

History

of the

U. S. Food and Drug Administration

Interviewee: Richard E. Gross

Interviewer: Robert A. Tucker

Date: January 20, 1999

Place: Rockville, MD

INTRODUCTION

This is a transcript of a taped oral history interview, one of a series conducted by the Food and Drug Administration's History Office. The transcript is prepared following the *Chicago Manual of Style* (references to names and terms are capitalized, or not, accordingly.)

The interviews are with persons, whose recollections may serve to augment the written record. It is hoped that these narratives of things past will serve as one source, along with written and pictorial source materials, for present and future researchers. The tapes and transcripts are a part of the collection of the National Library of Medicine.

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General Topic of Interview: History of the Food & Drug Administration

Date: January 20, 1999

Place: Parklawn Bldg., Rockville, MD

Interviewee(s): Richard E. Gross

Address:

Last FDA Position: Assistant Director for Liaison, Office of Health & Industry Programs, Center for Devices & Radiological Health

FDA Service Dates: September 1, 1968 - September 30, 1998

Interviewer(s): Robert A. Tucker

Address: Parklawn Bldg., Rockville, MD 20857

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RT: This is another in the series of taped interviews for the FDA Oral History Program. Today, January 20, 1999, the interview is with Richard E. Gross, former assistant director for liaison, Office of Health & Industry Programs, Center for Devices and Radiological Health (CDRH). The interview is taking place at the Parklawn Building in Rockville, Maryland, and is being conducted by Robert A. Tucker.

As we begin, Richard, we like to have a short resume of your background, where you were born, raised, educated, and covering any prior employment before you came to the Bureau of Radiological Health, which I believe we'll find was not in the Food and Drug Administration at that time. So we'll let you start in that way if you would, Richard.

RG: I was born in southern Oregon, Klamath Falls, Oregon, in 1944. I went to school there, grade school and high school, and went to college at Oregon State University where I got a bachelor's degree in general science and then went on to for a master's degree, on a PHS Fellowship in Radiological Health at Oregon State University under the tutelage of an old x-ray expert by the name of E. Dale Trout.

Dr. Trout had one of the few PHS radiological health training grants in the country. His particular objective was to develop a curriculum for x-ray physics. He had several PHS assignee's associated with his program at Oregon State, including several who became part of the FDA radiological health program as well. They included Robert Elder, Ph.D., who eventually became the deputy director of the Bureau of Rad Health under John Villforth, and William (Bill) Properzio, who retired from FDA as the Director of at that time I guess was called the Office of Training or the Office of Training and Assistance, which was the forerunner of the current Office of Health and Industry programs in the Center for Devices and Radiological Health. Also Bruce Burnett was there. Bruce spent most of his career in FDA at Winchester and became, I think, deputy director of that laboratory at Winchester.

RT: Let's see, was that called WEAC?

RG: That was WEAC, right. Winchester Engineering & Analytical Center, I believe was what that was called.

Another person who was at Oregon State at the time I was there and was a part of FDA was a guy by the name of Greg Barone. Greg retired and went to work for Siemens after about twenty years in rad. health. Greg and Bill Properzio I think would be considered the fathers of the current x-ray standard at FDA, responsible for the x-ray performance standard.

RT: Now you were at the university in this PHS fellowship. When did you complete that particular activity?

RG: I finished that in 1968, and I came directly from that program to the Bureau of Radiological Health. Actually, it was called the National Center for Radiological Health (NCRH) at that time. Interestingly, the name kind of went back to that for a little while and then changed again.

RT: At that time was it called the Bureau of Rad Health?

RG: When I joined in 1968 it was the National Center for Radiological Health, and then it was when we were put into FDA that it became the Bureau of Radiological Health.

RT: At that time was it in the traditional Public Health Service?

RG: It was part of the Public Health Service and it was part of an organization called the Environmental Control Administration. Environmental Control Administration lasted only a short period of time after I came. When EPA (Environmental Protection Agency) was formed, our bureau was still the National Center for Radiological Health--kind of floated for about six months until they found us a home in FDA, where it has been ever since.

RT: Do you remember what political administration was in and who was president at the time? Let's see, this was about 1970 or so?

RG: I think it would have been Lyndon Johnson, but I'm not positive.

RT: I was trying to put it in perspective. The Environmental Control Administration, was that a reorganization or a superior positioned entity to the National Center?

RG: There were several other national centers within that organization. But since I was so new to the agency, I didn't ever quite understand all that until later, nor remember what the other centers were called.

RT: When you came into the National Center, what kind of an assignment or what kind of a position did you have?

RG: I was recruited by Mark Barnett, who was at that time deputy director for the training program. It was called the Rockville Training Section, and my first assignment as a new commissioned officer was to the Rockville Training Section, where we put on short courses, one- and two-week short courses for people who wanted to know about radiological health (radiation protection techniques). We had state personnel, other governmental personnel, federal government, such as military, and then we had university groups and so on who were the students in that training program.

RT: Where did you go next from that particular work? I might first ask you, you mentioned the Public Health Service, so you were a commissioned Public Health Service officer in the Public Health Service. Did you come in with that status when you were first employed?

RG: That was how I entered, as a commissioned officer. That was during the Vietnam War, and serving with the Commissioned Corps of the USPHS was a convenient way to meet my military obligation in 1968. The Commissioned Corps of the PHS is one of seven uniformed services of the United States that also includes the military services. I was planning to stay a couple years, and I stayed a little bit longer than that. Twenty-eight years longer, to be exact.

RT: You were perhaps going to comment on what you did further than the initial training assignment.

RG: Well, my assignment was to develop an aspect of the training program in medical x-ray protection since my background had been in x-ray. Coming from the program that Dr. Dale Trout ran, I had a good experience in diagnostic x-ray and physics associated with it. My master's thesis program was focused on the impact of film processing on the quality of images. My major contribution to the training program at that time was to instill some information about the impact of film processing on patient and operator dose and on image quality. Dose and image quality has been a central point of my activities throughout my career, culminating with the mammography program.

RT: Was that prior to the enactment of the Radiation Control for Safety and Health Act?

RG: Yes. It was enacted quite soon after I joined the center, and there were a lot of reorganizations within the center that took place to bring people together to work the new standards. The first standard that came out was the television standard, but that was kind of a place holder as they worked on the more important, from a public health point of view, standards associated with the medical and dental x-ray equipment.

RT: Prior to enactment of the Radiation Control for Safety and Health Act, the role of your unit then was what? Was it sort of an advisory to x-ray practitioners, or was there an enforcement element?

RG: There was no enforcement element at all. This was the first time there was any enforcement responsibilities associated with our program. All of the previous work had been, as you say, advisory work with the medical professions. But more importantly, since public health activities were traditionally regulated at the state level, we had a strong effort to establish and then maintain the radiological health regulatory programs in the states.

Mr. James Terrill, who was then director of the National Center for Radiological Health, was one of the proponents of the assignment of federal personnel to state programs to improve or to actually establish and to begin new radiation protection programs in the states that would be used to control radiation sources in the states. At that point there were only two sources of information or support in the states for that area of public health and safety. One was from the old Atomic Energy Commission (AEC) which had a few people involved at the state level, and the Public Health Service, which really established programs focusing on naturally occurring sources of radiation, like radium and x-rays used in medical and dental practices. Whereas the AEC focused entirely on those radioactive materials regulated under the Atomic Energy Act, primarily man-made isotopes.

RT: At that early time the federal program assigned, as I understand, some of their personnel for technical and educational assistance to state organizations. In doing so was the federal person still a federal employee, or did they become a state salaried person? Were they paid by the states or by the federal program?

RG: There was a mixture of activities. Initially, they were paid entirely by the federal government. Then about the time I came in that was changing a bit, and part of the federal person's salary was paid by the state. Then many of the people, these state assignees, stayed

on and became directors of the programs in the states. They were initially put into the states under something like a cooperative agreement, and the federal government paid the salaries. Later the states themselves took over these programs, many times hiring the federal assignees to run the programs.

RT: How were states selected or how did states qualify for this type of federal assistance?

RG: That's an issue I'm not real clear on, but one of the first ones was in New York City, in New York State. Kentucky, California and North Carolina were also early recipients of this program. I think these were started more on the basis of a perceived need within the state, and the state made application to the federal government for them. But how they were distributed beyond that, I don't know. Certainly there weren't people in every state. They started out just in a handful of states, and I think the maximum was probably something over a dozen at one time in radiological health. Of course, other PHS programs also utilized the state assignee mechanism to support certain aspects of the state health departments. Some aspects of that program continue to this day.

RT: So the program never, if I followed correctly what you've said, reached a point where there were assignees in all states?

RG: Never. There were state assignees in different radiation control program areas too. For example, in some states there were people who were assigned to the occupational health programs, which were getting started about that time. The people that were in these occupational health programs were assigned out of the National Institute of Occupational Safety and Health (this is what it's called now--I'm not sure what it was called back then). Those assignees' primary interest was in occupational health, that is, preventing injuries to workers. But some of those people came to our training programs in order to get information

about radiological health, which they applied in their occupational work. Some of them also were able to deal with the medical/dental practices as well.

There's always been a conflict about how to deal with radiation health programs. Should it be in occupational health and deal with the people who are using it? Should it be a public health program and deal with the people who are receiving medical and dental x-rays? Should it be in an environmental management program where you protect the environment from different kinds of pollutants? The management question for states has always been at what point should use of radiation, which has never been a big thing in public health, be controlled? It was always considered to be so small and so complicated they never quite knew what to do with it. So the state assignees were often placed in any one of these three program areas.

RT: Were any of the states leaders or pioneers in some kind of a regulatory mode with regard to radiological devices in the medical profession? Or was it more of a voluntary and educational approach at the state level?

RG: Initially, the pattern was the public health advisory type of program, but California and New York led the nation in establishing some regulatory programs. I think New York City was the first to establish radiation control regulations and an enforcement program. When I came to Rockville, Saul Harris was a PHS assignee and was responsible for managing the program there. He eventually was hired by the city, and he ran the program until he retired. I can't remember if he was also responsible for establishing the first regulations there, but my impression is that he followed someone else who did.

RT: What years would that have happened in those two states? Would that have preceded the federal legislation in 1974?

RG: Definitely. Yes, that was well before then. In fact, that could have been as early as the fifties. I'm not sure when California's first laws occurred, but it was in the early sixties or the late fifties when those programs were established.

There was a state assignee in California at the time by the name of Simon Kinsman. Si Kinsman was the initiator of some of those early radiation control standards, some of which were used along with voluntary standards by NCRP and others as fodder for developing the regulations that were finally established under the Radiation Control for Health and Safety Act.

RT: How about the industry, the radiological equipment industry? Were they active in any kind of a cooperative way with your federal service agency and/or the states?

RG: I don't know that they had much relationship to the states, but at the bureau we had some rather positive relationships prior to the RCHSA. One of the things that some of these people who were at Oregon State learned from Dr. Trout was that the industry should be treated with some respect because of the background and knowledge that they have in the way devices are built. He encouraged us to work with them, because the device industry at that time really was interested in finding ways to improve the way radiation was used.

The industry had already established some voluntary industry standards as part of the American National Standards Institute and had developed in cooperation with the National Council on Radiation Protection and Measurements (NCRP) some voluntary radiation protection standards that the industry pretty much followed. The problem was that, although the industry would produce new equipment that met these new standards, there really was no effort or no movement to upgrade the existing equipment.

One of my first assignments when I came into the training program at the center was a short assignment downtown in the District of Columbia doing x-ray inspections. Some of the equipment we saw in 1968, 1969, before the x-ray standard, was really pretty scary. We saw bare wire x-ray machines where high voltage was being applied to these tubes that were

basically out in the open with bare wires. So even from a shock hazard standpoint they were really scary. Some of them were operating pretty well and produced fairly good images. Some of them were just awful from a radiation health and safety perspective.

RT: I believe 1974 was the year of the enactment of the Radiation Control for Safety and Health Act. Was that congressional initiative prompted or moved by reason of there being injuries from radiation equipment exposures, or was it due to another cause?

RG: I think the thing that finally kicked it into gear was the concern about color TV sets. When it was discovered that color TV sets were producing x-ray radiation as a result of their normal operation that would expose children to these relatively high levels--by today's standards they were certainly high--that kicked everything into gear and Congress moved on it. While there was some discussion about the exposure to people, the National Center for Radiological Health had already conducted a study on x-ray exposure--the X-ray Exposure Study of 1964--that had demonstrated that x-ray radiation in medical in dental uses was the highest contributor of exposure of man-made radiation to the population. But even that hadn't really caused the kind of effort that really moved the legislation forward like the color TV program did.

RT: In the early days when x-rays were first appearing in the offices of medical practitioners, apparently they were in some cases used for treatment of acne and that sort of thing. I know of a person in the Food and Drug Administration who was rather badly scarred, and he related the fact that as a boy he had been treated in a physician's office by x-ray for acne and obviously got much overexposed.

RG: There were a lot of different kinds of uses of radiation back then that we wouldn't consider anymore. Another example is the use of shoe-fitting fluoroscopes. Shoe-fitting fluoroscopes were very common within shoe stores. In fact, my uncle ran a shoe store in

Astoria, Oregon, and my brother and I got to see our toes wiggle in his shoe store. Of course, it wasn't very long after that that people decided that wasn't a good use of radiation, and so they were banned by state government action. It was not a federal action; but was a state-by-state action.

RT: Surely all can remember--I certainly remember as a lad seeing those in many shoe stores. That was the going thing for a time.

RG: Right. It was an effective way to check to see if your toes didn't come to the end of a hard-toed shoe, but not a very effective use of radiation. It did not meet the acceptance criterion, that the benefit of the use of the radiation outweighed the risk to the public.

RT: When this federal legislation was being considered in the Congress, what was the legislative history in terms of testimony by either government agencies or medical practitioners or whoever? What groups might have contributed to the legislative push for that law?

RG: Those are things I wasn't paying too much attention to when I first came in, but I do know that the American College of Radiology (ACR) voiced its support for improvements in radiological equipment and the effort to reduce the unnecessary portion of x-ray exposures caused by operators of that equipment. They were a very positive force in helping the Congress to understand that this was not something that was adversely going to affect medicine certainly. The ACR pointed out that the valuable aspects of x-ray exposure to people for purposes of diagnosis and treatment need to be carefully managed by people who are trained to do so, but the new standard could serve to improve the practice of medicine. And I think history has borne that out. It really has been a great improvement, not only as a result of the x-ray standard, but in general practices of medical and dental practice over the

years has really improved so that the unnecessary doses that people get for any exam are reasonably lower than it would have been in 1968 or 1965.

RT: The 1974 act then, having established standards, what enforcement provisions were authorized by the legislation, and who or what agencies were charged with such enforcement?

RG: I think the act was passed in 1970, and I think the x-ray equipment standard came out in 1974. So I think the act was in '70 or could have been a little bit before that in 1969. I wish I could remember exactly, but I think the act was passed soon after I came in. Then we worked on the regulatory standards enabled by the Act. The implementation of the Act was assigned to our center, and we worked to establish an enforcement program. I think that establishment of the enforcement program was well underway when we were reassigned to the Food and Drug Administration.

I think the Environmental Protection Act was passed in about 1970, and in trying to pull together people to implement that act they formed the Environmental Protection Agency (EPA). In forming that agency, they pulled out of the Public Health Service and other agencies as well. Out of the Public Health Service a number of people were assigned to various environmental activities.

The National Center for Radiological Health had at that point a fairly large environmental surveillance program where the Public Health Service had been responsible for monitoring fallout from atomic weapons testing that was done in Nevada and elsewhere. Again, there were Public Health Service assignees to states that were involved in the state monitoring programs. We had a fairly large contingent of personnel at Las Vegas, where we had a laboratory that was set up to monitor the weapons tests. We had an "air force" that would track the clouds that resulted from the tests. All this was a part of the Public Health Service.

When EPA was established, these environmental programs that were in the Public Health Service were then moved over to the Environmental Protection Agency. For the

National Center for Radiological Health, that meant pretty much splitting it in half. Half the people, half of the FTEs, and half of the budget that was associated with--well, more than half the budget--half the people, anyway, went to the Environmental Protection Agency, and the other half they didn't know what to do with for awhile. So this remaining half floated around for six or nine months maybe before we were finally included in the Food and Drug Administration.

RT: When you came to the Food and Drug Administration, did that seem to, in the eyes of those that were transferred over, enhance the compliance capability and philosophy of the program?

RG: There were some mixed emotions about that. Certainly FDA had a much more compliance outlook, much more enforcement oriented. So the people who were responsible for developing the standards under the Radiation Control for Health and Safety Act saw some benefits in working along those lines. There was a split, though, in how that was being done. Our standards, the Radiation Control for Health and Safety Act was oriented toward manufacturers, and that wasn't exactly the philosophy of the FD&C Act at that time, so there was some conflict as we sorted out how those compliance activities were going to be operated.

And then there was another aspect of the center that was still very much public health oriented, non-regulatory, and those folks were afraid of what would happen to them as they got into the FDA, because any non-regulatory position of FDA was hard to find. It was very difficult to maintain that non-regulatory, advisory, consultative approach for radiation control in the medical practices. That friction existed for quite a few years after that.

RT: Well the original or traditional Public Health Service, is it not appropriate to say, the programs there were generally more geared to educational activities rather than the cop type?

RG: Right. That was definitely true. You still have that within the Centers for Disease Control (CDC). It's a program that works to support the state programs, provide some leadership and coordination. As they develop new program areas, Congress provides CDC with funds to encourage the states to follow along, but there's little enforcement responsibilities. Congress has also in recent years had some difficulty in trying to sort out this role, but they've tended to retain the focus on the traditional public health activities and left the regulatory, enforcement, compliance issues to other entities, whether that be FDA, or other parts of the Public Health Service, or more often to the states in their traditional public health regulatory responsibilities.

RT: When your organization came into the Food and Drug Administration, was it then that it was identified as a Bureau of Radiological Health?

RG: Yes. At that point they changed the name to be like the rest of the entities of the FDA, to go along with the Bureau of Foods and the Bureau of Drugs. And we became the Bureau of Radiological Health.

RT: As far as management in the Food and Drug Administration is concerned, did that then move from the commissioned officer type of manager to a civilian or the regular FDA-type management? Was there any shifting in management personnel, or did the same people pretty much lead the program?

RG: The same people were involved. John Villforth was the director of the National Center and of the Bureau of Radiological Health during that transition. Mr. Terrill had retired, I think. He may have gotten another assignment--I don't remember which. John Villforth became the director in the early seventies, and he retained his directorship for a good long time. I don't remember when he finally retired, but he was the center, bureau, center--in

that order--director all that time. Within the center--under John--there were several civil service managers, so it wasn't totally a commissioned officer managed program.

RT: You had a cadre of people, of course, in the headquarters bureau. What moves were taken to place people in the radiological health discipline in the field organization?

RG: When we first were put into FDA, we were just lock, stock and barrel put into FDA, and so there were some field assignments that were really reporting out of headquarters still, out of the bureau. But within a relatively short time, the man who was responsible for that field activity, Dr. James Miller, was reassigned to EDRO, and he worked within the EDRO program until, well, I'm not sure how long. He was there for quite while. He did not retire from there. He came back to the bureau after the people in the field organization were integrated into regional and district offices.

RT: So this group of personnel . . .

RG: All the state assignees and the regional radiological health personnel, the regional compliance officers, who were responsible for assuring that x-ray machines, and microwave ovens, and TV sets were all in compliance, all those folks were moved into the field organization, which was called at that time EDRO.

RT: Now do I follow you correctly that . . . Let's say you had a field representative, an assignee, for example to the state of Kentucky. Did that mean that the person who was placed in Kentucky then was brought into a district FDA office and no longer operate at the state location?

RG: I think we only had maybe two or three state assignees at that point. We had one in the state of California, one in Florida, and I think we had one someplace else. Their

responsibilities were more in the non-ionizing radiation area at that time. As their reporting direction went from being somebody at headquarters to somebody I think in a regional office rather than a district office at that particular time, and then when those people's assignments within the states were completed, they came back to the regional offices and worked out of the regional office.

RT: I don't know where this occurred in the chronology that we've covered thus far, but there was an organization fostered by the bureau. I think it bore the name of Conference of Radiation Control Officials. Could you speak to that as to when that developed and what it was and so on?

RG: It was called the Conference of Radiation Control Program Directors (CRCPD). It was formulated in 1968, I believe--'68 or '69. It formed as a result of a need to coordinate radiological health activities better. The states, once they had established programs, had been kind of moving independently. There was a perceived need for some of the newer programs to learn from the older programs in the states and to improve communications and coordination. There was concern about the direction the federal government was taking in several technical policy areas. So in 1968, they met at one of the radiological health laboratories in Montgomery, Alabama. That was their first meeting, and it was at that meeting that the idea for special state organization was developed and shortly after that the organization was formally established.

Dr. Miller, who was at that time the director of Regional Operations within the center, the National Center for Radiological Health. He was responsible for the state assignees and the regional advisers. Dr. Jim Miller started this meeting and he later got support from the Atomic Energy Commission and their agreement state program to support this organization. When EPA was formed, again half of the National Center for Radiological Health went with that organization, so through EPA's support that portion of the radiation control program was able to reconnect with the radiation health community through this Conference of

Radiation Control Program Directors. For many, many years it has been supported jointly by the Atomic Energy Commission, now the Nuclear Regulatory Commission, EPA, and the National Center for Radiological Health and then Bureau of Radiological Health.

RT: As I recall, the federal agencies, the tripartite-type organization, was able to provide some funding for state personnel to attend the conference meetings. Is that correct?

RG: Initially, in 1968 and 1969, the first two years that meeting was held, the state people came to that meeting under federal travel orders, so we funded the travel and per diem for the state people to attend this meeting. The conference became an official organization being incorporated under the articles of incorporation in the state of Arkansas in the first place. This occurred because the director of the Arkansas program was one of the strong supporters of this organization, and he undertook the incorporation for the organization. Then it was able to receive government grants. Initially FDA and AEC contributed to the support of this organization separately but eventually money was transferred from the other agencies, EPA and NRC, to FDA which still maintains the cooperative agreement under which the funds are provided to the organization.

As the meeting grew, it was funded partly by federal funds and partly by state people who attended the meeting. I have no idea what the various proportions are, but it is now a truly joint federal-state organization. Now it's incorporated under the articles of incorporation in Kentucky, where the office is, rather than Arkansas.

RT: Do states in their contribution have a fee or a committed to amount of contribution? How do the state funds come into the organization?

RG: In three ways. One is through a membership fee. Another one is through . . . I don't know exactly what to call it. Some states are able to make a separate kind of contribution. I never really understood the mechanisms of that. I still don't. Then the third way is just

through attendance at the meetings. They pay for a registration fee, and that helps to support the conference as well.

RT: So, can one conclude from that state participatory role that the center, as it's now called, no longer picks up the travel for all state conferees?

RG: Right. The center doesn't . . . It would be ludicrous by today's standards to think of having a secretary sit down and manage several hundred individual travel orders to have people attend this meeting.

RT: Is it correct to recall that originally when federal funding was being provided for travel in order to assure all states' participation that there was a two-person-per-state stipend?

RG: No. I'm pretty sure initially it was just one per state; although there were some years when that might have occurred, it was not the usual practice. And the federal contribution to the conference is disassociated from those individuals anymore. The federal contribution now is for program areas and not for individual travel. The annual meeting is still an important part of the work of the conference, but it certainly isn't the most important.

I think the most important part now is the various working groups within the Conference that are designed to develop the model regulations. This organization established the model regulations. It was initially an activity within the old National Center for Radiological Health to develop and publish model legislation for states. Since then the model regulations, which are known as the Suggested State Regulations for the Control of Radiation, have been improved over time to be compatible with all the federal regulations, including those of OSHA (Occupational Safety & Health Administration), NRC, Environmental Protection Agency, and, of course, FDA. The waste disposal issues that are hot now, dealing with long-term disposal of radioactive waste. All those issues are addressed by these model regulations.

RT: Apparently, the result has been pretty much national uniformity in the radiation control field. Is that true ?

RG: That was the goal, and I think it has been achieved. The Bureau of Radiological Health up until about 1980 or so monitored that activity to assure that the regulations from state to state were consistent. Nobody has done that in recent years, but I think that if someone would do that now, we would be pleasantly surprised at how consistent the rules are. Certainly there are some program areas that are well behind where they should be. The District of Columbia is just one bad example of that situation. The rules in D.C. probably haven't been changed since 1970, so they're pretty far out of date and need to be improved. There are other states with similar problems. But I think most states recognize the need for keeping their regulations up to date and have put in enough resources to maintain those regulations as uniform as possible.

RT: One of the things that has occurred--and I'm not sure whether that occurred as a result of the Radiation Control for Safety and Health Act or the Mammography Quality Standards Act; the latter is one we want to cover--is the involvement of the states under contract to FDA. That program began relatively early in the time that the agency started contracting with states. Would you like to speak a little bit about those activities?

RG: Yes. These started with the x-ray standard and the Radiation Control for Health and Safety Act (RCHSA). The way the act was established and therefore the rules that came out of it, placed the enforcement action on manufacturers, not on, as the states had been doing up to the point, on practitioners and radiation users. States regulate the practice of medicine for the most part, so the enforcement activity of states is on practitioners, and for the federal government (under RCHSA) it is on manufacturers. But in the case of the diagnostic x-ray machine, one manufacturer makes an x-ray tube, another makes a control panel, another makes a table. And those might be three different manufacturers. The machine itself that is

used to produce the diagnostic x-ray does not really come together except in that doctor's suite. So while FDA could evaluate all of the manufacturers, the manufacturer of the parts in a factory, which was the traditional way for FDA to do that, there really wasn't a way FDA with the limited personnel available could really get to the point where all these pieces came together in the individual practitioner's office on a routine basis.

From about the 1970s on FDA's resources for that kind activity were continually reduced. So there never really was any resources available within the agency to inspect a significant number of competed x-ray units. The only way to accommodate that was to contract with states, train them in how to do these evaluations, and buy the surveys from the states who were willing to help us out. I think the agency has gained a lot of benefit from those contracts, because many states charged us very little for those contracts. Some did those contracts basically for free, because all they received in their program was training and loaned equipment. As their resources have been hurt, sometimes those prices have gone up, but those contracts served as a way for us to have control over how those surveys were done. The contracts provided that we would give these inspectors with the training and equipment that they needed to carry out the inspections, and they would provide the data to FDA.

Even so, under the best times, if you will, the financial best times, FDA never was able to look at every single unit that was installed. But that was okay. We focused on the assemblers, those people who were putting those pieces of equipment together, and as we got better historical information, we had a tendency to focus on the assemblers who had the most problems keeping the equipment in compliance. In recent times--this year, in fact--those contracts have been terminated because of financial constraints within the agency. Now the agency is going to have to wonder about how to maintain that oversight of the equipment that is actually in the field. Some states, I hope, will do it voluntarily. Others probably won't be able to. So I think the agency's ability to assure that the equipment meets the standards is going to be severely restricted by that turn of events. I'm convinced that this will eventually lead to some serious problems down the road and people will be hurt by the lack of oversight.

RT: At the time that states were involved in this under contract, do you happen to recall of about how many states participated in the program?

RG: At its peak funding it gradually increased, probably to almost 40 of the states. I don't think we were ever able to have all of the states involved at one time. I think in recent years it has kind of fallen back to the high twenties that still have contractual mechanisms. FDA field people still do a small number of in-facility inspections, but the number of those that can be done by the people we have in the field is going to be quite small compared to what we were able to do under contract. So it will be interesting to see how this affects them.

RT: We touched a moment ago on this other act that was rather significant in the radiological field, that being the MQSA or the Mammography Quality Standards Act. Can you elaborate a little on that particular legislation?

RG: Yes, let me back up a bit. One of the things that we did when Jim Benson became director of our, at that time it was called the Office of Training and Assistance, one of Jim's efforts was to try to make the resources that we had in radiological health more effective, so that we would utilize people in a different way and make them more efficient in reducing radiation exposures. As a result of some activities that were initially started by Ken Travis at the Winchester Engineering and Analytical Lab in Massachusetts.

(Interruption)

RG: Ken Travis was one of the physicists that worked up at Winchester Engineering and Analysis Center (WEAC). It had been previously called the Northeast Radiological Health Laboratory. Ken had developed an idea that we could evaluate x-ray exposures to people in a standardized way and use that as a measure of how well radiation

control programs were working. As was our normal practice at that time, we got together with the members of the Conference of Radiation Control Program Directors and developed a team to expand this idea and make it a practical one for states to implement. The resulting program eventually got the acronym NEXT, which stood for the Nationwide Evaluation of X-ray Trends.

This was, and still is, a completely voluntary program, but was a cooperative federal-state program in that FDA would provide the training for how this program was to be implemented and then capture the data that came out of it. For the first time since the old X-ray Exposure Study, FDA had up-to-date information about patient exposure to x-rays.

As that program matured, it became harder and harder for states to put the effort into the dental part of that which the directors of the NEXT program had anticipated. So an effort was developed in my organization to develop kind of a remote control program that we eventually called the Dental Exposure Normalization Technique (DENT). This program called DENT utilized TLD (thermo luminescent dosimeters) that were mailed by the states out to dentists who exposed these dosimeters as they would a normal bitewing radiograph. The dentist mailed the exposed card back to the state, the cards were evaluated by the FDA, and the results were then returned to the states. Part of the DENT program was an acceptable band of exposures, so for different radiographic technique factors a particular range of patient exposure was expected. If the exposure was high, higher than this acceptable range, then those facilities were identified as ones to send a state inspector to, and the state inspector would work with the dentist to correct those high patient exposures.

That program was responsible over the years for reducing the exposure in the dental facilities to about one-half of what it had been prior to the existence of the DENT program. So it was a very effective program in those states that implemented the program. Not every state implemented the program because it was completely voluntary, but most did, and certainly all the big states did.

In 1974 Pennsylvania was doing some NEXT-like exposure evaluations of facilities doing mammography exams. They found one facility that, as a normal part of mammography,

had a skin exposure that was about seven times higher than was considered normal at that time. This was at a time when breast cancer was just beginning to be targeted as a public health problem by the federal government, and there was a concern within many of us in the center that this could be a serious radiation exposure problem if screening mammography for breast cancer was to become widespread and there would be this opportunity for very high doses if mammography was performed improperly.

So we modified the DENT program for mammography. (It was called BENT (Breast Exposure Nationwide Trends)). Again a TLD card was sent around to mammography facilities by participating state programs. The mammography technologists were to expose it, and again, depending upon the technique that the facility was using, there was an expected range of exposures. When the facilities were outside the range, either too high or too low--and in a mammography situation they could be either depending upon the particular problems the facility was having--we would again target these outliers for a visit by a state inspector.

As a result of these inspections, it became evident that quite a number of mammographers were conducting the exam with inadequate x-ray machines and/or improper exposure techniques.

When the initial results were shared with the medical profession, especially the radiologists and the American College of Radiology, it caused quite a stir and the college reacted by developing a mammography accreditation program and offered it as a voluntary program to mammographers. This program did significant improvement in those volunteer facilities that accepted it. However, only about one-half of the growing number of facilities were inclined to participate. (The MQSA incorporated the ACR's program of accreditation, or one that would be equivalent, in the set of requirements that a facility must meet in order to continue to operate mammography.)

The first federal mammography bill was proposed several years later. It was called the Brock Adams bill after its sponsor in the senate. It was late eighties when this bill was being proposed. The BENT program had demonstrated that there were these problems with exposure and image quality. There was a debate going on about the value of mammography,

screening mammography. John Baylor had projected--John Baylor was associated with the National Cancer Institute--that screening done as it was at that time, mammography screening could cause as many cancers as it found.

So we had started an effort to improve the quality of mammography, and we did it with this BENT program and some efforts with the American College of Radiology to teach people how to do mammography in a better fashion. The National Cancer Institute helped to get the program started by providing FDA with funds to purchase the required equipment. At the same time, the film industry responded with faster films, and then finally film screen image receptors. Instead of using an industrial x-ray film--at the time this film was necessary in order to achieve the high resolution necessary for early cancer detection--the resolution was maintained, and the doses required to expose these films was drastically reduced with these new imaging techniques. But image quality remained a problem. As part of this national debate, CDC, NCI and FDA worked together with the medical profession to try to encourage better mammography.

The Brock Adams bill as it first came out was an attempt to regulate facilities that did mammography and to require qualified people. The primary intent of that legislation was to provide qualified people to do mammography exams. The supporters of this bill were concerned about some of the things that they had seen in the cervical cancer detection program where certain laboratories were just overwhelmed with pap smears and they couldn't manage the volume and retain diagnostic quality. They were concerned that mammography not fall into that same trap. But there was no image quality control in that first bill. I wrote a review of that bill for the department and was very critical of the bill, because in my mind it didn't deal with the real problem. It didn't deal with the image quality issues that I thought were more important.

For various reasons that bill didn't pass. I didn't have anything to do with it not passing, because the department never passed my review on to Congress. But it didn't pass. And then a couple of years later the issue of mammography came up again in a following Congress. This time the department was more anxious to be involved in the development of

that legislation. This group of the three agencies, CDC, NCI and FDA, were offered the opportunity to have some input into that process, so we were able then to get image quality aspects into a bill, and one was eventually passed. It was called the Mammography Quality Standards Act (MQSA). Most of that law was assigned to FDA for implementation. It took the department about six months to make the delegation to FDA, but finally they sorted it out to come to FDA, and a research part of the bill went to the National Cancer Institute.

RT: Did the agency get any additional funding?

RG: That was only one of the difficulties. David Kessler was the commissioner that time, and Dr. Kessler was adamant that FDA would not take on this massive amount of work regulating every individual mammography facility in the country without some additional resources. So once it decided that FDA was going to implement this law, the department pulled money from CDC and NCI and some people and temporarily reassigned them to FDA in a stopgap measure until Congress could provide FDA with additional funds for the implementation of that law.

These additional resources were of significant help to FDA in meeting the exceedingly difficult and short deadlines required by the law. These resources and especially the hardworking people who were assigned to the program were able to overcome the six-month lost time and eventually the agency was able to meet all of the deadlines and requirements of the law.

In the last stages of debate on the MQSA bill, several groups brought up concerns about the potential for exacerbating the difficult situations in the "medically under-served" areas of the nation. The concern was that the additional costs of mammography facilities to come into compliance by the statutory deadline would result in further restriction of mammography services in these areas, either by closing marginal facilities, or through increases in the costs to patients.

Soon after the passage of the MQSA, CDD's program to improve medical services in these areas was given a boost of funding by Congress. These funds were used to encourage "centers of excellence" in the under-served areas to demonstrate that these medically under-served areas could meet the requirements as regulated by FDA.

The interesting thing from our standpoint, from an image quality and patient dose standpoint is that mammography has demonstrably improved over time. From the first days of when we started the BENT program with the states, we had a fairly good handle on image quality and the doses involved. Often the doses in some facilities were low because the techniques that many of the facilities were using were poor and this caused the images to be poor. So as they improved their technique, patient doses actually went up a little bit on the average, but the improvement in image quality has been dramatic. We're now at the point where people really aren't so concerned about the quality of mammography anymore. The agency will continue to monitor it with this program with the states as required by the law.

We implemented the program with appropriated funds. These funds permitted the program to get started and continue to support the non-inspection aspects of the program. The law was written so that we would have facilities pay a fee to be certified and to be inspected. The collected inspection fee is used to pay the states in contracts. So now the state contract program in FDA funds the states to inspect these facilities on an annual basis. That data then comes back into the center and the agency is able to monitor the quality of facilities and follow up on non-compliant facilities to correct problems. Again, there's been a demonstrable improvement. A success story.

RT: Good.

RG: One of the areas I mentioned was that the Bureau of Radiological Health up until about 1970 evaluated state radiation control programs and maintained a statistical analysis of those programs. Eventually we lost the resources to maintain that effort as far as the federal government was concerned, but the Conference of Radiation Control Program

Directors provided a substitute by offering a comprehensive review of the radiation control program. A state interested in having a review would simply request that the conference conduct a review the program. The Conference management would pull together a team of state program directors and federal people familiar with the state operations and do a comprehensive review of the program.

This review included staffing levels, budgetary requirements, coverage, in terms of how well they cover the different aspects of radiation control from environmental, to waste disposal, to medical and dental x-ray programs, and so on, ionizing as well as non-ionizing radiation sources, and compare the program to the criteria documented by the Conference. The criteria represent a consensus about what is an adequate radiation control program. The criteria are used to compare the regulatory status of the program with the Conference's suggested radiation control regulations. The review team would be pulled together and review the state programs upon request.

RT: Since that's a peer review, so to speak, it probably would be acceptable to the states generally. Is that correct?

RG: Right. It was never done except by invitation. In other words, the state program director, a member of the Conference, had to request the review. For the most part these were done on the program director's initiative as a way of finding out where he stands, by stepping back out of his program, and having a more objective look at what he is doing and how well they are implementing the program, how effective they are.

RT: Has that sometimes, to your recollection, resulted in a state then having a basis for a larger budget request from their legislature?

RG: I think in most cases it has. In one case it had the opposite effect. In one state the program was abolished because the state legislature decided that they couldn't afford an

adequate radiation control program, and so rather than have an inadequate one, they were going to have nothing. That state, to my knowledge, still does not have a radiation control program.

RT: Is that a smaller state?

RG: One of the smallest.

RT: I see.

RG: But most of the programs, I think, even if they didn't get an increase in funding, were able to cause some redirection of the things that they were doing so that they could focus on more important problems and bring their programs in those areas more up to the higher quality standards that were established by the Conference. So I think for the most part it has been a very productive aspect of this federal-state relationship. The program review team is always managed by a state program director, so it really is a peer review. All the federal people who serve on the team are subordinate, if you will, to the program director that's directing the review. Of course the federal people have a unique perspective on some of these activities as well. Having this team of federal and state personnel coming together to look at what goes on in the program, I think, has been universally respected by those programs that have asked for the review. I can't remember how many states have gone through this, but certainly not all of them.

One state has actually had the review twice. The state of Ohio was the state that initially asked the Conference to form the team. A few years later after a new director came on board, he asked for a subsequent review to see now if the program had advanced. He wanted a current status report and potentially some support for changes he wanted to make.

I think that the program directors who serve on this review team have taken this process back and reviewed their own programs as a result of their now-broadened viewpoint,

and they've been able to make improvements in their programs as a result of it, too. So it has been valuable not just for the programs that have been reviewed, but for those programs that have provided people to serve on the review team as well.

RT: It sounds like a good initiative. The Conference, then, is alive and doing well in terms of the objectives that they earlier formed.

RG: Yes. I think the people who initially set up the Conference were ahead of their time in terms of thinking about what this organization ought to be and why it ought to exist. They really had great insight into programmatic function and how to rub programs against each other and find the best parts of them and be able to share that information. It's been a very, very productive aspect of the radiation control program in the United States.

(Interruption)

RG: The Radiation Control for Health and Safety Act covers only one part of what those of us in the radiological health area know was the overall radiation control problem. The Radiation Control for Health and Safety Act provided the opportunity for the federal government to set performance standards for equipment, but having proper equipment is only a part of the necessary elements to have a high-quality diagnostic image. Other parts involve having all the equipment operate correctly and having the technologist determine the appropriate technique factors for the radiograph examination.

So we thought about ways in which we could work on these other aspects of the program. There was no regulatory responsibility for these aspects (except as now provided by MQSA), but we still had the mission to improve radiology. One of the things Jim Benson did when he became director of the Office of Training and Assistance was to focus or refocus our attention on these non-regulatory issues. The steps to improve that, we finally called the Quality Assurance program, and that basic program was given lasting life by being published

in the Code of Federal Regulations at 21, Part 1000.55. This remains a recommendation, the elements are not regulations, but a voluntary recommendation for quality assurance programs in diagnostic radiology facilities.

This program is an approach to radiology that requires focusing on the elements of the process to produce a diagnostic radiograph, identifying those parts that are not necessarily working correctly, focusing attention on improving those parts, and then setting up an overall monitoring program to assure that the various elements continue to function properly. This basic philosophy was instilled in all of the programs that we implemented: the dental program called the Dental Exposure Normalization Technique (DENT), plus the one (BENT) that was initially developed for mammography. This basic philosophy became a core part of the Mammography Quality Standards Act and the way we implemented that act in the regulations. These quality control programs or quality assurance programs are essential to the regulatory approach to managing Mammography facilities.

The basic philosophy and the general procedures of all of the quality assurance programs are specified in this particular part of the Code of Federal Regulations. These fundamentals have also been picked up by the Conference of Radiation Control Program Directors in many of their programs, and the states have begun to think of their x-ray control programs along the same lines: to encourage facilities to make improvements in quality. In some cases regulations have been established in states to *require* facilities to establish these monitoring programs that will serve to assure that radiation is used efficiently and that the diagnostic results are maximized or improved. This first publication of this recommendation, was December 11, 1979.

Another of the programs that the National Center for Radiological Health had for a period of time was established at the University of Cincinnati in Ohio. The center had a nuclear medicine laboratory. Its objective was to identify nuclear medicine materials that would provide diagnostic information for nuclear medicine techniques, but to provide it with lower doses to patients. This research program developed new radiopharmaceuticals, some of which were, ironically, then regulated by this parent agency (FDA) and sister bureau

(CDER). But these were new techniques, and new equipment, and new drugs, new radiopharmaceuticals, that were useful in improving the diagnosis and treatment of several diseases.

(Interruption)

RG: The basic mission of the program in Cincinnati was to encourage nuclear medicine departments to utilize these new drugs and new techniques. They also established some quality control programs for nuclear medicine facilities, published several articles and manuals on how to implement these programs. But again their objective was to reduce the exposures to patients undergoing radiopharmaceutical examinations.

During this early time, when nuclear medicine was being developed, the techniques for developing safer radiopharmaceuticals were coming out of some of the research reactors and accelerators at some of the national laboratories that are now supported by DOE. There was a cooperative program established between the old Bureau of Radiological Health and, at that time, the research side of the old Atomic Energy Commission. These labs became part of the Department of Energy when that was formed; the rest of the AEC was renamed the Nuclear Regulatory Commission.

The research programs of the Cincinnati lab were funded under grants and contracts with various educational facilities around country; medical schools and so on. The lab developed specific phantoms for testing nuclear medicine equipment, testing their efficiencies and their ability to produce high-quality images with lower and lower doses. The one who was primarily responsible for those quality assurance activities was Dick Van Tueinen, who was associated with the public health effort to get these new techniques and new radiopharmaceuticals into some of the hospitals.

That program was eventually terminated as resources continued to decline within FDA, and this fundamental conflict within the agency between being responsible for regulating pharmaceuticals under the Food and Drug Cosmetic Act and developing new

radiopharmaceuticals was resolved. The remnants of the lab are now run by the University of Cincinnati (nuclear medicine laboratory), and some of the former FDA employees are still there working there.

RT: I recall that there was a program for checking radionuclides or radiation fallout that might have occurred from atomic plants or other sources of radiation exposure as it might impact on the food supply.

RG: This was originally part of the bureau's responsibilities in its environmental surveillance program. Most of that program went to the Environmental Protection Agency when that was formed. But the agency retains some responsibility for assuring a safe food supply and works with some of the state programs to maintain a small surveillance program. When the reactor accident at Three Mile Island released some radionuclides from the reactor into the environment, the Public Health Service decided that in addition to the programs that the Department of Energy and the power plant and the state had to monitor the release, the Public Health Service should have a backup program to evaluate the potential exposure that the population might receive around Three Mile Island.

Our bureau director at the time, John Villforth, pulled together several of us from the center to work as a team to establish this environmental surveillance program. It focused on where people were. It was my responsibility to establish a TLD (thermo luminescent dosimeter) network around the reactor. We placed the dosimeters that we had been using in the DENT and BENT programs in hundreds of sites around the reactor in and outside of homes to evaluate the potential for exposure that people might receive during this incident.

For several weeks we hung these dosimeters around on people's houses, on telephone poles, throughout the places where people lived in a twenty mile radius around the reactor. We replaced those TLD on an every-other-day basis initially, and then later on, as the reactor incident settled down we finally scaled back the frequency of replacing these TLD. Eventually the overall surveillance was picked up then by the state of Pennsylvania. This was

a supplement to the state program in its initial phases, and then the state was able to eventually pick up the entire responsibility for the program.

The evaluation of the doses to the population was coordinated by Marv Rosenstein, who at that time was director of our Health Physics Office. Marv also served on a federal inter-agency program set up to oversee the problems around that particular incident at Three Mile Island. That program, as it turned out, led to a healthier cooperation among the federal agencies involved in radiation protection, and the leadership for that cooperative effort was eventually taken over by the Federal Emergency Management Agency (FEMA).

FDA still has a responsibility within the federal effort to monitor the potential for radionuclide fallout, whether it be from nuclear weapons testing by foreign countries or from accidents such as the reactor at Chernobyl. FDA's responsibility now is more limited to the impact that this radioactive material might have on the food supply. FDA's responsibility is to assure that the food supply is safe and that when these incidents occur that we know when and how much radiation fallout occurs so we can determine what to do about those food commodities that might be affected by the fallout.

RT: One of the principal foods of interest, as I recall, was milk.

RG: That's correct, although it all depends on the source of potential contamination, the exact nature of the release. The radioactive iodine that comes from reactors as a gas is concentrated by the cows when they eat the grass where the Iodine nuclides fall on the grass. The grass is eaten by the cows, and the cows concentrate the iodine in the milk. The FDA surveillance of milk was expanded to include a specific effort to check on the potential for contamination of the milk supply.

The evaluation procedures that are used are those that were developed way back when we were responsible for environmental monitoring, and the laboratory at Winchester was geared up again to deal with those incidents as they came up. They still maintain a small effort that can be cranked up to full speed when these rare incidents occur. Unfortunately,

most of those occur outside of the United States these days, so it's a matter of watching for the material to come across, and then monitor the impact that it might make on us. So far, that impact has been very, very small, and we haven't had to worry too much about it. Hopefully, that will remain true.

RT: Well, in addition to the concentration in dairy cows, on a body weight basis, milk as an infant food, would create an even greater concern.

RG: It is certainly more of a problem for infants on milk than it would be for adults. Adults, especially as we get older, we drink less milk as our primary source of nutrition, but also whatever radiation might be in that milk is going to have less of an impact on us than it would be on the children. The iodine concentrates in our thyroids. Adults are less impacted than children because the adult thyroid is bigger and is fully developed. Radiation risks are greater in developing tissues and in higher concentrations.

RT: Well, Richard, we've covered a rather broad array of topics relating to radiological health and nuclear considerations. Over your nearly thirty or perhaps more than thirty years of service in this field, do any particular individuals, commissioners, members of Congress or others come to mind as having been rather outstanding in their support of these programs?

RG: Certainly. I think that early on, when the Radiation Control for Health and Safety Act was passed, Representative Paul Rogers was very forceful in the House in supporting the Radiation Control for Health and Safety Act. He was also instrumental, I think, in helping us to retain our public health focus in dealing with medical and dental exposures. After the act was passed, his efforts continued in the House to hold hearings on how well we were doing in the public health area, what actions we were taking to implement not only the bill itself, but also to retain and build on some of those public health activities that we established: activities like the quality assurance program; some programs that we had established to make

recommendations for when certain examinations should occur, such as when a chest x-ray should be taken, when skull x-rays should be done, how to reduce x-ray exposures to women who are or, more importantly, might be pregnant. All those were issues that Paul Rogers had interest in, and he was able to support these programs by making sure that upper management within the department saw to it that they were continued. When he retired from the House, no one else has shown that degree of interest in this public health issue.

Then when the Mammography Quality Standards Act was passed, Commissioner Kessler at that time was very effective in assuring that the program was adequately funded before he would accept responsibility for implementing the program. His efforts to work directly with the Secretary's office to assure that this program got off on a decent financial footing, especially in light of the very short deadlines that were established in the bill, made it possible for the Mammography Quality Standards Act to be effectively implemented and gave it a chance of becoming successful.

Then, when the MQSA was up for reauthorization five years after it passed, Barbara Mikulski, Senator from Maryland, was very instrumental in assuring that the MQSA was reauthorized without being fiddled with. She was able to prevent changes in the law that could have watered it down, as there was some interest in doing. Her efforts to assure that the law maintained its strength I think led to its reauthorization with only minor changes. In fact, most of them were technical improvements. So those are three that I would name in response to your question.

RT: Okay, Richard. I think we can conclude on that note. We appreciate very much your participation in the FDA Oral History Program.

RG: I certainly thank you for the opportunity to participate. It's been great.