

Well in the worst case I brought some old technology in case the slides just don't make it. We'll give them another minute to get started, we're going to be talking about HDR and HDR is really what I guess one would call it an older technology now; it's been around for a long time. What is beginning to happen is that there has been more and more applications of HDR as LDR is gradually disappears and there's also been the beginning to have more and more mobile HDR systems, so for a lot of regulators this is a new area for them and they don't really know exactly what to do with us. Okay, what do we got here? Okay, alright, well lets us first of all define what – HDR is. First of all it's a brachytherapy procedure. It uses a 3-10 curie source, so we're talking about a lot of activity. Typically the sources will come in at about 10 curies and then people will use the source until it gets somewhere 3-5 curies, at which time they replace the source. Its iridium 192 half life is 73.8 days; it's also referred to as a RABHDR, which is remote afterloader brachytherapy. This compares, like I said, to LDR and in the LDR days, which is what all the initial brachytherapy was, you were dealing with millicurie amounts. Typically you would use cesium or cobalt needles in the older days and these tended to be fairly large in size compared to what we're dealing with now. They'd be like 2cm, long three millimeters in diameter and again your dealing with millicurie amounts. There's also, in Europe you'll find something called PDR, PDR uses the source which initially is about 1 curie. This is a method to simulate an LDR case and in the LDR, the patient is typically in the hospital for 54-72 hours lying in bed. You have to have nurses and family members go in and out and they're receiving some exposure. With the PDR method, what it is, is you take a high activity source and what it does is it pulses, it will be in the patient for a few minutes per hour and then its out. So, while the source is in the patient there are door interlocks and such that will prevent entry and if someone were to enter the room the source would be pulled out.

Okay, but that is not allowed in the United States, there are no PDR devices in the United States. They're basically two main manufactures of HDR units in the United States, one is Nucletron, which has the bulk of the market and the other one is Varian, and Varian is actually marketing two different systems, one is the GammaMedplus and the other one is the Varisource. This is the Nucletron unit. The Varisource is a little different in that the source is actually contained in a wire; it's a one solid wire that moves in and out as compared to the Nucletron and the GammaMedplus, where you have a sealed source that is basically welded to a cable, so this is really pretty basic technology. We have a source that goes out to the known distance and then is pulled back.

So, why do HDR? Well, there are some real benefits, first of all its an outpatient procedure versus inpatient, so the patient is not lying on they're back for 54-72 hours with a bunch of applicators inside of them, which is very uncomfortable for the patient. There are also certain financial benefits to both the hospital and to the patient, because it is much less expensive to do things on an outpatient basis. And so, in some ways the financial aspects is driving us as compared to LDR again, Medicare last year reduced the LDR payments for the technical aspects of the treatment by 95%, and so that means facilities cannot effectively do LDR treatments without losing lots of money. It has a much smaller diameter; the sources out there typically are about a millimeter or less in size, so you can go many more places than what you would otherwise. This means that the applicators that you're sticking in the patient aren't as big, and again, this is a comfort issue to the patient. You could also go into places that you could not go before, because it is done HDR, you're talking about treating in minutes instead of days. There are places you can put the sources that you could not put before. For instance, you couldn't, obviously could not have a source sticking in somebody's lung for 54 hours, 72 hours or even if

you took a bunch of LDR sources and put them back to back with the fairly high activity you're still talking about extended times.

So, with HDR you can go in there do your treatments in 3-5 minutes you're out of there. And, so this allows the RABHDR to treat things that he could not treat before, he can treat bile ducts, he can do the lungs, you can stick a tube down the esophagus --, the esophagus can sometimes present problems, cause you stick something down your throat you want to expel it back out, so you can have medications to temporarily avoid that issue. You can have a little better localization in that when you put applicators in a patient and then you put them in the room for 54-72 hours that patient is going to not just be fixed, they're going to be rolling around, they're going to sitting up partially and that's going to cause some movement of the sources. You can tailor the treatments, again with the LDR type things you have fixed sources, and so each source you may choose a 20 milligram or a 10 milligram etc., but they're a fixed lengths. With the HDR you can take that source, which really, as I said, has a diameter of less than a millimeter and they're typically 3-4 millimeters long and you can position it and by deciding how long you want to keep it at a spot you can make any distribution you want. Of course, another advantage and this is compared to the HDR is now being used not only for GYN and such activities, but its also being used for prostate seed implants, for prostates I mean in lieu of seed implants where ... with the seed implants the patient goes home and then they are radioactive for a period of time. With the HDR you put the source in, it goes out and everything, there is no more radiation involved at all. So, for personnel, when you're working with HDR, basically there is no radiation exposure, you're outside the room, outside a shielded room. it'd be only in what is really a fairly rare event where a source gets stuck and you'd have to go in on an emergency basis, but generally there is no exposure to personnel, just basically the radiation levels about the units are about at background levels.

Again, this is all scheduled; you do all your HDR during normal hours. I've never have seen yet an emergency HDR case and this contrasts with the LDR cases, again, where the patient had the sources in them and they're in the hospital for 54-72 hours and, you always had to carry a pager, every once in awhile you're going to be called in to solve some problem with that patient -- either the nurse thinks the applicators have moved or occasionally what does happen is some patients remove their own applicators in the middle of the night. And so, you don't have to worry about that. Sometimes, because you want to have the source treat to a certain dose it would happen to be that that time for the source to come out might be in the middle of the night and if you could manipulate the time any other ways your whole crew would have to be going into the hospital in the middle of the night in order to take out the sources. So, from a personnel point of view this is all neat and tidy, you have set times, you treat, it's all during the working hours, you know your staff is here, you can schedule everything. The work is usually done in the radiation oncology department, again with the LDR cases, with the patient being in the hospital, you would have to walk up carts and other devices and take your survey meters and all your equipment to put the applicators in, the applicators are put in the OR, but to put the sources in you had to pull that into the hospital, so now everything is within the radiation oncology department and so it's a much smoother operation. Fewer individuals to train, this was really a recurrent problem again with the LDR cases, because what happens is you have so many nurses that are working on the oncology floor between the transition from one shift to another from the fact that the nurses stay there then they go get another job, and so you always have an influx of new people. Now, it's within your radiation oncology department and you're very limited to the number of people that have to be trained at all. And again, it's everything is set up so there is no

exposure to the worker, you don't have to worry about the family coming in to visit the patient, nurses who take care of the patient, somebody to draw blood or anything like that. So, we have no nursing or visitor concerns.

Why not do HDR? Well, obviously, bad things can happen in very short time when you're working with a 10 curie source. There have been a number of issues that because you have a computer program controlling the insertion of the source. Things that don't happen in LDR do happen in HDR. In LDR you are physically there taking the source and putting it in, you see where it goes, you know what's happened. With HDR it's happening in a room and you're not actually seeing the source as it, where it goes into the patient and so we get some positioning errors that occur. With the LDR case, while the patient may for like a GYN, while the patient may be in there for 54-72 hours, they typically only go to the OR once to have the applicators put in place. When you do an HDR, what they do is typically may have 3-7 fractions of treatment, that means 3-7 times they have to go into the OR, if that's the choice of the site, and most the places I work with they put the applicators in the OR. So, they have to go to the OR and they get anesthetized 3-5 times or 3-7 times. There are certain radiobiological concerns, all the LDR work was done under low dose rate, and so the radiation exposure and the doses add is desirable developed over a period of many years and we know what to give. With the HDR case, when you for instance, when they started doing prostate a few years ago the question comes up, well what is an equivalent dose?

So, you had that concerns as to whether you're really giving the right amount of radiation. There are certain problems; the HDR units are now going for about 300,000 dollars a piece. The sources tend to be about 35-40 thousand a year. The treatment room, if you have to build your, this iridium so you need substantial concrete in order to shield the source and so the treatment room if you're building it can cost 150-200 thousand dollars. It requires that the authorized user and the authorized medical physicist presence for all these cases and there really is an expense "expense for that" because your taking up the physicians time and time is money for them. There are time demands again with the LDR case you put in the sources and you can do what you want during the day, but now you have to have everything scheduled, that physician cannot start an HDR case and then go see a patient on the floor. Everything has to be controlled with this time and there is obviously increased QA with this mechanical device.

What sites are common? Typically we do brachytherapy, we do GYN cases and this can be done either LDR or HDR, vaginal, cervix, endometrial some of that's with applicators and then you can do the same thing by sticking doing it interstitially, which means that your putting needles into the patient and putting the sources exactly where you want to. They're using HDR for breasts. They used to do interstitial LDR, in fact, we used to do this substantially with breast, where we would put lower activity of iridium seeds in treating the breast. Typically, if it's done interstitially that means that we're using needles and catheters again, that's generally only done with HDR now and then of course we have the MammoSite device that has had a great increase in use in the last year or so and that is a balloon that you put into the breast and you fill it up with saline and you treat the surrounding tissue to that, that's all done with HDR. Brachytherapy is used for the prostate and again that's usually done with LDR with I125 or palladium and now places are doing with HDR. Endo bronchial, we used to do Endobronchial with LDR. We would stack the sources to give us as high activity seeds that we could get in order to make the treatment times fairly small, but then we had to handle all that, we had to have a nurse sit outside the room for a half hour or so while the patient was being treated. And so, now that is all being done through HDR. Esophagus, again that's done through HDR, I've never seen an LDR case.

Sarcomas, sarcomas typically occur in the thigh, could be deep in the abdomen and that can be done LDR or HDR. Intraoperative, a few years ago, well actually its been more than a few years ago, they tried putting accelerators into the OR so that you could do surgery, have the patient be opened up and then you'd use an accelerator with it's electron beams to treat the open bed of the surgical site.

Well, now some places are doing HDR to do the same sort of thing. We started a program last year in St. Louis we're doing the exact same thing, the surgeon opens up the patient, we have a special applicator that we put right on the site of the using site, like a rectal occurrence, they take out what they see and then we treat the tumor bed and that, we are actually doing in the OR and that took a little bit of convincing with the NRC to allow us to do that. It's done for rectal lesions and then some people are using HDR to treat skin lesions.

Where is it performed? It can be performed in hospitals, can also be performed in free standing centers, generally its either performed in a dedicated room, which a lot of places have an old cobalt room, which ideal for the HDR or it gets put into the accelerator room and when that happens, typically the treatments are occurring before the day starts, over lunch time and after the day ends, so using 8, 12 or 4. Then there was a company that tried to establish a dedicated truck that would drive around and able to do actual HDR treatments within the truck, but I don't think they have been successful, I think the asking price they're wanting for this is nearly a million dollars. Believe me with HDR you would never pay that off. The kind of licenses involved, well obviously you have broad scope, you have specific licenses for the community hospitals, for the free standing centers etc.

With mobile units, you have two different choices for licenses with mobile units, we run a mobile service with HDR and we in essence, what we do is we rent the unit out, all that we do is we bring the source to the site, we do the survey and we turn it over to the facility and then everything that's done in treating the patient is done under the facilities' license. We're working in NRC states assures would be basically the same in the other states in the agreement states, but basically they want to know who is responsible for treating the patient. In our technique, what we do is bring it there, we turn it over to them and then the hospital or the free standing center has their own license and all treatment is done under their license. The other option would be to be responsible for doing everything, in which case you have a license where not only can you transport it, transfer it to the people, receive and store which you'd also have a license to treat. In which case you'd be the one, you're employees would be the ones responsible for treating and making sure that everything was done properly, billing issues and things like that, it's just much more complicated way of doing things. Not to say that the license cost more too.

So, what are the safety concerns? Well, you have to think about exposure to the general public, you have to think about what are the regulations involved with transport and shipping, you cannot have exposure to people along those pathways, you have to be concerned about what potential unintentional exposure the patient might get or the workers going to get and then 9/11 threw into the whole pot the idea of terrorist and having 10 curie sources that your taking around. Now, as far as exposure to the general public under the NRC rules it's basically tendency of our part 20, there is still OSHA rules that are around. I'm not really going to talk about that because this is pretty well established and is really not a lot of question about it. Apparently, it must be adequate because I don't know of any case of a person in the general public who's received an unusual radiation dose due to HDR. So, I think we are safe in that point of view, that's excepting that case of the Indiana Regional Cancer Center and that was a case of where a source broke off in the patient and the facility even allowed the patient to leave the site not knowing that the

source was in the patient. Okay and then this little nursing home got substantial exposure etc. the patient died, it was a pretty ugly situation.

Now, in going through the licensing process, these are some of the things that I found. First, most of the sites that we service and we're servicing about 8 or 9, the unit is being used in an accelerator room, but on the other hand, during the licensing process we're having to, I mean it doesn't take that much time, but it's just a question of whether this is something that's really needed. These walls in the accelerator room typically at a minimum are 30-36 inches of concrete and so there is no radiation that's going to come out of that room due to an iridium 192 source. But, part of the process is in filing for the license application is that we're having to do all these calculation points around the room, up above we have to talk about use and occupancy and all these things where really when it's in an accelerator room one would think that you could de facto say, this is an accelerator room with a minimum wall thickness of 30 inches. That would sort of speed up the process a little more. We also ran an, and of course when we do the calculation the first time we bring the source to the facility we of course take surveys to confirm everything and that's really what's important that a survey is taken prior to use so you know if there is a problem or not. But, we also ran into a situation where we did a survey with the source being at about 8 curies, only to have an inspector and I understand that this is a lot of new things for the inspector so the first time through they haven't really thought through the process that much, but they wanted us, they told us that should we get a source greater than 8 curies we would have to go back and do another survey. And, of course, that's not really true, because if the source is 10 instead of 8 it's just simple mathematics as to what the maximum exposure is in the case. Early on there was, before the new Part 35 came out, every time there was a source exchange we were having to do a survey at the site to show that nothing had changed, of course that is without having any renovation or any repair to the facility that's really kind of a needless process.

Transport and shipping, this is generally covered through the DOT rules and regulations. They're obviously, and I'm not going to go through a HAZMAT course here, I just want to run through a couple things, obviously there has to be shipping papers there are a number of things that must be included on the shipping papers, most and this I'm talking about the shipping for both when the source comes to you in a mobile HDR situation when your transporting it from one site to another we have to have shipping papers every time we leave one site and go to another. Typically, the unit, the exposure rate is a white one, when we have a real hot source our exposure rate can just barely be a yellow two. We have to declare the contents to make that statement. The limits for shipping is 200 millirem per hour on a surface and a transport index less than ten and that's not even a question with these type of units. Now this, actually, this is in the same sheet of paper, this is not what the transport rules are and that's been changed and that will be coming out in if you get the final version (Comment: the slide as shown is not correct), but basically a white one means that your transport index is zero, which they define as being less than .05 mr per hour. Then on the surface it has to be less than .5 millirem per hour. A yellow two means that it is zero to one and then on the surface it has to be between .5 millirem and I'm not quite as sure of that. This is where we run into an issue, the surface of the HDR unit is what sometimes makes it a yellow two for our particular unit and when we have a brand new source the surface level may be slightly more than .5 millirem per hour.

Again, for mobile units, if the transport index is less than .1 there are no requirements on where you put the unit within the van, we have a van that picks up the unit to transport it around, again our true transport index is typically around .04-.05, so we have no rules, but if you did

have a hotter source then you would have to make sure that the source, that the unit would not be more than one foot from the driver. You have to set up the equipment so that there is bracing, so it could not possibly roll about in the van, can't shift during normal travel.

This is a comment as far as the shipping, what you find out with these HDR sources is when they ship them to you and you got this source that is 10 curies, typically the locking mechanism on the shielded bucket that they send you is one of these little red plastic locks, and so you got this big 10 curie source, but you got this little plastic lock that you can take a pin and put it in and twist it'd break. But, that is allowed. We also had some issues in that at first they were requiring us to have two people to be involved in rolling the unit from the van to the hospital and some of these units they're not really intended to require two people they move very easily with one person and that is not really necessary and we had that changed. Initially, there was some concern about whether every time you go to new site where you're connecting cables and doing all this, whether that would be considered a new install, well if you had to do a new install you'd have to do a full calibration every time and you would add on an hour to every time you pulled up to a site. Really, that's not the point, the point is at a given site is the shielding proper, do you have proper cabling, do you have the correct door interlocks, all those concerns.

Now as far as the terrorist rates, and these are not in final form yet, I was concerned initially about the possibility of the HDR units being under the rules and regulations, but as it turned out, the heard proposals have a 20 curie limit on the source, and so since the sources that are shipped to us are 10 curies, we are exempt. However, facilities that have more than one HDR unit might possibly fall in under the terrorist rates and there is, that adds another whole layer of documentation that you have to have, because now you have to do background checks on all these people, you have to have fingerprints, it just goes on and on, fortunately we have escaped that for the most part. I think people with two HDR units are going to schedule their sources so that they never hit the 20 curie limit at the same time.

Safety concerns, next going to talk about patients and workers and this basically is handled by Part 35 or whatever the state corresponding rules are. The main concern, you know we're dealing with a 10 curie source compared to these millicurie sources that we've done for a long time. Again, the Indiana Regional Cancer Center had that source breakage and one of the side bars of that is that they even had a meter there that went off and the people just assumed the meter was wrong instead of investigating it. You have the possibility that the source could be stuck, in which case you have a high activity source that's outside the patient or inside the patient, but is not going back into the protected shielding of the unit. You can have mechanical positioning problems and this has happened a number of time where the source does not go where you intend it to go and so you're radiating the wrong site. You can have problems with the inner locks, so that if the door lock would fail and someone would enter the room the source may not come back. And there are a number of issues associated with planning, when you first do these what happens is your doing this case and you have this patient whom may have a tube stuck down his esophagus into his stomach. Well, you can hear him coughing in the background, you may have family members around, you're really doing all this under a very stressful situation, because you want to get this done so you can treat the patient, get it all printed out, get it reviewed and everything in as short a time as possible. And this introduces stress, the first time we did our cases we had the unit and we thought we could do this right by the treatment room, well we quickly found out that that was the wrong concept and so what we do now is we intentionally we do all our planning remote from the family, the patient, the staff so that we can do our planning and make sure that what we're doing is correct. Because, when people are

hovering around you, you know, the physicians they all want to know when is this done and when it's going to be done, it just puts stress and you can make mistakes and this isn't like an LDR case where if something is not as you like you can go up there and change the sources and you really haven't changed the dose associated with the patient. You know, once you treat this patient, it's done; you cannot get that radiation back out, so it's important to take that into consideration when you establish your programs. The medical events, you could have a possibility of having excess radiation, so if the script is that the patients going to get a 15 gray and 3 fractions and maybe to like a 20 gray, that's a possibility. You also have the possibility that you're going to do the planning and a patient is only going to get 12 gray. Well, most of the time, if you treat the right site you're going to get the right dose, just the way that things work out.

What is the major problem with HDR? It is treating the wrong site. For one reason or another in the planning process or in the actual treatment of the patient, they treat the wrong site and that is a medical event. Wrong patient, I don't think I've heard of any case where HDR or anybody's treated the wrong patient, usually they're the only patient that has an applicator in them. I did a review of some of the events that's been reported to NRC and I just grabbed 14 of them. Of these, we had seven of them that dealt with the catheter or the tube length or the source transfer tube, that is the distance between where the source is in the machine to where its suppose to be in the patient. Of the 14, seven of them had the wrong numbers entered into that part of the program. Then there are step size errors, again the way that we treat with HDR is you have a source and the way you sculpture the radiation dose distribution, the source is going to be, go to the defined point for so many seconds, go back to another point for so many seconds and you just go on and on. Now, if the step sizes that you're programming is suppose to be 2 millimeter steps and what's entered is 5 millimeter steps, obviously what's going to happen is you're going to have 10 steps that you're going, let's see 10 steps that's 41/2cm, instead of being 10 steps being 2cm. That is a potential problem. You could have a treatment planning entry error or you may call up if they have a defied applicators in the system, you might call up a similar applicator, you might enter in the wrong data for one reason or another and then the other two were applicator problems themselves where there was actually some sort of mechanical issue with the applicator that allowed the source to go to the wrong site.

I'll be honest, we were involved in one case like that where we had a vaginal cylinder, very simple thing, that where we tightened down on the transfer tube and we thought we had it tight, and then what happened was somehow or another the applicator tube slid out of the patient partially, in which we discovered afterward. So, those things can happen, since then we have taken all sorts of steps to make sure they don't happen, but applicator mechanical problems can occur. Now, on the length errors, why do we have these length errors? Well, first of all there are over a period of time some of the initial applicators on the older units they were developed where the intended source travel was basically about a meter. Later on they realized that this is really difficult clinically to get the HDR unit close to the bed so we'll make these other applicators a meter and a half. Well, the problem is, is that when they go to treat the patients if you have both kinds of applicators you have to remember either to put in what is 995 millimeters for the shorter one or 1500 for the longer ones and if you have somebody who's newer at this or you get distracted or whatever and you put in the wrong set of numbers because you did the last four cases and they're all 1500 millimeters, all the sudden you've put in the wrong numbers. The manufacturers have allowed the programs to put in numbers, whatever number the user chooses and I think that's a mistake, I think what should happen is that the applicators in the future

generation the HDR unit should all be encoded, so that you know exactly that this applicator, this transfer tube, requires that 1500 be entered into the program and if not it sends out a flag. Part of the reason why this has been left in the programs is that typically - take again the esophagus case, you stick a tube into the patient and it will go into the stomach - so the first dwell position is into the stomach and so lets say you want to treat a 4cm length, well what people do is they fool the system and anytime you get into a process where you're intentionally fool the system you're sooner or later you're going to become the fool and have a problem occur.

So, you fool the system and say that lets say it's a 1500 millimeter case and the applicators 10cm further than what you want, well you really don't want to be pulling it back because that's too hard to be exact, so you just take films to see exactly where you want it to be and so then you put in instead of 150cm you put in the number 140cm. And that's the reason why they're reluctant to remove the option, it's a convenience item. Also in the endobronchial, same thing, you put a catheter into the lung it goes further into the lung, you don't really want to treat there, you want to start from here, well it's easy just to say that you want to treat a 6cm length and so you act as if that the 6cm length is going to be at the end of the length and you fake it out by putting in a false length of the catheter. Now, there are ways to get around that and the way is that most of these systems have these is that you can put in an offset so you tell the system that it's truly 1500 millimeters, but you tell it that the starting point has some sort of offset of 10cm, or whatever and that can be handled that way. That way the system always knows the correct length. Some of the systems out there have before they treat, when they send the cable and all these systems there is always two parts of treatment. First of all a cable goes out through the transfer tube to the applicator to the end of the catheter, whatever, just to make sure that's it's all clear and free, that there's no kinks. Well, there are systems out there where the cable, it goes out and it expects to hit the end of the applicator and so when it hits into the applicator that raises the current on the driving mechanism and the system says, this is exactly what I expect, I expect to hit the end of the applicator. And, if you have that type of mechanism put into the systems to check that, too forcefully, forcefully as just touching is sufficient, to touch it and sense that then you know for sure that mechanically you have confirmed that you're at the right distance. And then as far as most nearly all HDR cases that we get involved with are done at 5 millimeter steps.

I think that one of the things that should occur is when you use nonstandard settings, and some of the units you can go 2 millimeter steps up to 50 millimeter steps or whatever, it should have a warning flag that this isn't a standard number so that if you inadvertently put in a wrong number or you hit the wrong key as your stepping through that it, that the program recognizes that this is nonstandard and that's okay, but just tell me this is really what you want to have and that's a software issue. Now, as far as the actual rates, obviously the 35.600 requires that you have approved sources it would be nice if all that you had to do was reference the sealed source and device registry, but because of a glitch in Part 30 that requires you to specify models of each source, we are still having to list any potential source that we would use with the HDR. You're required to have all new licensed personnel to service the unit, which makes a lot of sense, pretty much the same as the cobalt-60 teletherapy type rule. You have to do the survey of the patient and equipment prior to release and that is a rule that came about because of the Indiana Regional Cancer Center issue. As I said, a lot of this equipment is being used in accelerator rooms, we had one that was used in a combination superficial/HDR room where they, you are required that you put in some sort of key switch or some method so that you cannot use the accelerator, the accelerator cannot be turned on while the HDR unit is turned on, so you have to put in a method,

usually it's a key switch in the door interlock. You're obviously required to have emergency procedures; you're required to annually review these procedures with the people that are involved. This isn't an issue; you cannot do an HDR case unless the applicator can be expeditiously removed. There are certain things that particularly if you're using catheters and needles you want to make sure that you have some method that you can get that catheter out right away. Obviously, you have to secure the unit when you're not around and then you store it away typically in all our places are seasoned source room is big enough that we can put it away and lock it away at night. They do a lot of the presence of an individual during treatment and this is, would be rare at best, because there's really not much reason to be in the room during a treatment. Training and experience, you have to have an authorized user who is, this is what's typically there certified by the ABR in radiation oncology, typically you have an authorized medical physicist who is again, typically certified by the ABR or by the ABMP. There are alternate pathways to be approved, but generally these are the people that are working with the unit. They have this comment here that the amp and the AU must be "physically present at initiation" and then after they get started you don't know longer have to have the authorized user there you can have a physician who has been trained in how to remove the applicators etc., be the responsible party, so the authorized user can basically, only needs to be there at the initiation.

The medical physicist needs to be physically present during the continuation of treatment and also what does physically present mean? Well, in one of the NRC documents and I'm not sure how the various states are treating this, physically present meant to be within normal voice was the wording they used, but it's really not clear, does normal voice mean, normal voice as in your speaking with somebody or is it okay to be in a distance where if I yell the person is close enough, but the main thing, I think is it's not an electronic voice, you can't be in a situation where you're picking up the phone and saying, hey we got a problem here come on down, or you're paging over head or something like that. So, it's not exactly defined, but it's probably close enough. In some of these issues is that some of these treatments may take up to 20 minutes or so and of course the physicians they want keep treating patients. If you have a number of cases during the day, do they want to stand around the HDR room, within 50 feet or so? No, they want to still be seeing patients and so the question comes, well, if they're in an exam room is that okay? If you yell loud enough they could probably hear, but is that really okay? I think part of the answer is, is that the physician is really only going to get involved if you have to remove the applicators on an emergency basis. So, if you have a situation where a source would be stuck if you did, you yelled out and the physicians in the room you are going to be doing things to try and get the source back long before we worry about getting the applicators out. Getting the applicators out is a last resort, you're going to go in the room, you're going to press the emergency off in the room, you're going to try to do the hand crank, try to do anything you can to get the source back it's only in the last step where someone's going to be trying to pull the applicators out. So, anyway, just my own personnel suggestion, maybe readily available might be the appropriate wording for that. Then there are rules associated with the treatment planning computers. Nearly all the systems for the HDR, all the systems for the HDR, they have the source specific parameters in there and the user really just verifies them. You have to verify for every treatment the accuracy of the dose at dwell time, the treatment calculations at selected points. Somewhere along the way we verify that the plots of the graphic displays are okay. You have to verify that the digitizer program is appropriate, because some of these programs, if the isocenter isn't, when you take, most the times if you're not doing the CT-based planning, if you're just using plain films using orthogonal films, if you have you're isocenter right near the

applicators then the magnification is pretty much within the limits that the system will tolerate. If someone would happen to take a film where the applicators are not near isocenter and they're 10cm down and 5cm over, sometimes the error induced because of magnification factors maybe such as to create a small error, and so you need to know what the limits are in your system for inputting in the points. You have to verify the accuracy of transfer and that's typically done by reading off the print out the plan and typically the physician and physicist are there, one is reading the number of seconds for each step from the paper work and the other ones looking at it on the screen and confirming it. Then, of course, we have requirements for their authorized medical physicist to do the full calibration. It use to be that we had to do these monthly, I believe some states still are monthly requirements, now with the way Part 35 is now in an NRC state you really only have to do the full calibration at source installation.

So, you're doing it once each time. You are required to do the source positioning, to show that the unit can put the source out to the desired place, plus or minus one millimeter and of course, we have to remember that this is a measurement that you do under ideal conditions. It's clinically we are not going to get that source within one millimeter, because, for instance, with endobronchial you got the patient breathing, with the esophageal you have patient movement you have those type of issues, but the physician in planning the case allows for the concept of the applicators and stuff moving. So, that's all taken as part of the physician judgment. So, so the point is, is that the one millimeter really only applies to this QA test that we're talking about. Another thing that you have to do is you have to check that the, if all the power goes out in the hospital or wherever you're at, that there is a battery backup that will pull that source back. There are various timer accuracy tests, you have to test the timer accuracy for the range of times that you'll be using, so anywhere from 20 seconds up to 15 minutes, 20 minutes, whatever. You have to measure the length of transfer tubes and applicators and this is sort of, so we are required at each time we do the full calibration to take all the transfer tubes that we have and we have to measure them. Well, there not really going to change much, maybe there might be a little humidity type issues where maybe it changes half a millimeter or something like that. The problem that this, I think was trying to address was all these length errors and that is not the fact that you don't know this is a 1500 millimeter transfer tube or 995 transfer tube, it's that the person puts in the wrong number. Then you have to test, there are various tests that you have to do in order to show that the unit recognizes whether there is this transfer tube connected to it, because you wouldn't want the source to come out if there is no transfer tube. And even that doesn't solve the problem, there is recently a case where a lot of these other endobronchial catheters, you're really just dealing with just a straight catheter, which is just a long tube and then you have a little adaptor that you put on the end that mechanically holds onto it. Well, you didn't put that into the machine and normally the cable goes out the adaptor through the catheter to the very end and what this facility did was they had intended to use a step number; the channel number one and they had left an adaptor at channel number 20.

For various reasons the source went out to channel number 20, because the adaptor was there it went out in the middle of the floor and treated the floor instead of treating the patient. So, those are concerns that people have. I guess one way to do that is that if the system should be checked if there's any applicators sitting in there before you go to load up the patient in the first place, so when you first turn on the machine it should just tell you to get out that adaptor. Additional QA there are a variety you have to confirm the door interlock works, you have to see that all the lights are working on your front panel; you would hate to have a warning sign flash at you only to have that light bulb be burnt out and not see it. You have to have your emergency

response equipment there; you have to have a survey meter, obviously, to go in the room in case there is a problem you do the survey on the patient before and after. You have to confirm that the system has the correct activity of the source for that day. If you have a mobile HDR unit you're required to do a whole other series of tests because you're bringing it to the site and there's concern that there may be some mechanical issues that occur during travel, so if it's in your own hospital you only have to do the source positioning test with part of the full calibration, when you do a mobile unit and let's say you're doing more than one site, you have to do that at each site and we've had this happen, where we treated one site at 8am and treated another site at noon and come back to the original site, that means you're doing three QAs for that day. You also have to have a radiation area monitor with the mobile system to take with you. You always have to simulate a cycle of treatment, in other words you have to go through a planned program to show that the whole process is complete and that you can go through, treat these sites to a certain number of seconds and the machine will turn off when it's suppose to. Where we're at is each year there gets to be fewer and fewer LDR sites out there and in fact this is a separate issue, but there are many, many hospitals that have cesium sources just sitting in safes in the source room and they don't know what to do with them. For awhile there we were hoping that the so called dirty would voluntarily take these off your hands, but that hasn't happened, so lots of places have all sources and cesium has a half life of 30 years, and so when you have a 30 year old source, what are you going to do with it? It would mean that a treatment that originally was a two day treatment is a four day treatment and you really don't want the patient to be in there for that long. That's a separate issue that's going to need to be addressed, but in the meantime the LDR is coming in and it's partially because all the things LDR can do, all the sculpting of doses, the issues with, it's being done in prostate HDR and there is certain things with prostate HDR that are better with than seeds, for instance, when you put the seeds in, depending upon how many times the prostate gets poked, it's going to swell and the amount of swelling will affect the dose that's delivered. At least with HDR you put your needle in and you're treating exactly what you planned for that day. That is growing; certainly the HDR has eliminated all the personnel exposure issues.

Just for a rule of thumb, in the hospital situation with the LDR cases the nurses would average anywhere between 2-8 millirems per shift is what we found out. The providers, who's doing the service, I think this is important in that they recognize that this is a very stressful situation for the people involved and so there needs to be taken, whether it's increased training, so that everything is very smooth, or you find your little place where it's quiet, that needs to be provided to the site and the manufacturers need to take steps to eliminate what is really the most potential, the absolute recurring problem is this issue with having a wrong length and treating the wrong site, but I think that could be a manufacturers improvement in their design and that may be an FDA issue actually. And that's it, think we're ready to go eat.

We got one question.

Thank you, Herb Moore liaison with the American College for Medical Physics. Dave, you mentioned something which made me think back to Melissa's talk earlier and Rick's talk earlier, certainly for HDR and I'm not sure the regulations specifically state for HDR there is the regulation that only one source of radiation can be activated in the room at a given time. As we get more into more future modalities when we have pet CT we get into image guided radiation therapy where we've got two diagnostic x-ray units running at the same time that we have a therapy unit running, I think it would be a could time now for us to come back to our regulators and say, oops, we may be getting caught in something here, how should we rework this so that

we try to prevent those things which we don't want to happen, but provide for our patients in the community that which we are moving into with these new modalities. So, it's not really a question to you, but sort of just a comment I have noticed between those three presentations.

Well, certainly the rules I stated out applies strictly to HDR, it's a 35.600 rule.

Thank you David.