radiums – that is, the naturally occurring isotopes that were around for the turn of the century – radon, which was a gas but was used in medicine in certain therapeutic applications, and thorium was another in certain medical applications. And these isotopes had no regulatory control by the Atomic Energy Commission. As the states started to become involved with the medical area, they realized that the users of radium, primarily for radiation therapy – almost exclusively radiation therapy – in many cases were having accidents and problems with their sources; they were inadequately shielded, the users didn't know about radiation protection; they were using techniques that they had learned in 1920s or thirties or forties which were not consistent with the more current procedures of radiation protection. And the states were saying, "This is a problem. We need to fix this. We need to get these radiation sources under control."

Now coupled with the normal problems of use of radium in medicine were the cases where there were accidents, where some of these sources would rupture or break. Then we had concerns that the hospital or the facilities or it could be an industrial facility would have radioactive dust, radium dust, spread around the area which had to be removed. These were very expensive operations and decontaminations when hospitals certainly didn't want to face those consequences, and there were cases where these were ruptured in medical facilities and caused extensive damage and closing down sections and wings of hospitals.

So that problem needed to get some attention. There was no regulatory authority to do that at the federal level. The Atomic Energy Commission had no involvement with it.

DH: John, let me interrupt to ask a question.

JV: Yes.

DH: Why do you think that Congress, when they passed the Atomic Energy Act of '54, never addressed the naturally occurring radionuclides, like the radiums and the radons and things? Just even today they're still talking about, you know, whether or not to change the act or not.

JV: Yes that's correct. That's right. It still is not regulated at the federal level. The answer to that, I don't know that I know. I have been told – I don't know if this is correct – that there was just a concern that the medical community, who already had the radium, didn't want to see the Atomic Energy Commission, who was getting started in a regulatory program, retrospectively go back and regulate that segment of the medical community. Whether that's the reason or not or whether the medical folks who had an influence on perhaps the hearings, and the Atomic Energy Commission were reluctant to move forward on it, I don't know.

DH: I'm sure they didn't realize the impact that, you know cyclotrons and other kinds of things. The only thing they looked at, at that time was. . .

JV: Was radium, yes. The accelerator produced radioisotopes essentially really were of any kind. . . Although they were there, and they were even used. I guess in the first nuclear medicine some of that was stuff accelerator produced back in the forties before it was a very, even the late thirties, but that was really research-type stuff. But I don't think anyone appreciated what the accelerator, what we have today with accelerator produced isotopes, which are not regulated by the Atomic Energy Act.

So radioactive materials and specifically radium was a problem, and we developed some recommendations on what should be done. One of the big things that could be done with radium programs was these radium salts, which were encapsulated or sealed into usually platinum tubes or needles – and, of course, these tubes or needles then were inserted in the tumor by the radiation

therapist – that these tubes should be tested for leaks, because the joints or the soldering where the platinum was put in there, where the platinum sealed off the tube, could easily break or fail. And sometimes taking these needles which were like nails, looked like nails, which were inserted into touch tumors, there was quite a bit of stress and strain on the sources.

Also, there were problems with these needles being removed from patients or the bandages and poor accountability. Dr. A put the X number of needles in, and Dr. Y removes X minus one needle, and of the needles is still in the bandage and goes out in the trash, or in some cases it was left in the patient or was unaccounted for. There were all sorts of stories and interesting, fascinating stories through the thirties and forties written by a Dr. Taft, frorm South Carolina, who published a book called *Radium: Lost and Found* of his experiences in trying to find the lost radium sources. They weren't interested in it from the biological concern. But since radium was an incredibly expensive material, it was running at the time up to $180 a milligram, and a physician may have at least a hundred milligrams of inventory. That was a lot of money for a clinic or hospital in the thirties and forties. And if those sources were lost, you would want to recover those as much as possible.

So there were people, and like Dr. Taft, who would be retained by the insurance companies to try to relocate these sources. If you ever can find that book, it makes fascinating reading of how he went about collecting these sources that were lost in sewers, lost in dumps with instruments that consisted of nothing more than electroisotopes that had to be charged rather than the sophisticated instruments that we have today.

I'm digressing, but one of the most fascinating elements of one of his recoveries was the source that got into the sewer. He knew it was between point A and point B on the sewer because he knew where the manholes were, and he could get some readings, but he didn't know how far between from one end to the other it was. So he took a piece of movie film in the darkroom and threaded it through a garden hose, sealed it off, ran the garden hose down and laid it in the sewer, ran it through the sewer so it was lying next to this unlocatable source somewhere in there, brought it back, exposed it, processed the film, and found by measuring how many feet, how far it was from the one manhole and how he could go in

there and reclaim the source, which he did. So there were all sorts of original techniques and fascinating stories.

But those losses which were pretty common in the thirties and forties were continuing in the fifties and in the sixties, and the value of radium was dropping. The use of other materials and better. . . Certainly, Cobalt-60 was becoming more popular. Teletherapy and brachytherapy was getting mostly limited, had some head and neck work with needles and some ob-gyn work, caner of the cervix. But the use of it was decreasing. Many of the sources were being left in hospitals unattended and not maintained. Widows of radiologists or oncologists ended up with the material in the safe deposit box, because it was understood that it was a big investment and more valuable than gold. Therefore, you kept it in a safe deposit box, and when the oncologist died, the widow inherited this material, and she didn't know what to do with it. So the sources were out there unaccounted for.

The same thing was happening, of course, with the government. The government was getting rid of all sorts of materials that had radioactive materials after World War II, the voluminous compounds ending up in the aircraft industry. So radium was showing up in all sorts of places, in war surplus, government, General Service Administration (GSA), sales of sources, and this was quite a concern. So we tried to mount a program of education, alerting, and making the states aware of it. We like to think we may have done some things to help out there.

Right around this time, I guess it was the early sixties that the Atomic Energy Commission developed its State Agreement Program where they were starting to turn over the regulation of the byproduct material to the state agency. The governor of the state would sign an agreement with the Atomic Energy Commission, and the regulation of these byproduct radioisotopes was handled by the states. That was starting to take hold in the sixties, which meant that the states then had the authority for byproduct radioisotopes. Now some of the states then picked up state authority for radium and added it to the regulation of the byproduct materials. Others didn't do this right away, but regardless that put the state inspectors now in a position of examining the use of byproduct materials, and they were finding

radium problems when they went into hospital, clinics, and industrial facilities that needed attention. So our activities in the radioactive materials program were directed in that regard.

One interesting project that I got involved with had to do with the, this was in 1964, decontamination of a private residence in Pennsylvania, in Lansdowne, Pennsylvania. There was a physicist who was affiliated with the University of Pennsylvania, who during the 1920s-30s was processing radium in the basement of this duplex house in this residential area outside of Philadelphia in Lansdowne. He and his wife did all the final states of the radiochemistry, refining the radium through fractional crystallization, and then drying it, and then he had a contract with some jewelers who produced the platinum tubes and needles. He filled these materials, the radium, in the needles, and then sold them to the physicians around the country.

It sounds like I'm digressing here, but it isn't. The Atomic Energy Commission in the fifties and sixties became increasingly concerned about the biological consequences of plutonium, because of its use in weapons and nuclear power and so forth. The best index that was available was, what were the long-term consequences of those people who had dealt with radium, primarily the dial painters, but other people who used and were exposed to radium, whether they deliberately ingested radium in the twenties as sort of an elixir of life, if you will, a compound known as Radiothor, which would cure almost any problem you had. People who had ingested large quantities of this had some consequences. There were people who were deliberately administered radium in psychiatric hospitals in Illinois and so forth.

The Atomic Energy Commission said if they could locate these people – or exhume them – to determine what the level of radiation was in the bones, because radium went to the bones, they might be able to get a better handle on the consequences of the isotopes like plutonium or even uranium as the atomic energy program moved forward.

So they hired people to collect every bit of information that they could about these radium workers. Dr. Robley Evans of Massachusetts Institute of Technology (MIT) was perhaps the leader of this. He was a physicist, and had a large program wherein he tried to measure the exposure and the materials that were left in the bones. There was a similar program at Argonne National Laboratory, and

there was another program I think it was in the New York Health and Safety Laboratory. These three centers, New York, Chicago, and MIT, retained people to try to find the names of folks who had been exposed to radium.

The Public Health Service had a physician who was working in the state of New Jersey to help with this project. That was Dr. Sam Ingraham. Sam Ingraham, of course, was in the rad health program, was involved with our early training program, and his son, who you know, was a pharmacist in the rad health program and also in the Division of Rad Health. Sam's job was to try to get people to try locating these people. And there was a former detective in the state police who was assigned to Sam to actually go around and interview people who were known radium dial painters, if they were still alive, to show them pictures of the company picnic in 1920, and say, "Do you know where Sally is? Have you communicated with her? Have you sent Christmas cards or what's her address?" and would go around and try to locate these people. If they were alive, they'd get permission for biological samples when they expired, as well as collecting samples when they were alive, and if they were dead, to try to exhume them.

Well, they knew that this physicist in Pennsylvania was around, but they didn't know where he was. They knew that, word had gotten around that he might be a person who would be exposed to a large amount of radium if in fact he was processing it in his house. Finally they located the head of the. . . I guess the Occupational Radiation Program in the State of Pennsylvania was working with the State of New Jersey's program to help them, sort of a consultant to the state, to try to locate people in Pennsylvania, and he identified where his house was. Tom Jerusky, who ran the radiation program at the time in Pennsylvania, went around and checked the house, and lo and behold, found that it was quite radioactive. A family was living in it that was unrelated, fairly recent, you know, probably ten years – I don't remember the details – and had not known the history of the house or that it was radioactive. So the question came up, what are we going to do with this? How do we deal with it?

Well, obviously, this house which was valued, I believe, at like $13,000. The family was not wealthy at all. The question was how do you force them to pay for this decontamination? What do you with it? Obviously, they couldn't pay for it. There was no insurance. Their insurance would not cover

any radioactive decontamination under the Price-Anderson clause of the Price-Anderson Act. The nuclear exclusion clause of the insurance company prevented anybody from reclaiming damages from radioactivity problems. So there was no way you could claim, use your insurance to get recovery. The recovery would probably be many, many more times expensive than the cost of the house. So the best that could happen is, of course, they could force the people out of the house, close it down, but then who has it? The state takes over the house? What are the consequences and so forth?

So the state said, "Well, this is not acceptable. You can't put a radiation monument in the center of the town of Lansdowne and seal it up and maintain the integrity and keep the homeless and everybody else out of there without being a problem." So the question is how to solve it with the Public Health Service? Would the Division of Radiological Health like to be involved? So it was agreed that we should help the state and decontaminate the house as a research project to learn about the extent of the contamination that occurred, the removability of the contamination, and then all sorts of decontamination techniques.

So in the spring of 1964, with cooperation from the United States Air Force that provided us a radiochemistry trailer, tractor trailer with a complete radiochemistry laboratory, with the help of the state people and the Division of Rad health folks, we went up there and physically, you know, put on the suits, went down in the basement, and tore the place apart, and reconstructed, and ended up, I guess about four months later. We moved the people out, obviously, into a hotel, and four months later got the place back into shape.

Obviously an old house like that that had broken concrete and mud splattered stucco walls, in the basement is not, the normal techniques of decontamination of modern laboratories didn't apply. So we ended up really just removing as much of the material as we could. I forget, there was something like eighty 55-gallon drums. I can't remember the number. And I believe eighty millicuries or milligrams of material of radium were removed altogether at a cost of over $100,000.

We felt we had learned a lot about it. We learned the consequences of the carelessness. The irony of all this was that both the physicist and his wife died of a heart attack unrelated to radiation.

There was no indication of having done all this work that there was any radiation. The radiation damage was not obvious.

DH: Did they do a post on them?

JV: Yes, yes. And at a reasonably ripe old age. I can't tell you what the age was anymore, but it was sort of ironic. So we, as I said, we learned some things.

The post script on this was that in recent years, in the last, oh, say in the middle nineties, that under the Superfund, this facility was now, with the Environmental Protection Agency (EPA) looking for Superfund sites, this house was not relocated, not identified, and found the levels of radon were unacceptably high compared to the EPA's requirements. So the house was then confiscated, completely. The duplex was completely torn down, and the land all around it, because some material which we had missed was buried around the area, was removed, scooped up, and cleaned up. The town was resurveyed again, and as I recall, there was found to be another processing facility in the town of Lansdowne. That whole facility, the Lansdowne area, is many, many, many, many, many, many millions of dollars invested, you know – like over a hundred million dollars – for the decon of this whole site.

Some of the tailings from the milling operation in the industrial part of Lansdowne, we didn't even know existed. That was unknown at the time. No one seemed to know anything about that, and how it was uncovered, I don't know the details. You'd have to check with the EPA. But the residue for that ended up in building materials just like the problems out in Colorado for the uranium tailings that ended up in building materials. So the contaminated byproducts of the radium processing ended up in houses, several houses in Lansdowne. So that whole thing became a total mess.

Again, I'm good at digressing. You can see that.

But that did give us a handle on the consequences, and right at the time we were doing this decontamination, the hospital in Americus, Georgia, broke a radium needle, and some of our team went down there and worked with the state to decontaminate that hospital.

(Interruption)

JV: … into all of us and to the state people that radium really is a problem, and one needs to find substitutes that do not have the consequences, biological consequences of radium. Because of all the radioisotopes, you're dealing with an isotope, radium, that has a long half-life – 1,600 years – that's basically a salt or a power, generally is soluble because a lot of the earlier sources were radium chloride or radium bromide which are very soluble, that produced this radioactive radon, that could build up pressure inside the needles, that had all the bad characteristics compared to other, more recent atomic energy materials like radioactive Cobalt wire was used as a replacement for some of these needles and tubes, and then you had a discreet piece of wire. Cesium was used, and the cesium was placed into microspheres, so you didn't have the concern of the solubility of the microspheres, and the microspheres were not soluble like the radium.

So there were a lot of advantages of other radioisotopes over radium, and the direction was to try to encourage the states to bring radium under control. So that radium management program, which we launched in the mid-sixties, was directed at that regard.

The same sorts of problems existed in the industrial side of things. Whether it was radium used in well logging, whether it was radium used in thickness gauges, whether it was radium used as static eliminators, there were better isotopes that were available under the Atomic Energy, byproduct materials under the Atomic Energy Act, and there was a need to move to the isotopes that were specific to that. Radium is a luminous compound, had some disadvantages. Tritium had much greater advantages, or even krypton had much greater advantages over radium. So there was a need to move in this new direction. So one of the thrusts of our program was to try to get the radium out of circulation that was of no longer a value and replace it with more specific radioisotopes that had less of a hazard.

Now one way to get rid of it is, first of all, you have to identify it. Then after you identify it, you find the widow who has the source in the safe deposit box or the hospital that's no longer using it, you

say, “OK, well, get rid of it.” There’s no way to get rid of it, because, first of all, there’s no shipping container. No one knows how to build a shipping container. Not all waste disposal sites would take it. It would cost a reasonable amount of money to build the shipping container, a proper shipping container that met the so-called Bureau of Explosives requirements. So people were stuck with it. They said, “Well, I’m not going to pay a large amount of money to get rid of this source, which first of all you told me was very valuable. I paid $180 a milligram: now you’re telling me it’s not worth anything. Now I’ve got to pay to get rid of this radioactive material. I don’t think so.”

So to keep people from throwing it away inadvertently into the sanitary fill or just mysteriously losing it, the states decided that if they could collect it at the state laboratories, shield it properly, and if the old Division of Rad Health would set up a program to collect it from the states, once a year, we could send out properly designed shipping containers, take the materials from the state and store it. We then set up a laboratory in Montgomery, Alabama, which was sort of a radium disposal project that received all of the radium sources from the state health departments that were donated to the Public Health Service so we could get them out of circulation. Then, ultimately, those sources were packaged up and shipped to a national laboratory for proper disposal. But it was rather interesting that if we didn’t have, that we needed to have. . . We couldn’t just talk about getting rid of radium, we had to provide and facilitate getting rid of it. These were the efforts that occupied us from the middle sixties to the latter part of the sixties.

We actually even designed a shipping container that was what we call foolproof, because there were several cases reported where the people did ship radium in containers, in which the wooden containers broke apart, the shielded lead containers came off, and the radium sources came out along the…

I remember one case that a source was lost somewhere in the West going back to the, I guess, it was the radium chemical company’s laboratory in New York, and it dropped out of the train box car. We had, you know, we knew approximately what the box cars were, and we had people running around the country picking up these radium needles at freight yards, and state people relocating them. We found

many of them. But the incident caused a lot of attention in the press, discredited the whole radiation program, because how could you have this stuff dribbled out all over, out of box cars around the country?

So we designed a shipping container to eliminate some of these problems. We designed all sorts of techniques to measure the leakage of radium sources. We tried to educate the medical community about the importance of proper controls and monitoring and nursing people as well to teach them about it. We had projects with places like 3M to look at ways to make better radium sources, better sources for brachytherapy using substitutes for radium, using cesium specifically, and we like to think we had some influence on all of this.

We held a meeting in 1964 with some of the leading radiation therapists, brachytherapy (?) people, to talk about radium, which was good about it, what was bad about it, and what should be done about it. It was generally recognized that there were some characteristics of radium that the oncologists were very reluctant to give up on, but it was recognized also that there were some problems with radium, and that we really needed to put more money in developing better brachytherapy sources. So, you know, it's come a long way to sources that like palladium-107, I guess, is one of the newest isotopes now that's being used for certain things like prostate cancer. So there's been a whole series of isotopes that have been developed or that have been tested and used as substitutes for radium in more recent years. So it's interesting to see.

But that whole program, which was called the Medical and Occupational Radiation Program, in the late sixties dealt with the x-rays, dealt with radioactive materials, medicine in industry – all this was medicine and industry, because we dealt with industrial x-rays as well as medical x-rays, but the industrial side was always much less – and had some educational components in it as well as some minor testing and research.

I was involved with that activity until the division got into the x-rays from television problems in the late sixties. We got a call from the City of New York about a television set produced by the General Electric Company that produced x-rays inadvertently. Francis Bradley's program in the Labor

Department of the State of New York had a requirement that any device that emitted x-rays inadvertently, and there were things like high-voltage vacuum tubes, switching tubes, tubes used in radar, such as magnatrons and thyritrons and so forth, these things inadvertently may emit x-rays – if they emitted x-rays in excess of, I believe, a half of a millirems per hour, that device had to be labeled as, you know, "Caution! X-rays."

The General Electric Company's x-ray television sets that emitted x-rays emitted in excess of this amount, and they wanted to get the state to exempt them from having to put a label on it. They figured they could not sell a television set to put in peoples' homes that had a label, "Caution! X-rays." It didn't seem very practical. So the only way to solve the problem was to request the state to waive the label requirement. I think the state said, "I don't think so," and said would we look at it. So we sent some people up and did some surveys, and lo and behold, the problem was attributed to several tubes, high-voltage rectifier tubes in the sets – a shunt regulator tube, I believe it was called – that as a result of the quality control of the making of these tubes caused excessive radiation. So it wasn't a problem so much in the design of the tubers per se, but rather the sloppiness in the construction of the tubes. The answer seemed to be, to us, that it was not a case of labeling; it was a case of fixing the tubes. The General Electric Company didn't want to do this, because they had a lot of sets already out in the hands of people, and they felt this was going to be bad publicity.

We started a whole series of investigations. It got into the press. It got up to Congress, and the question was, what's going on here? How many more of these tubes, how many more of these sets, and how ubiquitous is the problem? Well, the old Division of Radiological Health, which became the National Center for Radiological Health by that time and was put into the Environmental Control Administration – it was an element under the Environmental Control Administration – the National Center for Radiological Health did some testing of other sets and found this was more common than had been anticipated, and, in fact, there was not only these high-voltage tubes and shunt regulator tubes, but also some picture tubes that emitted radiation out of the front of the set.

As a result of this concern, Congress held a series of hearings. In the House, Congressman Paul Rogers (Florida) held the hearings, and these were in ’67 and ’68, and these hearings looked at not only the problems of x-rays coming out of television sets, but the problems of unregulated radiations which may have had biological consequences, and that is, x-rays and medicine, linear accelerators, x-ray diffractions in industry, as well as the new kinds of radiation which were becoming more popular: microwaves – which they were going to put into microwave ovens. Ultrasound – what do we know about the biological consequences of ultrasound? What about this thing called the laser? What might it do? And who’s going to regulate it, and who’s going to have control over it?

Well, all of these hearings and this oversight resulted in the passage in October 1968 of the Radiation Control for Health and Safety Act which the responsibility was delegated to the National Center for Radiological Health to implement the regulation. Basically this law required that any electronic product that emits radiation which means any electromagnetic radiation or sonic, infrasonic, or ultrasonic radiation that would have any biological consequence. That electronic product would be regulated by a series of federal performance standards to make sure that the product wasn’t a problem.

This kept any overlap with the Atomic Energy Act which dealt with radioactive materials. This had nothing to do with radioactive materials. These were the radiations, the lasers, the microwaves, the x-rays, et cetera, that came from electronic products, which was entirely separate. This was the first time these products were regulated. The control was to be put in through federal performance standards, mandatory federal performance standards that the manufacturer would have to adhere to.

DH: John, let me interrupt for just a minute. What was the Atomic Energy’s position on this? Did they cause any particular problem? Were they basically involved in the hearings? Did they have anything to say particularly in this area?

JV: I don't remember that the Atomic Energy Commission was involved or had any influence in the hearings. They may have testified, I'd have to go back and check. I think it was out of their area, and I don't think there was any resistance.

DH: They didn't see it as a diversion?

JV: I don't think they saw it as a threat. No, no, no, and I don't think there was a question of whether this should be put into the extension of the Atomic Energy Act, but rather being a whole new area under Health, Education, and Welfare, primarily because so much use of it was in the medical and industry – well, medical.

There were other provisions in the act which allowed for, if a product produced radiation which that the government felt it was a detriment, then the government could declare a defect action against a manufacturer, and the manufacturer then must either repair the product, replace it, or refund the money of the purchase.

There were also provisions of civil penalties if the manufacturer had a problem and didn't get it fixed. So there were some teeth in the act, and there were opportunities for a well-balanced program. It didn't mandate performance standards, but if you did see a need and you developed performance standards, they were mandatory. But it didn't say that every product would have to have a performance standard. So it gave some discretion. It gave some balance. And, of course, the old National Center for Radiological Health came out with a series of performance standards for all of the different products that were . . . microwave ovens, x-ray machines, television sets. . .

DH: TV's came out first in '69.

JV: Yes, I have those. I was going to look at the dates for all these things. I can't find them anymore, but you probably. . . Well, anyway. . .

DH: Here.

JV: You've got them? Good. Oh, you wrote them down. Because the whole concern stimulated from TVs, the first thing we had to do was go after the television manufacturers and make sure that they understood this. So we set the standards. The standards were performance standards. We didn't care how they designed the set, but what we were concerned with was to make sure that when the TV set was on under any sorts of unusual conditions of use, that the radiation levels would not exceed some predetermined number outside, and that number was specified.

TV manufacturers then would have to submit to us their engineering program as to how they were going to solve that problem, that is, their design characteristics and how they were going to solve it. We looked those over. If we weren't satisfied with them, we wouldn't allow that product to go in line.

Secondly, we did testing of these sets under real conditions, conditions of use or abuse to make sure that there was not a problem. So we had some assurance that not only the design was okay, but the testing of the sets under unusual conditions was okay. Now that was a spot checking of just a sample of tests.

We also look at and visited the facilities and looked at their quality control. For example, one I remember distinctly, the assembly line of one of the manufacturers – I think it was a Japanese manufacturer – was very proud of the fact that every set going through the assembly line went through a monitor that would monitor 100 percent of the sets for radiation x-rays coming off the set and were proud to show – this was reported to me, I didn't get involved personally – were proud of this assembly line quality control.

What turned out was that the particular radiation detector was insensitive to the low energies of the radiation, so that even if it did leak, the detector wasn't picking it up, because the kind of radiation you were looking for was a low-energy radiation. This had too thick of wall, and it was not the right detector. So here was a case where the visit of the plant and to look at the quality control on the assembly line picked up a problem which might have resulted in sets going out inadequately.

As you pointed out, the first one was on television sets; then cathode ray tubes; microwave ovens; the diagnostic x-ray equipment, which was in 1972 which was very significant; 1974, which was the so-called cabinet x-ray which was very important for the airport x-ray luggage inspection. All of the units at the airports that inspect luggage, or any other place for security purposes that inspect luggage, come under the definition of the cabinet x-ray. You know, the assurance there is that those devices won't leak. Lasers, sunlamps, ultrasonic therapy, and mercury vapor lamps are all examples of the kinds of standards that were developed.

I should point out one of the processes that we were required to go through was to present the concepts and the approach that we were using to an advisory committee. This was a committee called the Technical Electronic Products Radiation Safety Standards Committee of fifteen people: five members representing the consumers, five representing the government or public sector, and five representing the industry. So we had a mixture of people on the committee who looked at the evolution of all of our standards as we went through various preliminary concepts, the final concepts, and so forth. This, I think, gave us an appreciation of the value for advisory committees and the importance of contributions of different segments of the population, that the consumer movement and the concern of the consumer, had to be reflected, was reflected by the makeup of this committee. People were there to make sure that we were not just in the pocket of the industry representatives or the government scientists, but rather we had a sensitivity to the consumer. I think that worked very well.

I think it was one of the most beautiful, that Public Law 90-602, or the Radiation control for Health and Safety Act, piece of legislation, because it gave the rad health program the tools it needed, a variety of tools but didn't mandate the course of action. It said, "Here are the tools you need. The only thing we're mandating is that these products must be safe. You figure out, use the tools you have to make it safe."

Congressman Paul Rogers (Florida), who was instrumental in crafting this bill, was also instrumental in crafting the Medical Device Amendments in 1976. Fascinating to me was that the Medical Device Amendments don't have that discretion that the Radiation Control for Health and Safety

Act had. Medical Device Amendments say, "All medical devices will be classified. They'll be classified into three categories – Class 1, Class 2, Class 3 – and those actions you take, once you get them classified, you must take certain actions on these devices." No discretion. You know, you start the process by classification, you start by then following through on these steps, and it doesn't have the tools. And the Medical Device Amendments don't have a civil penalty provision; they have just a criminal penalty.

That difference between civil penalties and criminal penalties was debated for a long time until FDA finally and fairly recently extended its authority to include civil penalties. I always felt that when you were dealing with high-tech areas, lasers, microwaves, x-rays, and the manufacturers of these products, that the problems that one would encounter with excessive leakage or whatever were not so much problems of deliberate corner cutting, but rather the complexities of the technology you were dealing with, and the potential for those technologies sometimes to go awry. And the penalties were better, I felt, better by civil penalties than by assuming that the CEO of the company was a crook and should be put into jail.

The FDA approach has traditionally been that if you've got a problem like this and you've got a bad actor, and you've got. . . The penalty mechanism is one of putting somebody in jail, and I just never quite agreed with that. I always thought that the two. . . It's nice to have criminal penalties, because there are some situations where you need it. But the more frequently used tool, and I think the more responsible tool, is civil penalties. And we did use them, and the fines were excessive, and the publicity that went with those fines were excessive.

I think the existence of that law and the influence it had over products is fascinating. People don't think of radiation coming out of television sets because that's solved now. It's solved in part by the standards, and I'm going to have to admit, of course, it's solved more greatly by the technological changes of TV sets and solid state devices that replaced the old tubes that don't exist anymore. People don't worry about lasers in the shopping centers or at the supermarkets. They did at one time; there was a lot of anxiety. Those have all been under standards. People seem to trust them.

People don't worry about their microwave cooking ovens. But when those first microwave cooking ovens came out and the public first got involved with them, there were some real problems of anxiety. And we had some problems of anxiety. Basically, the levels of radiation, microwave radiation in those ovens were high. If the doors were not interlocked so that if someone opened it while the oven was still on, that it would automatically turn off, if that didn't occur, then people would be getting a pretty good dose to the face.

DH: That's an example where the original standard for microwaves did not include the safety interlock. Was there something particular that occurred that stimulated the bureau to go back and revise that?

JV: The concern over microwaves was, again, you don't want to have people getting zapped while they're cooking – zapped two ways. One, as I said, if the door goes open and they forget to turn it off, that's intolerable. Number two is, what should the microwaves leaking out around the cracks when the door gets closed? Is it possible that they don't fit quite tight, and how do you fix that? Because you don't want to have a low level of leakage around the door any more than you don't want to have a full blast in the face because the door doesn't have an interlock. So the concern was, how should the standard address these issues?

Well, there was a leakage standard around the door which said what we won't accept for leakage, and the other problem was around the interlocks. How do you make sure the thing gets turned off, the oven gets turned off when the door gets opened? Well the obvious thing is you put an interlock in, like you do the lid of your washing machine when it's on the spin cycle. If you open up your washing machine, it turns off. So the obvious thing is to put an interlock on it.

Well, what happens if the interlock fails? The obvious thing is you put two interlocks in. If one fails, you've got another one to back it up. Well, that'll solve the problem, not completely. If the second interlock and the first interlock go through the same relay, suppose the relay fails? Then both interlocks

will. Well, okay. So maybe you have to have the first and the second interlock independent, electrically independent so that there's no chance for one feeding back.

The evolutionary thinking and steps came as a result of some real world experience with these and seeing problems. I mean, we actually did life testing of ovens. We had the laboratory in Winchester, Massachusetts, which actually took ovens and ran through life testing and so for we noticed where there were problems.

What happens if you have two independent interlocks and somebody decides to fix it? How do you make sure that he doesn't get in there and jerry-rig the interlock? Well, one of the interlocks must be concealed so there's no way that you can stick a pipe cleaner or a hairpin or a paper clip in there and jam that. It has to be concealed.

So you go through all of this, you know, what ifs. Now, I happen to think we probably, in retrospect, may have gone too far in setting up the concepts of design that made it sort of totally foolproof. But we did lay out these concepts, electronically independent, conceals, et cetera. Then we had to figure out, how do we define concealed? What is a concealed interlock? Well, you must not be able to put a bent wire that's bent more than so many degrees in the hole and trip the, you know, all sorts of these details which unfortunately, I think, got us into a morass in the minutia.

But the important thing I believe is that by our making the influence of a regulatory program known to the industry that said, "We're not going to fool around with this. This is what's required. We're going to test. We're going to monitor. We're going to see your engineering programs. We're going to check your quality assurance. And we're doing biological testing back here about the consequences, so we understand the biology of this, we understand the engineering of this, and we're going to be on top of it." We had an influence over the changes in design. And the final product is that people don't think when they buy a microwave oven, "Gee, I wonder if it's leaking." I mean, I think that whole stigma has been replaced.

Now there were lots of recalls in the seventies as a result of these ovens, some of these ovens failing. But I like to think of it as a good example of a success. You know, lasers, I think, are in the same

way; and I think all of the standards, medical x-rays and TVs, that the government's intense regulatory program reinstated the confidence of the consumers – and most of these things, were consumer products – that it was not a problem.

So I think that's the best part of all regulation. The question is, you know, were we overly tough? Probably, you know. Might we have backed off a little bit? Maybe. That's all philosophy.

I just want to make another observation. The organization, the center, had as components, a compliance group that was looking at compliance and a group that was looking at the integrity of the products. There was a science group that was doing science testing. There was a biologics group doing physical testing. There was another biologics group doing biological testing.

So, we brought to the table, I think, a thorough understanding of the biology of these problems, whether it's light, ultrasound, mercury, ultraviolet, micro, or whatever. We brought to the table an understanding of the engineering and the testing and the measurement. We were I think very, very capable in the science of measuring. So we knew what we were talking about. So when you sit down with the manufacturer, opposite the manufacturer in a discussion, we were always well armed with expertise. I think the importance of the science base to the regulatory process is incredible.

I remember one situation where we met with the manufacturers of the microwave ovens on this discussion of the electrically independent interlocks. I still remember Bob Elder, who was a deputy director at the time, center director at the time, or the bureau director was trying to convince the industry that you've got to have the electrically independent interlock, and the manufacturer said, "It can't be done. We can't do it." And Bob anticipated this, had the mock-up on a bread board laid out, got the technician to come into the conference room and said, "Now, maybe you couldn't do it, but we can. Here it is." How much of that was B.S. I don't know, but Bob convinced them that we know what we're talking about; don't mess with us. And I think it was effective.

I think there was respect – I'd like to think there was a respect from the industry for that program. And we accomplished something. But I'm out of sequence again. You asked what I did.

DH: Oh, that's fine. We'll come back around to that in just a minute, but, you know, there was to me, there was a second area that I'd like to give a little bit of attention to at this point. Beyond performance standards, there was education, there were voluntary activities. Would you like to say a little bit about some of that?

JV: Yes, yes, yes. Very important.

Well, as mentioned earlier that when we first looked at the medical x-ray problem, we sort of simplified it by saying the problem broke down into equipment, technique, and judgment. That, in principle, I think applies to everything you deal with. If you're looking at a microwave cooking oven, however, technique and judgment don't exist, because you can't. . . You could solve the problem by having a single interlock with a label on the microwave door that says, "Always make sure you turn off the oven before you open the door," but people are going to ignore the label. So you have to then put everything in the equipment, so that when you're dealing with a microwave oven or a television set, you can't put instructions on how to use it.

You may remember when the television radiation problem came out, the surgeon general came out with an advisory that said, "Don't sit closer than six to eight feet from your television set." We didn't know how extensive the problem was, what sets were involved. We knew more than just the General Electric set was involved, so we knew that there were some reasonable exposures off the front of the sets as well as off the sides from these different shunt and high voltage tubes; there was the picture tube as well. So we didn't know what the problem was, but we didn't think that people should be sitting in their living room being exposed to x-rays. So the question was, what are we going to do about it?

Well, initially until we could get a handle on which ones were involved, how to get them fixed and how to get them retrofitted, the surgeon general came out with an advisory, "Don't sit more than six to eight feet away from it." Well, one could have ignored the problem and just come out with a general advisory that we could be living with today. Did I say "more than?" "Don't sit *closer* than eight feet to

your television set," but that's not a very practical solution. It was all right for the emergency or the interim until we got a handle on it, until those sets got repaired, but not for the long run.

So the technique and judgment factors don't really work for the consumer products. But for radiation, medical x-radiation, radioactive materials, the technique and judgment concepts become increasingly important. That philosophy of having a professional educational awareness and consumer awareness in some cases fed into the overall problem of trying to solve such things as the medical x-ray emission.

We had the federal mandatory performance standard for x-ray equipment. Now, again, that only applied to new equipment that was manufactured. All of these federal mandatory standards under the Radiation Control for Health and Safety Act only applied to new equipment manufactured after a certain date, so you still had old equipment that was around for a while. But the standards, the reality was that even the new equipment that met the standard could still result in unnecessary exposure. So you had constant educational programs for the medical community.

One of the aspects of that involved technique was as simple as the gonad shield that we tried to get the medical community to encourage. In certain situations, if one is examining an x-ray of the pelvis or an x-ray of a small child, it is very difficult to keep the reproductive organs outside the field. Usually the reproductive organs are in the x-ray beam. Therefore, if they can be shielded with a piece of lead or something like that, you can reduce the genetic consequence of that radiation. So that may require localized shielding or gonad shielding.

The awareness, the importance of that then is something one has to get back into the technical schools for x-ray technologists. One has to get the radiologist to be aware of it and be supportive of it and to cause it to happen. One has to encourage the film to be processed properly, and more and more facilities were going to automatic processing so that the film didn't have the problems of, as I described earlier, with site developing. Those problems were slowly getting solved. But there was still a need for educating the technologist and the physicians about their technique.

There's also a need to bring the consumer into these issues. If the concern of medical x-ray exposure is, "Gee, you, the consumer, ought to be sensitive about this," then the consumer can play a part by suggesting to the physician, or advising the physician or the technologist that they want to make sure that there's some shielding the reproductive organs, that the dentist should have a shield, or that the proper precautions are taken by the consumer. We were anxious about what consequences would happen if a person, a woman who was in the early stages of pregnancy were to get an x-ray of the abdomen. What impact would that have on the fetus?

Well, first of all, you can't do anything about that unless the patient declares to the physician that she may or may not be pregnant. Then secondly, the physician may say, "Well, this x-ray is so very important, it's more important than, you know, we've got to get the x-ray right away. More important than the risk of the radiation." Or the physician may say, "Well, let's wait until after your pregnancy, and we'll take a look at this."

So the idea of the consumer taking charge of their own heath and describing, and telling the physician or the technologist some information of that would be helpful about reducing the consequences of the exposure I think becomes important as well.

So the programs that we set up were not just hardware or equipment-oriented, but to talk about the technique and to talk about the judgment factors. The judgment issue gets very difficult when you look in things like the sophisticated procedures of x-rays used in emergency rooms for head trauma. There were some studies that suggested that many times the physicians and the emergency room would order a skull x-ray for head trauma more from a medical-legal standpoint than they thought that there was some value in the radiograph for clinical information.

So that procedure was decided to be looked at and as a result of some work that was done at the state of Washington by John Loop and others, identified certain criteria – that is, presenting signs and symptoms – that if they were not present would suggest that the x-ray was not necessary. Low backs for employment, pre-operational chest x-ray films, et cetera. A lot of things like this that affects the judgment of importance, and we had a program to work with the profession on that.

Now when we did these things obviously the National Center for Radiological Health or the Bureau of Radiological Health obviously didn't have the expertise to deal with that. So you had to work in collaboration and conjunction with the medical community that was expert. If you're dealing with x-rays in the pregnancy, you want to make sure the ob-gyn community gets involved as well as the radiology community. So we would use advisory committees to help us come up with these recommendations and help us to than amplify whatever recommendations came out. They would publish these recommendations in their journal, we'd publish them in our media, and that's the way to get the information out to the medical community. We think we may have made some impact.

I should go back to that 1964 x-ray survey, because I think it was interesting that the. . . I mentioned the largest source of unnecessary radiation that resulted in this genetically significant dose with was at fifty-five millirem.

DH: Millirem?

JV: Millirem was the consequence of the x-ray beam being too large, and if one could restrict the beam to the area of the film, then one could, I believe, reduce that number to something like nineteen millirem.

Therefore, we really focused in on the concept of collimatin of the x-ray to the area of the film so it didn't spill over and hit the rest of the organs of the body. We figured one way we could do that was, again, design an x-ray machine. We went to the companies and asked them what they could do about it, and they didn't have any solution, and they didn't seem very interested in it.

(Interruption)

JV: Jim Terrill, the deputy director of the Division of Rad Health, convinced Harold Stewart to see what he could do to design a device that would be fully automatic. Basically what they did was to

convert sensing devices which would sense the size and the orientation of the cassette, 14" x 17" or 17" by 14", would note the height of the x-ray machine above the table, and would determine automatically, would feedback automatically to a set of leaves or collimators that would collimate in a rectangular fashion to match the area, so when the beam was projected it would match the area of the film. It was called positive beam limitation, or originally called automatic collimation.

No matter what size film cassette, no matter what the orientation was, no matter what the height of the x-ray machine was above the drawer where the cassette was placed, the cassette being the holder for the x-ray film – no matter where that was, it would automatically limit the size of that x-ray beam to no larger than the size of that film and therefore reduce the overflow.

Harold and the laboratory people built that device, put it into effect, and tested it, I think at NIH and probably at Hopkins. I know there are a couple of facilities where they tried it out. And they said to the medical community, "We think you ought to build one." There was very little interest in the medical community to accept this. It was more expensive; it was cumbersome in the medical industry to build it. The medical community and the technology community would use the usual arguments, "Well, we have our people trained. We have radiological technologists that understand this. We don't need to have a piece of hardware to do this for us." So there was not a lot of enthusiasm.

When the X-ray Performance Standard was developed, that concept was cranked into the X-ray Performance Standard. It was included in the X-ray Performance Standard. So the positive beam limitation, so-called PBL concept, was a part of the x-ray standard. So equipment today basically has that provision.

So it was an example of, going back to the early sixties, which resulted in the X-ray Exposure Study of 1964, identifying what the primary source of medical radiation was, that the primary source was from collimation, to working to get that implemented, you know, trying as best you can to get that collimation done through cooperation, and then ultimately recognizing that the ultimate solution is through the regulation in the mandatory Federal Performance Standard. So I think today that is almost another example of a non-issue.

Now, unfortunately, the irony of the whole situation is that we may have had a false assumption. The contribution of collimatin to reducing that original genetically significant dose from 55 millirem to whatever, 19 millirem, turned out to be slightly in error. I don't remember how much the error was, but the error was the result of the computer program that determined each of the projections of all of these patients that were a part of the census study. Those are the chest x-rays, those are the pelvic, lumbar spine, skull, all of the different examinations we had factored into that and worked a calculation to determine what the dose was to the ovaries and to the testes, and then calculated that based on the age to come up with the Genetically Significant Dose (GSD).

One of the computer programs mathematically placed the testicles on all lateral examinations at the point of the entrance of the skin, therefore, relocating the testicles from their normal position to on the hip. So when the x-ray beam on the lateral hit the patient, it hit the testicles, and the dose to the testicles was much higher. So that the collimatin figures were slightly off, and we were . . .

DH: And Joe Gitlin has never lived it down yet.

JV: Well, he never lets me live it down. As you'll notice the picture on the wall behind me of the character holding my head, if you'll notice the fig leaf is on the lift hip of that caricature which points out I almost lost my head when we found out the testicles were not located on the left hip. At any rate, although there was an error, and I can't remember the magnitude of the error in that program, the issue was still important, the collimation was still important, still needed to go ahead, and I think it was a good example.

(Interruption)

JV: We're talking about the educational aspects, whether it's professional education or consumer education, in dealing with these programs such as medical x-ray. The help we got from the medical

community was usually funneled through the Medical Radiation Advisory Committee (MRAC), which was a group made up of clinical experts and physicists who would be a sounding board for our ideas and help us provide the collaboration with the organized medical units like the American College of Radiology, or ob-gyn (American College of Obstetrics and Gynecology) or whatever – American Association of Physicists in Medicine for the technical area.

This was a committee that had no statutory mandate, but it was a committee that evolved out of long-standing understanding that if we moved off from the medical area, we'd better have the clinical people signed on around the table by the committee like this to help us. I had mentioned earlier about the Technical Electronic Products Radiation Safety Standards Committee and the role it played in the evolution of our performance standards. The Medical Radiation Advisory Committee was sort of a counterpart in dealing with the area, primarily, of technique and judgment, and was extremely beneficial, and had some outstanding leaders, such as Dr. Richard Chamberlain, who I guess I would call the premiere radiologist at the time, who was chairman of that committee. So we were getting excellent advice and guidance from that group, and it just was outstanding.

I think historically, a strength of the bureau and its center or of the division had been a recognition, although we had a lot of competence in the details or the technology – whether it was radiation biology, or radiation physics, or the science of measurement, or engineering or what have you – that you really needed to get the input of the users and the input of the consumers and the input of the scientists in our programs, and that was built in from really the very beginning. So I think that was a quite a bit of strength to our activities. If we got out of line, these people had no hesitation to let us know that we were out of line, so it was valuable.

I wanted to just go back, just to revisit my own involvement in all this stuff. As I described all this, I want to make sure you didn't, the listener does not think that I ran off this stuff. But I was responsible for – in the middle sixties, from 1963 to 1967 – for this Radioactive Materials Section. This was the group, I was explaining, that started the radium program and tried to give it its input. I then had the opportunity to move up and become the head of the MORP, Medical and Occupational Radiation

Program, from 1967 to 1968. Then essentially the same program became a division, and it was called the Division of Medical Radiation Exposure from ’68 to ’69. So the combined activities of all aspects of medical – that is, x-ray as well as radioactive materials and some industrial activities – fell under the unit that I headed up from 1967 through 1969.

In 1969, I had the opportunity to be selected for the director of the National Center for Radiological Health or the, I guess it was the Center for Radiological Health at that time after the, well, after the present leadership changed hands. I was the head of Bureau of Radiological Health from 1969 up through 1982, when that bureau was combined with the Bureau of Medical Devices, and became the Center for Devices and Radiological Health (CDRH) in the Food and Drug Administration.

Let me go back to 1970, specifically following the Presidential Reorganizational Plan of 1970. The president mandated that the radiation programs of the Public Health Service would be placed into the newly established Environmental Protection Agency. Well, the plan was Plan No. 3 in 1970, the end of 1970, EPA was organized. By presidential reorganization and then ultimately approved by legislation. The EPA had no resources other than the resources that were available in the existing programs in other federal agencies.

The air pollution program, the water pollution program, the solid waste programs, and the water quality programs that were in the Public Health Service up to this time, up to 1970, were transferred *in toto* to this newly formed EPA, and they became the nucleus of the EPA.

The radiation programs were also scheduled to be moved to the EPA at the same time. There was a big debate, should the Environmental Protection Agency have regulation over the products that were under the Radiation Control for Health and Safety Act: the x-ray machines, medical x-ray machines, and so forth? So there was some discussion within the department as to whether that should take place or not.

Finally, they decided that all of the environmental radiation aspects of the Bureau of Radiological Health would go to EPA: that is, the air pollution program, the radiation air pollution program, the fallout, the radioactivity in the water supply, the environmental, the nuclear power, nuclear waste activities that we were involved in. All of those things would be transferred to the EPA, and the

remaining activities would be those dealing with the Radiation Control for Health and Safety Act, the electronic product radiation.

At the time of the split taking place, in essentially 1970, at that time, the combined activities of the Bureau of Radiological Health were 711 budgeted positions and 137 reimbursable positions. This is down from what it had been in the late, about 1966 or '67, when there were over 800 permanent full-time positions in the Rad Health Program, and almost 250 reimbursable positions. These 250 people were at the weapons testing site either at the Pacific weapons testing area or in Las Vegas, and their job was to be responsible for the radioactive material that may have gotten offsite from the weapons testing. So the Rad Health Program had combined almost a thousand people at the time.

When EPA was formed, the program was cleaved such that the remaining function of the Radiation Control for Health and Safety Act, ended up with almost390 permanent full-time positions left behind to deal with the implementation of the Radiation Control for Health and Safety Act.

Now, this mentions our parent organization, the Environmental control Administration, which had under it air pollution, water pollution, solid waste, and radiation. Since the Environmental Control Administration was gone, and all of their sister or sibling functions were gone to the EPA and the half of us that were left, the 390 positions that were left had no home. They didn't know what to do with us. So from the establishment of the split, which took place in January of 1970 when this was finally cleaved and these 318 positions were left behind, we had no home. So they reported us directly into the Assistant Secretary of Health. At this time it was Roger Egebert. Roger didn't know what to do with us, because we were there alone.

So we hung around until May 17. I guess it was like May 16 – I don't know if this is the exact date or not. I got a call from the deputy commissioner, Jim Grant, of the Food and Drug Administration. He said, "Since you don't have a home, it was thought maybe that you should fit into the Food and Drug Administration, that this is where you belong since you do some regulation and the Food and Drug Administration is the only other element in the Public Health Service that does regulation. What do you think about that?"

I said, "Well, I think it's a bad idea." I said, "I don't think we have the mentality to deal with FDA. You are a regulatory program. You have a reputation of being cops that are out after trying to enforce the law and put people away to jail. We see ourselves as public health people who try to solve public health problems using the tools that Congress has given us in the way of regulation. If I had my choice, I'd rather be in the Health Resources & Service Administration (HRSA), one of the other elements which deal more in the educational area, because I think the strength of what we can do is better defined by education than by regulation."

I think he said something like, "Well, why don't you think it over." And I think what happened the next day I got a call from the secretary's office saying in effect, "You have now been reassigned to the Food and Drug Administration." To which I think I went back to Mr. Grant and said, "Forget what I said the day before. I'm here. This is a wonderful place. I'm really happy to be a part of the Food and Drug Administration," or something like that. I'm not quite sure. But it was rather interesting.

I remember Charlie Edwards was the commissioner, and he gave me an opportunity to present what we were all about to the, at my first staff meeting for me with the other center directors. There was a drug center and a food center, and there was a product safety center – which ultimately left and became the Consumer Product Safety Commission (CPSC), and a veterinary medicine center. There wasn't a biologics center at that time.

So I had the opportunity to present. I remember going into the staff meeting armed with all of the technical reports that we produced or I thought were appropriate, and I remember throwing them on the table and explaining all of the wonderful things we were doing through science, and education, and cooperation, and collaboration, and I was becoming aware that I wasn't making points. Somehow they tolerated this impertinent guy trying to suggest how to do the job.

But it was always amusing to me that I felt we went into an organization that had tremendous reputation and tremendous responsibility – FDA – but was not necessarily attuned to some of the kinds of issues that we had to deal with. I think the very nature of the FDA products that were regulated back there in 1971 when we joined them were such that they didn't quite require the same degree of

sophistication and technology that we dealt with. That sounds a little bit snobbish, but FDA was not geared to the same level.

People would joke with us – or maybe it wasn't so much joking – but would comment that years later, probably in the eighties, there was soon going to be time for the old Bureau of Radiological Health to join FDA, even though we'd been in it since 1971. They'd say, "Well, when are you going to finally join it?" I don't know whether we ever fully joined them or not. I think there was quite a philosophical difference between how we did things.

I would like to think that some of the things that we did may have in fact influenced FDA to do things a little bit differently. And, of course, when the programs got more sophisticated, and the biologics program came on board and became a part of FDA, it carried with it some of the similar type of high-tech sophisticated, science-based program that we had. And then the medical device program was very similar. So I think FDA, by and large, had changed away from what it was in 1971 to be more able to cope with some of the technology, and I guess I'd like to think that we brought something to that program and may have helped FDA.

The work that comes up to me from the very beginning of my involvement, getting out of the Air Force all the way through my years with FDA as I like to think of as collaboration and collegiality, these two words. Because I think that the value of what we could bring into the, and the value of how we did things was by being collegial. We had tremendous expertise, but we didn't have it all, and we were able to bring the expertise that we didn't have into work with us by collaborative efforts.

For example, even in the very beginning when we, under the state program, the states had the potential for authority to do things about radiation that we didn't have. So you want to get the states to understand the problems; you wanted to develop suggested state regulations – which I didn't mention, but which we did for a long time – to try to help the states develop model regulations. We even developed models enabling laws so the states could get the authority to do things about radiation. Then after they had the enabling legislation, then we proposed regulation as to how they might implement a regulator program for radioactive materials, or x-rays, or what have you.

So all of this was done by cooperation, collegiality, cajoling, and I would like to think with respect. I think we all respected each other, and that was one of the big strengths of the program. Whether you're dealing with the states or whether you're dealing with other federal agencies – like the Atomic Energy Commission and later the Department of Energy, or the Nuclear Regulatory Commission, or even in the Department of Defense, or even in National Aeronautics and Space Administration (NASA) or what have you – it was very exciting.

I participated in the ill-fated Apollo XIII launch down at the Cape, because that particular flight had a rather large radioactive source in it for power. The concern was if this thing went off, failed at launch, there was an awful lot of land down there that might have been contaminated with radioactive material. So I was sitting in the control room when that went off with a team of other people all stationed around the site.

That always gave us a sense of what was going on. We dealt with what were then the Weather Bureau people. We knew them because we had to depend on them for predicting fallout patterns. We worked with the old National Bureau of Standards, which is now the National Institute of Science and Technology (NIST) it was downtown on Van Ness, downtown in the district, and now out in Gaithersburg. These were the people that had superb science in the measurements of radiation. We had to work with them. The Department of Defense had all sorts of activities dealing with radiation, and we collaborated with them. The Central Intelligence Agency (CIA), the Federal Bureau of Investigations (FBI) even, on use of x-ray machines for clandestine operations. U.S. Department of Agriculture (USDA) from food irradiation issues.

We were just about in every phase of government, either as consultants, collaborators, or on committees with these people. I think that it gave us a, or gave me a strong appreciation of and respect for the colleagues sitting around the table and that these people could help develop programs.

We brought also a presence to these other elements, DOD, NASA; you name it, National Bureau of Standards, and the states. We brought a presence of public health to it, and that is an understanding, an awareness of the protection of the public and the consumer and what it was all about. So there was a

leadership element. When we went to these meetings and we became involved with these people, we planted a public health flag and said, you know, "This is important, and this is what we're all about." I think that if we weren't there, some of these concepts may not have been implemented as fast or as effectively as having us be there.

But it came about through collegiality and it came about through cooperation, and I guess that was one of the very gratifying things about my career in the Public Health Service, to feel that you were part of this broader team, and that you had a role to influence others.

DH: You mentioned Charlie Edwards. Did his involvement as far as being commissioner, was he receptive to what Rad Health was about?

JV: He was forming and restructuring the FDA at that time, and there was some question of whether we should be an entity by ourselves or that we should be merged with something else. The decision was that we should be left as the Bureau of Radiological health. You know, we were around, very similar at the time that the old biologics program came out of NIH and joined FDA. And pretty much that program was left alone.

Where I felt a little bit sad, but I can understand in retrospect where it had to be, was that we had in the old Bureau of Radiological Health, we had regional people in all of the Public Health Service regional offices who were radiation specialists. We had state assignees, and coming into FDA, we had the laboratory in Winchester, Massachusetts. The other laboratories, the one in Montgomery, Alabama, and the one in Las Vegas, were moved over to EPA. But the one that was left behind, because they were doing some of the type of testing that was related to the Radiation Control for Health and Safety Act, that lab was left with the Bureau of Rad Health. So we had a field laboratory, plus we had rad health people in the regions, and that all sort of changed when we joined FDA, those regional people went over to the FDA people. The FDA people didn't quite understand this way of operating.

Also the bureau did its own inspections, under the Radiation Control for Health and Safety Act. FDA didn't quite understand why we should be doing inspections. The inspections were done by regional people. Our point was that the kinds of inspections that we were doing were sort of sophisticated engineering inspections, that the people doing the inspections are the ones who reviewed the engineering drawings, reviewed the materials that came in from the manufacturers, and were best able to do this, go out in the field and do the inspections.

In retrospect that's expensive, because everybody comes out of Rockville and does the inspections. The FDA philosophy was, well, you have regions and districts around the country, and those people who are closest to the manufacturing point can do the inspections. We never felt that in the beginning stage and I think we were right, that they had the level of understanding. Now FDA slowly has then brought up the quality of the people to understand more of the sophisticated areas, and I think in recent years they've got some extremely talented people that understand high-tech areas, software, you know, design qualifications, design characteristics, and so forth. So it's been a big improvement from the way it was in 1971. But FDA was evolving then, and we didn't quite fit in, in the very beginning.

We gave the laboratory up in Winchester, Massachusetts, to FDA. They took it over and did some drug functions and some other things there. We gave the field people, the regional people, over to the FDA regional folks, so we lost some director control over there, but I think that was inevitable and probably was appropriate. I know it was traumatic at the time, but it probably was necessary.

DH: Following Edwards, is there anything particular about any of the other commissioners that was of note?

JV: Well, I always felt we got support, and I think part of that support came from the appreciation that we were a little bit different and we had some competence. I think it came from respect.

In 1979, when Three Mile Island occurred, at 4:00 in the morning on March 28, but who's keeping score? When Three Mile Island did occur, Don Kennedy got heavily involved in that and so did FDA, because a lot of samples had to be collected of milk, and produce, and so forth from that area.

DH: Your experience then with the old radiation surveillance network?

JV: Deals with that concept. But again, you see, EPA had been formed by that time and was well established, and EPA had some responsibilities at Three Mile Island. The Department of Energy had a response team for these sorts of emergencies; they had a presence. The Nuclear Regulatory Commission licensed it; they had a presence. And, of course, the state was there. So Three Mile Island in '79 was kind of a replay of all the good things that we could deal with. We had a person on site that was – Charlie Cox who stayed up there for most of the time – who was able to be a liaison with all of these different agencies.

But throughout all of it, Califano (Joseph Califano), secretary at the time of the department, said, "Well, we're going to maintain the public health, you know, we're going to have some things to say about public health here. Well, they're going to be interested in other things; ours is going to be public health." And he was tough. Kennedy, Don Kennedy, in the same way was very supportive of public health.

Califano asked me to be the departmental coordinator, in addition to being the head of the Bureau of Rad Health, so I was coordinating all of the departmental functions. Center for Diseases Control and Prevention (CDC) had a role in the secretary's office, NIH, of course – there were some real nervousness at that time that the so-called bubble, the hydrogen bubble, might blow, that the containment might be breached, and some of this radioactive iodine, which should have been around but didn't seem to be around, could have been a problem. And it wasn't quite clear whether that was going to go or not. So there was a need for constant communication. There was a need for constant cooperation with the other agencies. When we got samples of milk, we'd split the samples with the laboratory in Montgomery,

Alabama. Charlie Porter, who was head of that laboratory, and I collaborated on checking of the results, so we weren't coming out with one number that was different from their number.

One of the exciting things to me at the time was we started using a fax machine. To me that was sort of the first time we ever used a fax machine. I think we had one or two fax machines in the whole FDA. We had one and Charlie had one, and we were shipping results back and forth. Today that's a piece of cake, but in '79 – and that's not that long ago – but it was difficult keeping current with what was going on. But we were using the fax machine, and it was a slow fax machine.

But all of that collaborative cooperative effort kind of worked out very nicely, and I think the people on the job, particularly the Department of Energy people on the job, understood where Califano was coming from. He was very insistent about what he wanted to make sure the population was protected. He initiated studies, for example, getting the people involved with mental health, to do a study of the mental health consequences of the people that were involved with this kind of trauma. So he was far-sighted.

And Don Kennedy, testified and was very supportive, and right behind him, Art Hayes was involved with it. We had both of those people up on the site, took them for tours. We've had good support all the way through.

(Interruption)

DH: Is there anything in particular in closing, John?

JV: Well, as I look back on the radiation program, and thinking since this is 1997 and I retired from the Public Health Service in 1990, and I've been involved with the combined medical device/rad health program since 1982. . . I'd say from 1982 to the present, I really haven't been paying as much attention to radiation as I would have liked, or I thought I would when I started all of this. I've been thinking in more in terms, certainly more in terms of medical devices or in more recent years, FDA in general.

Although I may have made some comments earlier that might have been critical of FDA, FDA is a very special organization. There's some high morale, high enthusiasm, and I see this as a, this is perhaps nostalgia, but I see this among the folks who've retired or left FDA. There is camaraderie; there is a rapport; and I think a good feeling about that, those people in FDA.

Very similarly, those people who were involved with rad health during those sixties and seventies I think feel that what they did was important. I certainly felt it was important. I think we made a difference, and that's an incredibly gratifying situation to be in, to feel that you made a difference, that what you did was important. That was, I'm guessing, the big turn on.

My regret is that I haven't paid more attention since 1982 to the radiation side of things. But certainly my radiation experience was just nothing but positive, and I'm just very thankful for the opportunity to have been exposed to it and been given the responsibility in those various elements of that program. It was great, and the same way, if you were to look from 1982 forward, I feel the same way I think about the FDA.

If there's any way I can mentor others to get that experience that I had, I would like to do that, because it was rewarding. In a similar fashion, as I look back at the people who influenced my life, whether it's Russell Pierce, or Jim Terrill, or Don Chadwick, or any of these people who I worked for, Dr. Raymond Moore, all seemed like they were eight feet tall. They were all giants that I had nothing but just tremendous respect for, and that was very gratifying. So I feel very fortunate to have been a part of that.

DH: Well, I think that was obvious that it was inherent in your leadership, that you passed that on to those that came through the bureau. I don't think there was any question about the ability to collaborate and be collegial with your peers out there, that they, you know, the rad health group was as successful as it was.

Thank you very much for this opportunity to reminisce about some of these things, and we'll call it quits at this point.

JV: Thank you, Don.

(End of interview)