Thank you for coming. So this talk will be a little bit different from the discussions we've had before. We're still talking and still going to care about what the physicist would need to do in their clinic, rather we'll focus on more behind the scenes, you know, regulatory work, not direct, you know, patient care, as the other speakers were looking at, but rather what the quality assurance recommendations might be. I want to just really underscore before I move into this, these are not AAPM recommendations, there are no states' regulations, these are just the thoughts from, you know, a combination of myself and Kathy and others as far as what might be the most desirable way to sculpt a quality management program for a device in which there's not a lot of recommendations and guidelines out there. So just want to make that clear. So, you know, we're at AAPM, we have to focus of course on, start from what reports and guidelines, through the AAPM, are possibly appropriate for considering setting guidelines for the Xoft remote after loader and its source. So, I kind of start from a top-down approach of first, let's characterize the source and its radiation dose distribution. We could go at that from a variety of ways. We could, because of its energy, we could use a x-ray based, a teletherapy-based protocol, but we could also consider using a brachytherapy-based protocol. So, you know, there's some advantages to each solution but, each choice, but it seems that this approach here seems to better integrate the product into the clinic. So, I'll, you know, this is just a high-level guide description of the reports. I'll jump into each of them momentarily. So, in addition to the source then being characterized, we have to develop now a whole plan and project for which we'll set up the quality program within the department. So that's where this Task Group 56, though really geared solely for radionuclide-based brachytherapy, there are many aspects of it with which we can draw and apply for this example. And then even more specific, not just radionuclide-based brachytherapy, but high-dose rate brachytherapy perhaps solely based on HGR, iridium 192. So that's what TG 59 offers. And then there's the CLA sub-committee, Calibration Lab Accreditation sub-committee of the AAPM, they have a report by DeWerd et al, which came out in 2004 which specifies the frequency and rigors of source calibration. So, again, know these reports specifically addresses electronic brachytherapy, so we're offering our interpretation. So, for AAPM the Task Group 43, the idea is to characterize, as you can read right there, characterize the dose-rate distribution in an infinite washer phantom. Of course we know that we were hopefully not too equivalent to water and that at lower energies, at least in comparison to iridium, the importance of deviating from, you know, water to let's say characterizing breast tissue and other materials properly, that needs to be considered. So, but at the moment, you know, the Task Group 43 formalism makes that assumption and we're proceeding in that vein until further results are in hand. So, one would need to both measure and calculate the dose-rate distributions. You wouldn't want to just go with one, because there needs to be checks in place because, for a variety of reasons, a calculations could be incorrect or the measurements need to be validated and extended. So in part of those efforts for characterizing the dose-rate distribution, we first have to start out with some overall assessment of the dose rate. So there's this term, the dose-rate constant, which allows one to correlate source strength with, you know, the dose rate at a given point, a reference point, perhaps. So, again, referencing Larry DeWerd and his group at University of Wisconsin, they're working very hard, as well as with NIST to establish a means to calibrate these sources. It's not like you can just go off the shelf and find some appropriate detector to calibrate it, this new and novel source. So, equations – I guess it is afternoon, so we won't go, though, in too great detail into these – one can find a means in which to calculate the dose-rate distribution around the source in a 2D context, two dimensional that is, r being radius, theta being the angle from the source long axis. Like other HDR sources, which are not symmetric through the parallel bisect, perpendicular bisector, the variation of the dose rate as we had seen in clinical/practical examples, there will be a – I like this example, or this description – kind of like a tomato shaped dose-rate distribution and that has to do with attenuation within the source just like for iridium. So that anisotropy of the radiation dose distribution is largely accounted for with that *f of r theta*, those 2D anisotropy function. Because due to the nature of the small size, you saw like fitting on a finger, the small size of the – thank you, I tend not to hold this because my hand shakes and it makes you all dizzy – the, due to the small size of the source relative to the treatment distances, one can approximate, very accurately, that the source is a point source. Even like 3.0 mm away, the distribution upon which radiation is coming from, it still can be approximated as a point source therefore the geometry function, which you know, normally might be complicated with a line source approximation, can be readily characterized as a point source with that R_0^2/R^2. So that would be for TG 43, now as far as Task Group 56, what can we draw from that guidance document? Well, I've outlined them here. I mean a high-dose rate, remote after loader, it is a remote after loader, you don't manually put the source in yourself. As far as being remote, I guess you could be, you know, five feet from the source, it's got that novel aspect where it's very readily shieldable. Basically a high-z napkin, if you will, covering the region will protect the people right adjacent to the treatment. So, in this TG 56, there is some recommendations as far as, you know, the frequency and the scope of work and I think, you know, largely many of them are applicable, however, they need to be, you know, these guidelines should be customized I think for the application at hand. So I've just kind of sampled here at some of the QA that we believe would be appropriate. Notice though, like in Task Group 56, a positional accuracy says 2.0 mm. It does not say 1.0 though many manufacturers, many sources out there, like HDR remote after loaders for iridium, can achieve 1.0 or less. Also for the source calibration frequency, there, you know, there's no decay, it's not radioactive. So as far as, you know, the frequency in which things would be measured, there are recommendations how that should be done. We're going with the mantra that before every treatment, the source strength should be measured – not a before and after and not, "Oh the source just came off the loading dock, we'll put it with the controller for treating this patient and we won't measure it again." So there's a happy frequency, I think, that we've ascribed to fit in with the clinical procedure that's reasonable for everyone and sufficient. So here just showing, for instance, with – I guess I will use the laser pointer, I'll try and hold it still – that would be this high-z shield in which one would be able to protect yourself very easily while being at the controller here, that would be the TV screen of the controller and then translating and moving the arm in and out. So that's, for instance, how some of the studies were done earlier. I'm just trying to show it graphically. It fits in with the TG 56 guidelines. So we had seen these before, these are six single-source, single-position dose distributions just like we do when we get a new HDR iridium source. I think that one we want to qualitatively just say, "This is what I measure with film. This is my SPECT and planning system and that there's good agreement." I don't think that one would need, just like we don't do with iridium 192, I don't think that one would need to go and measure, you know, for every source and verify things. If someone's got a lot of time, God bless you, but there's no precedent for that in the clinic. So, then the other report TG 59, specific to HDR, remote after loading therapy, I think that it's an amazing report and a lot of it is applicable and, you know, these are some of the issues that we've identified that seem to fit in with what we would do with this type of therapy. So, I mean, they look very familiar, I imagine, to many of you who have experience with HDR devices. So it's not, we can enjoy that it's a new product with some nice new features, but we can also rely on the established, you know, and the maturity of the guidelines are out there to make this roll out properly. So, some other aspects for the QA protocol. I draw this from one of those tables, I think it might be TG 56 as far as they have some recommendations on tasks and frequency and the key down here showing your purse source, perhaps on a quarterly basis, you know before the use of a new tube or before, you know, every treatment. So here we've outlined what a possibly suggested frequency would be. And for instance, you know, this, you know, timer offset I'm glad to see, you know, that the measurements are in fact, you know, typically less than this so this system can comply with these tolerances and this, then would be the frequency in which they'd be performed. So an additional AAPM report, maybe not a task group, but is this CLA sub-committee report came out in March 2004. That perhaps is somewhat applicable, but let's take a close look. It primarily is to address low-energy photon emitting LDR seeds for permanent implantation. It basically discusses the NIST and ADCL standards and the frequency in which manufacturers would send the radioactive sources. However, we don't feel that this report, in general, is appropriate for comparison and ascribing calibration frequencies and guidelines for the source. We think that it's more important and more appropriate to compare with iridium and the standards that are out there. So let's take a look and see what those are. We know that there's no national or primary standards laboratory calibration for iridium, so it's good, you know, that there's efforts in place for electronic brachytherapy to perhaps supersede and improve upon what we have for today's iridium. I mean, how do they do it? Well there's a variety of techniques. One would be the seven distance technique that was done for iridium; however that's not really appropriate in this case for the calibration of the source. So that's where Dr. Larry DeWerd and others are working on setting a standard calibration procedure and then trying to transfer that to NIST with Dr. Mike Mitch, who I think is also in the audience. So it's a little more complicated than perhaps iridium because this is not a radionuclide-based source. We don't know, we can't look on the National Nuclear Data Center website and see all the spectrum and photon lines, so these also tend to be of lower energy so what happens is that it's more important to account for the attenuation scatter and other detector specifics than with these other types of radiation emitters. So here's a snapshot we mentioned for brachytherapy. There is a, this is a very well known detector for the calibration of low-energy photoning sources. The thing is that, you know, you imagine a source as sitting – I guess I should try and hold this really still – the source is sitting right around here and the radiation isotropically emits and part of it gets collimated and is measured by that ionization chamber. The point is that that's a fairly large chamber, it's, it can measure, you know, the sub-millicury seeds. So, this is a high-dose rate source, where the source strength is thousands of times higher and the detector's way too sensitive. So, you know, this isn't compatible, thus we mentioned earlier about using this technique, you know, as done as being developed at Wisconsin. And then, so what would the user have to do? Do we say, "Okay, you have a tube calibrated, here use it and have fun"? No. We had recommended and believe it's prudent to measure the source strength preceding every use and how would that get done? With something, with some special custom device? No. This very well established reentrant well ionization chamber can very readily serve that purpose. It would need to be calibrated, you know, with the insert with the chamber; it would need to be calibrated for this type and model of source and it would have to be calibrated every two years, along with electrometer and along with all the things that we normally use. So that would be, that was for, if you will, the AAPM guidelines in which we're interpreting what would be appropriate. Being that there are no established AAPM guidelines, that's our interpretation. Similar for the state guidelines, the stuff that we'll present here, there's no set established rules so we're going to look at what's out there and make some proposals. So typically your state would have regulation over x-ray sources, over your LINACs or your superficial unit or your simulator. And, you know, here, you know, typically for therapy that would include LINACs and superficials, as I'd mentioned, and for imaging these items here. And with this oversight that's currently in place, there's really nothing that's directly applicable as far as how they would formulate their regulations. So here we have a simple proposal in which that there would be some guidance issued and that there be some requirements, again these are regulations. So unlike the AAPM, which can recommend to us when the state says, you know, you have to do something, if you don't do it you'll be in trouble, you'll be fined, cited and be seen out of compliance. So because these are, these are not established yet, there is lots of discussions ongoing between the Conference of Radiation Control Program Directors, which I think we have a representative in the audience. And between them and Xoft, to work out a convenient process for states and users to have the regulatory oversight. So then that was state, you know, federal here – so we know that this was cleared in 2005, for breast brachytherapy by the FDA and, you know, the idea is that it would be used to replace whole-breast – and the idea that it would be used to replace whole-breast, you know, teletherapy if you will, that's not been established, but that's also just this thing that we have with MammoSite. So it would be being used for the breast, you know, post-lumpectomy. So this idea, the idea was already mentioned that this would be used under a trial first and then open for sale. The trial would address the specific site of the breast and would try its best to follow this, you know RTOG/NSABP trial that's ongoing. So that's for the FDA, then for the NRC, I mean talk about not applicable, this is, there's nothing nuclear about it. So one must take very, you know, creative leaps to try and find similarities on how there might be some potential, you know, guidance. And do we say that the NRC would be regulating this? No, of course not. But again, there's a mature environment in place for high-dose rate iridium and it would be foolish not to look there and see if some cases and some recommendations can be put in place to assist the safe use of this product. So, you know, most of it as you imagine for nuclear, you know, radioactive stuff, it's not relevant in this case. However there are these sub-parts, specifically manual brachytherapy and photon emitting units – that's actually how it's described – part we can draw from those two sections, those two sub-parts and see what may be applicable. So for the first sub-part, here, I mean again, it's largely based on byproduct material, so the idea that one would have like a registration and license of it, you can see these parts are just inappropriate, whereas, what might be applicable, again, not that NRC would set regulations but what we, as users within the AAPM and the state may use would be to have some of these recommendations in place here. So, again, very useful notes because there was some concern, I think a while ago, that oh, well this is something new. Every user would have to characterize, you know, every source. I just think that's poppy-cock, in fact here, you know, no one does that for any other source and then, you know, here it's in fact explicitly mentioned that it's not required. Then for the other sub-part, this part H here, again, largely based on byproduct material, but again we find that there are some good things that we can draw out towards proper clinical implementation. So again these are just recommendations of, let's say myself and Xoft and they don't reflect any findings or regulations by the NRC. One thing that is true is that with the states and even within hospital boards, there's more and more interest to move away from radioactive sources. At my institution, we just put in a 7,000 curie source for our Gamma Knife. And in Boston, of which we know two of the, you know, planes flew out of Boston a few years ago for the World Trade Center, what happens is we had men with machine guns watching over the installation of the Cobalt 60. So there's also more and more concern about these 10 curie, is it now going to be 12 curie iridium sources. So there is a lot of interest for minimizing potential, be it dirty bomber terrorist activities, by moving away from the radioactive materials just as we have with teletherapy to enjoy the advantages of electronic, you know, x-rays for teletherapy. Here a complimentary thing for brachytherapy. So in summary then that, you know, there's all these, you know, guidance documents, be it from the AAPM etc. even the regulatory aspects of the NRC, nothing really is set to address this for electronic brachytherapy. But we can look to that; we can distill what would be appropriate and develop a program of quality to assure safe and proper implementation. So, you know again, as I've mentioned, with electronic brachytherapy, much less onerous and less challenging to control in a, be it a large hospital or even a small clinic setting, then your radioactive materials. So that's all I have to say, thank you.