



HIT Policy Committee Implementation, Usability & Safety Workgroup Final Transcript February 20, 2015

Presentation

Operator

All lines bridged with the public.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you, good afternoon everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Health IT Implementation, Usability and Safety Workgroup. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. David Bates? Larry Wolf?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Larry. Alisa Ray? Bennett Lauber?

Bennett Lauber, MA – Chief Experience Officer – The Usability People, LLC

I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Bennett. Bernadette Capili? Betty Mims Johnson? Ed Lomotan?

Edwin A. Lomotan , MD, FAAP – Pediatrician & Informatician – Health Resource Services Administration

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hello. George Hernandez?

George Hernandez – Chief of Applications and Development – ICLOPS

George Hernandez here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, George. Janey Barnes?

Janey Barnes, PhD – Principal & Human Factors Specialist – User-View, Inc.

Janey Barnes is here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Janey. Jeanie Scott?

Jeanie Scott, MT, ASCP – Director, Informatics Patient Safety, VHA Office of Informatics and Analytics/Health Informatics - U.S. Department of Veterans Affairs

Jeanie Scott is here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Joan Ash?

Joan Ash, PhD, MLS, MS, MBA, FACMI – Professor & Vice Chair, Department of Medical Informatics & Clinical Epidemiology – School of Medicine – Oregon Health & Science University

I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Joan. John Berneike?

John A. Berneike, MD – Clinical Director & Family Physician, St. Mark's Family Medicine – Utah HealthCare Institute

Yes.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, John. Lana Lowry? Megan Sawchuk? Mikey McGlynn?

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Siemens Healthcare

I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Mikey. Michelle Dougherty?

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Michelle. Mike Lardieri?

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Yeah, I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Mike. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Paul. Robert Jarrin?

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Robert. Steven Stack?

Steven J. Stack, MD – President – American Medical Association

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Steven. Tejal Gandhi? Terry Fairbanks? And from ONC do we have Ellen Makar?

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology

I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Ellen. Is there anyone else from ONC on the line? Okay, with that will turn it to you Larry.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, I wanted to welcome everybody today, thank you for joining us, as we were saying it is very much winter I know that scrambled a lot of people's schedules. We have a pretty interesting day in front of us. We have been talking about the dual aspects of the certification program that has the requirements to report on usability assessments but also to look at the quality management system that the vendors have in place and today we have a deep dive with one of the vendors, Cerner, that has been willing to share what they do on their side. So, I think it will be pretty interesting as one example and remembering it is just one example of what one vendor is doing but I think we will get a pretty good feel of the kinds of things that are in a quality management system and hopefully it will lead to some pretty good discussion. So, that is the plan for today and I think if we go to the next slide, if I have the right window up, let's keep going, this one, thank you.

So, this will be the last of a series of meetings that we have been having and then we have a short gap leading up to the Policy Committee meeting in early March and we are expecting that the NPRM for certification will be out by then and that we will be asked to comment on aspects of it and then that shapes most of our activity for the subsequent couple of months. So, that is our overview of the work plan. Any questions before we dive into today's presentation?

Okay, we'll let's move on then. Next slide. Okay so this is a reminder about the current certification criteria for a management system and that basically it is an opportunity for the vendors to tell us what they are doing and to report that as part of the certification program and so we will be seeing an example of that today. Next slide.

Okay, so take it away Shelley and Sharon. Are they on? Are they on mute?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

It doesn't look like we have either of them right now but we're looking. Hopefully they may be called into the public line and we need to pull them over.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Okay.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

So, Larry if you could do a little dance until we find them that would be great.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

I think I'm just going to give us a few moments of silence we can practice that.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

There you go.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Just hang out and if you're an overachiever you can take a look ahead at the slides.

Paul Egerman – Businessman/Software Entrepreneur

Larry, this is Paul, I have a question about the quality management certification process?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Sure?

Paul Egerman – Businessman/Software Entrepreneur

It says here, if I'm reading it right, that the vendor has to like somehow identify what they're doing, what happens to that? Does that go into the CHPL? I mean, how does that work?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, that's a good question. We have asked ONC if they can tell us what they've learned and they say they are working on it but they don't have anything to report back yet.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, because I guess my question is, what is the purpose of this identification is it for ONC to do research or is it to help purchasers or providers and hospitals decide what is an appropriate, you know, source for their software, appropriate vendor for their software? Because the feeling I get is it is really being used by ONC to just gather data but I don't know if that's right.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Yeah, I don't know either, Paul. I know in the run up to the current requirements, current certification criteria that there was discussion about whether this should actually have any kind of requirements around it and in many ways like the usability testing I think in the end they said they would just collect data rather than set any kind of bar about what was needed.

But to your point I don't know how available this information is. I don't think I have found it in my casual browsing of the CHPL over the last couple of years but I think it's a good question for us to bring to ONC about how available it is and what they can bring forward.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

This is Mickey, I can comment on that. If you go to the CHPL and find a solution say, you know, the solution you have installed and go to the specifics there is a PDF right at the top that you can click on and then the certification...I mean, the QMS is probably, it's toward the bottom, it's about a 10 or 12 page document and then you can see that vendor for that product their response to the QMS criteria and the same with usability that's there as well.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Thanks.

Paul Egerman – Businessman/Software Entrepreneur

And that's helpful and I don't know if this is appropriate while we're waiting for the Cerner people, but the thing that I'm raising is...

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

I think we have Shelley now.

Paul Egerman – Businessman/Software Entrepreneur

Okay, well, then why don't we go ahead with that then.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Yes, good afternoon, the is Shelley Looby.

Sharon Muehlmeier – Senior Manager – Cerner Corporation

And this is Sharon Muehlmeier. Hello.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

So, thank you for...

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Welcome.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Inviting Cerner to speak today. Sharon and I would like to give you some information regarding the Cerner Quality System and then how our quality management system, known as CQS to Cerner Associates, is used throughout our company and we are going to focus in then on our IP development area at the end of this. So, I will begin, I am the Director of Regulatory Affairs Quality Assurance at Cerner Corporation. I am going to give you an overview of the Cerner Quality System and then Sharon will follow-up after my comments with more specific information on our risk-based development processes. May, I have the next slide, please?

I thought the best way to start today to give you a good thorough overview of the Cerner Quality System was to provide to you Cerner's attestation response which we first gave in spring of 2013 and have used throughout 2014 through the attestation process. So, our system, CQS, as I mentioned before, is a homegrown quality management system meaning it was designed and developed by Cerner Associates for use in all of Cerner's locations and for all of Cerner's processes.

It is based on 21 CFR, Part 820, the quality system regulations, the ISO 13485 medical devices quality management systems requirements for regulatory purposes and ISO 9001/2008 quality management system requirements.

We developed our quality system based on our commitment to our clients and the patients that they serve and keeping in mind the interest of public health and also our Cerner Associates who could be both patients at one of our client's sites or other client sites, or other medical sites and understanding that we could be effected by what is happening here at Cerner or a family member, or a relative.

Our CQS, Cerner Quality System, establishes how we embody quality throughout the lifecycles of our solutions and services that we provide to our client base. We refer to our solutions with that term so it's a product maybe to somebody else who doesn't understand our use of solution, so our software products are referred to as solutions, services we provide support implementation training, the CQS also applies to that. So, if I use these terms throughout I wanted you to know what it meant to Cerner. Can I have the next slide, please?

This is the attestation response continued. Ours is a dynamic system intended to remain so throughout and supervised continuously monitoring and feedback by internal quality audits, external audits, management review and corrective and preventative action. So, the plan, do, act cycle that I'm sure most of you are aware of is used by Cerner CQS to show continuous improvement throughout our company. May, I have the next slide, please?

All of the processes that we perform at Cerner regardless of whether it has to do with solutions or services we are providing to our clients falls under our Cerner Quality System. It is the way we do business. Each location, each associate is responsible for understanding the Cerner Quality Management System and how it applies to their role in what they do within Cerner.

There are a list here of bulleted items of the actual subsystems that make up our quality management system starting with overall management review, there is also document control, record retention, CPA, complaint handling, evaluation of materials, suppliers, equipment to our facilities and patrol over those, obviously around the solutions there is design control and change management, production and process control and internal audit. These are all important systems that make up the Cerner Quality System. Can I have the next slide, please?

Each group at Cerner must establish quality objectives that support the Cerner Quality System and that is important because we have overall company-wide imperatives that are placed for us and then based on what the group performs, whether it's the creation, solution, support of a solution, a creation of a service, deployment of a service, etcetera, everyone is responsible to have goals and objectives that support that and those are continuously measured and monitored throughout the year and if we find that we are identifying trends whether they be positive or negative there are actions that are taken to ensure that we either maintain positive results and focus on sustainability or identify breakdowns, correct those and then prevent them from recurring. So, this helps us maintain overall quality throughout either a solution lifecycle or a service or any other business activity that Cerner might be pertaining to.

We do take very seriously our obligation to public health. We make actively regulated solutions and we make things that are considered medical devices and those are not the only things that we worry about with regard to safety or quality or effectiveness or reliability. It is every solution and every service that Cerner creates that falls under the Cerner Quality System and we have an obligation to ensure its quality throughout its lifecycle. Next slide, please.

So, historically the Cerner Quality System began way back in 2001, it actually started before that but in the state that it looks like today, the most recent history, would date back to 2001. We implemented the Cerner Quality System corporate-wide meaning every associate at every location and that's quite a large group today and many locations. We did this by creating a corrective action board and this board was identified associates across the organization who looked at their specific processes, identified what needed to be solidified as far as a process with a documented process support, what needed to be corrected, what needed to be improved, what needed to be maintained. Each corrective action board member was really focused on their area but communicated amongst each other on a regular basis so that we did nothing in a silo.

In 2002 we gained our first certification and that was to ISO 9001 and we were one of the first companies to do that. In 2004 we then formed what we call today our quality representative community. So, each group and location within Cerner has a quality representative or multiple quality representatives depending on the scope of their business activities and size of their organization. These people are actually the stewards of the Cerner Quality System and are responsible to make sure it is fully implemented within their group. They have reporting up to their management and also...reporting to the regulatory affairs quality assurance group. The quality representative community is a rather large community, there is a formal training program for them and there is ongoing education and communication that is provided to this organization.

In 2005 we added another ISO certification and that was to 13485/2003 and that is only for select locations. And the reason that is for select locations is that not every one of our locations is involved with any task associated with our actively regulated devices. Next slide, please.

This slide depicts the components of the Cerner Quality System, there are seven components and all of these components are required to work together to support the development of Cerner Solutions and Services and also to ensure quality, safety and effectiveness of those solutions and services. Next slide, please.

Most of what we do with regard to our services and solutions with regard to development of them, maintenance of them, support of them is done based on risk and so we have a well-defined risk-management process that we use and it's done through the development of documentation and maintenance of our risk analysis process and also I should add education there.

So, we have various parts of our risk management and those are listed at the top of the slides, so there is information technology, security and privacy, risk-management evaluations whether it be business risk or a solution service risk. Then there is another hazard analysis or solution risk documents that pertain directly to the solutions or services that Cerner provides and then we also evaluate a business continuity and disaster recovery because we know there are no downtimes in healthcare and Cerner is a provider to this healthcare community and so we have to be able to know how to keep our business up and running to support our clients 24/7/365.

Through our risk management process we make sure that risks are identified and then managed effectively. We also want to look at any vulnerabilities and weaknesses and make sure that we understand what those are so that we can manage them. And then we look at hazards and threats that could harm our business and then try to provide mitigation to eliminate hazards and threats that could harm the business.

So, the continued overall quality and protection of Cerner's business activity is managed through our risk-management process and this is ongoing, this is not a one and done, it is something that we do on a daily basis through a variety of things and Sharon will touch on those that pertain to our solutions. But it is also done from a business perspective, a client perspective and an associate perspective. Next slide, please.

So, Sharon is now going to talk to you about our risk-based development processes and how that pertains to not only the Cerner Quality System but also to the solutions and services that we provide to our clients.

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Well, thank you, Shelley. This is Sharon Muehlmeier; I'm responsible for IT development process and quality improvement here at Cerner. As you can see what Shelley was mentioning earlier, software development processes are designed to maintain compliance to Cerner CQS and industry regulations.

Risk-based design and development offers three separate processes based on risk. As you can see the high-risk solution, high-risk bucket would include the solution team that meets the definition of a medical device and when they need a 510(k) or demarking or technical file submission and also need any sort of regulatory or competent authority review for submission. So that will fall under the high-risk bucket.

The low risk bucket, including the solution that does not meet the definition of medical device and also has no patient donor or end user safety risk, no risk for fraud introduced and any solution that does not fit into either low or high definition will fall into the medium risk bucket for Cerner.

Each process, like Shelley mentioned before, includes an ongoing assessment for selecting and evaluating the appropriate process. Security, privacy risks are also managed separately by...we have an enterprise security group but that's also embedded into the development process as well. So, next slide, please.

Software development processes are modeled by agile linked software development principles to allow clients and end user engagement throughout the entire development lifecycle. These software developments primarily use a scrum XP hybrid that produces working codes that at the end of each iteration that becomes a release candidate. Release candidates that meet functional and performance quality standards are made available to clients.

In general new functionality is released to a solution partner who will collaborate on the development and then client site testing. Solution partners then take the functionality into a production setting then the code is released to all Cerner clients.

Corrections typically leverages linked processes, event processes where complete development is made available in the next service release. This approach increases the speed and quality of each item as well as more flexibility to deal with changes in priority prior to development starting.

As you can see we are color coordinating some of those workflows as well, the gray tasks here that you can see they are the ongoing and one of the examples is the control risk tasks, they are ongoing throughout the whole entire solution software development lifecycle.

The blue color that you can see here they are the project level tasks that will be multiple iterations throughout different projects.

The green tasks you can see here are release level tasks, so before a solution, a team is ready to release they have to complete those green tasks. Next slide, please.

So, our Cerner's risk software development processes are based on the standards development lifecycle model that prescribes quality focused development activities. So, prioritization uses a portfolio management approach for project planning.

Like I was mentioning earlier Cerner utilizes a portfolio management approach, client needs are gathered by Cerner agile business units per line of business in the development portfolio blend is determined by business leaders based on the severity criteria.

The approved projects are funded to meet the market demands and solution partner clients are directly engaged to work with development teams. The portfolio is changed...and leveraged...approach that allow for change in the future project to adopt the market needs.

The continual risk-management to assess control and evaluate the solution risk and I think that is the area that Shelley has covered earlier, that for high risk-based models will evaluate the risk of a project, of a solution throughout the whole entire life development cycle so they do not end when you finish document requirements that is actually something that we would consider and evaluate continuously.

And Cerner also leverages a user centered design methodology for applications to optimize end user experience and productivity. Cerner software development process currently incorporates best practice guidance during the user interface requirements definition review and testing phase.

The development team does follow human factors standards defined by Cerner user experience team. Those standards include definitions of proper use, adherence, behavior and technical usage of user interface elements that make up Cerner's solutions.

The objective for those standards is to develop a consistent, extendable, technically sound and visibly appealing design guidance to build our applications. User experience here at Cerner consists of a dedicated team of interaction designers and usability researchers. This core team defines the strategy for user centered design methodology by incorporating the latest research in testing of solutions across the development team.

And the next bullet I would like to cover is validation and verification. As you can see from the slide that I had shown prior to this that we inject early and often verification and validation throughout the whole entire development lifecycle anywhere from unit testing, interaction testing, functional testing to regression and deployment testing throughout the whole entire lifecycle. Then on top of that we have special usability testing, performance testing also embedded into the development lifecycle. And we have quality insurance activity in place in the development lifecycle to monitor, assess and drive process development.

In our review quality task which has root cause analysis data with all the defects in coming, client defects that meet the criteria we perform post market surveillance and also review additional quality data that might be affecting our solution software code quality and we create a quality plan at the end to track our improvement items.

So, this has concluded my presentation here. We will open it up for questions.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Thank you, Sharon.

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Yes you're welcome.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, let's hand it over to the Workgroup what would you guys like to talk about?

Paul Egerman – Businessman/Software Entrepreneur

So, this is Paul Egerman, I have a couple of questions. First of all I want to say thank you this is a great presentation and very thorough and certainly a thorough presentation on an impressive quality program.

My question is, as I understand it and I might understand it incorrectly, as I understand it this is the process you use for software development, to what extent do you use this same process when installations occur and in particular when there is any customization or like a new interface that occurs during an installation? Do you use this exact same process or is this really limited to software development?

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Hi, this is Shelley Looby, and yes we use the processes consistently throughout the lifecycle. So, if you need a new interface it's all handled, that might be a new development or it could be a correction or an enhancement and it's all then controlled through the change control process that is embedded within our low, moderate and high software development processes.

Now with regard to installation that organization does have to follow CQS and they have processes and procedures that they use for installation of the software that we consider part of the software lifecycle because then it goes on to have another life where it is used in a client's production environment and so it is handled the exact same way and has to live up to all the check points and measurement, and correction or improvement that anything else would at Cerner. Did that...

Paul Egerman – Businessman/Software Entrepreneur

Okay, yeah, that's helpful.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Okay.

Paul Egerman – Businessman/Software Entrepreneur

And so...and I appreciate that answer and the other question I have is, I saw your slide, I think it was slide 11 that showed the history.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Yes.

Paul Egerman – Businessman/Software Entrepreneur

And it seemed to stop at 2005, does that say that you have used the same process in place for the last 10 years or has the process changed since 2005?

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

The process overall has not really changed but we are challenged to continually improve so we may improve in one of these seven components which you will see on slide six, but the CQS structure, I should say, probably became solidified in 2005 and that structure has remained and we have, you know, tried to improve upon it as we go but I would say that 2005 is as close as it looks today as it did 2001, 2002 or 2004.

Paul Egerman – Businessman/Software Entrepreneur

Great, thank you.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Sure.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

This is Mike Lardieri.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

...

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Oops, go ahead.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Go ahead.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Okay, so...and thank you for the presentation it's very helpful and I know Larry said, you know, this is one, but from your work with other organizations in the business are most of the other EHRs close to the same place you are or are you far ahead different than most of the other vendors?

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Well, I can't comment specifically on other vendor's quality management systems. When Cerner does partner with other companies we are required to do our due diligence with regard to, you know, risk, quality management system, etcetera, and we do look at and for other companies that hold ISO certifications. I would have to say there are not a lot of other manufacturers that hold both 9001 and 13485 but then, you know, other manufacturers may not be designing, developing actively regulated devices.

So, I really can't comment on a number and I really can't comment on what their systems look like but we do encounter other companies that have ISO certification and again it is something that Cerner looks for when we partner or, you know, do business with other companies, is do you have an active quality management system and how is it deployed across your organization.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Okay, thanks.

Janey Barnes, PhD – Principal & Human Factors Specialist – User-View, Inc.

Hi, this is Janey Barnes; again thanks for the presentation it was great. I guess my question, I just want to confirm, like so we're sitting here with a group that is focused on healthcare IT but as you were talking if you were building a device that was in the high-risk category from, I think it was slide 14, then we could of just as easily been talking about a medical device that was regulated by the FDA that you would be following the same quality system process that you described is that correct?

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

That is correct.

Janey Barnes, PhD – Principal & Human Factors Specialist – User-View, Inc.

Okay, thanks.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Yes, Cerner's quality system is applied to everything we do at Cerner it is essentially how we run our business whether we are providing a low-risk solution, a high-risk solution, a service, training, etcetera, it all falls under the same quality management system with the same requirements.

Janey Barnes, PhD – Principal & Human Factors Specialist – User-View, Inc.

And then I guess a follow-up question is, so related specifically to the safety enhanced design is what ONC calls it and the human factors process which the FDA calls it, is it that one area is more mature, like is usability in devices more mature or the same maturity as in healthcare IT in your organization or are they equal maturity in terms of carrying out and implementing a process?

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

I would say, and Sharon can certainly comment on this as well, is I would say they are equal and the reason it is equal is because in a healthcare environment our end users are using medical devices and they are using HIT so it's very important for us to make sure that our solutions are usable and safe for use because they are going hand-in-hand with the medical device that the clients may be using. So, it is something that we have tried to introduce and mature, and sophisticate across the board for design and development.

Janey Barnes, PhD – Principal & Human Factors Specialist – User-View, Inc.

All right, thanks.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Hi, it's Larry Wolf, let me jump in with a couple of follow-up questions to some of the things that are already raised. So, you just talked now about level of maturity but given your risk assessment it's possible that the process might be, I don't know what the right word is, looser because it's lower risk for certain things so even though you're looking at quality broadly and you have a similar process you describe different risk levels and it sounds like process becomes more rigorous in some ways at the higher risk level is that right?

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Yeah, I probably wouldn't use the term looser, this is Sharon, so you are right they are going to be more...there are additional artifacts that the high-risk solution team has to produce due to the submission and technical files, but I think the basic principle of CQS is embedded throughout the whole entire...all three of the development lifecycles. So, I would say the guts of the process there are all the same, they all have to meet the ISO standard regulation and they all have to meet the CQS standards.

So, I think above and beyond...there are some above and beyond artifacts that I think it does get a little heavier when you go through the high set of the risk bucket, but I would have to say other than that they are pretty equal.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Okay, but there is a difference beyond just artifacts you're saying, right? As you go to higher risk...

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Right, right.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

I assume that aspects of the process look to do, I don't know what, more testing, more thorough testing...

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Well, it's...

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

More error conditions, something?

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Yeah, if I could refer you back to slide 8 and under the high-risk you will notice that there are more bullets, right?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Right.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

So, there are more things that have to be performed, completed, challenged to meet 13485, to meet 14971, 62304, 62366 above and beyond what would have been done possibly at a medium risk solution or service. So, yes, it's more than artifacts it's all these things that they have to do to meet the additional standards that we require compliance to for those solutions or services that fall under high-risk.

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Yeah, maybe I need to clarify a little bit as well, that when I talked about the principle they are the same. So, for example, tracing would be something that doesn't matter which risk bucket that you are falling under we would require traceability back to your project identifier, but, you know, how much detail do we require from the tracing that might be a little bit different depends on which bucket you're falling under.

So, there are some...the bigger principle higher level picture they all look similar but going down to the actual, you know, line up to do they will be a little more additional steps that need to be complete for the higher risk team.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

And I guess continuing the actual use process and picking up on Paul Egerman's question, so it wasn't really clear to me from your answer how much you engage the customers, the actual providers who are using the systems in the quality process and perhaps actually extending to them your own best practices around risk management as they implement the software or are you really only looking at the Cerner side of the equation?

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

No, we definitely include the clients and we include them early and we include them often. So, when we understand that a client has a need or a want we try to use their input frequently as we do design because we want to make sure we're making the right thing and then we are, you know, communicating with them throughout that design period.

The development period that is pretty much a Cerner project because it is our engineers creating the code and challenging the code from more of a black box type approach if that makes sense to you from an engineer's lingo.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Right.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

But then when we come out on the other side and we have, you know, did we make the right thing, is the right thing usable, is the right thing going to support your workflow end user, we also re-engage them to make sure that, you know, we're doing the right thing. Are we actually going to create something that is usable, that is going to support their workflow and that provides them ROI?

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Yes and just to add to that is every development enhancement investment that we have we actually, Cerner, requires to define a solution partner in its success criteria for that project.

So, like Shelley mentioned earlier, we engage with the partner and key stakeholders early and often, and throughout the whole entire lifecycle we have, you know, places that we allow them to comment on their feedback, we have places that we actually allow staging environments for them to take a sneak peak of some of our things and provide feedback.

So, we definitely are, you know, because of the implementation coding phase I think everything else is...we have multiple touch points throughout the whole entire life development cycle to ensure that we are not only developing to meet the delivered deadline but we also meet their needs.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, I guess I continue to hear this as really focusing on the Cerner development exercise creating new features and functions, and extending the capabilities of the application, but my sense is that as health systems implement their EHRs, implement their other Health IT that they're making lots of choices, everything from, you know, who are the users who are interacting with the computer and at what point in the workflow and how do they use the computer system, and, you know, how do they do training and there is a huge amount of things that happen outside the product and the software that are really important to ultimate success of the use and the safety of the use.

And I'm wondering how much you bring the, you know, 15 years or whatever it is of experience that you have to your customers as part of implementing with them so it goes beyond just the quality of what you deliver is high but the subsequent use by them also is high.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

So, we do that in a number of ways. We have what we call "user groups" where clients with the same functionality deployed at their location, similar type institutions work together and then provide feedback to Cerner on, you know, things that they like, they don't like, need improvement, etcetera and those go on throughout the year.

We also have an annual Cerner Health Conference, that's held in Kansas City where we are headquartered, where our clients come in and actually do presentations to other clients and to Cerner Associates about the software or solution, or workflow, or whatever it is that they're utilizing Cerner software in so that we get a better understanding of how this is used once it is deployed to the client site and we understand the client's use of it and I think that provides us a very good background when they do ask for changes or enhancements we have a much better context as to why they are requesting this and how it would be, you know, utilized going forward.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, let me rephrase what I'm hearing, so if...you know earlier you talked about post market surveillance...

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Right.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

And it seems like you're describing something that I would include under that umbrella.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

That is one of the parts of our post market surveillance, yes.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, would you talk a little bit more about post market surveillance and how you address that and the kinds of things that you're looking for?

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Yeah, under our post market surveillance we review relevant post production information and matrixes that do not fall within Cerner typical quality reporting, you know, when we talk about internal versus external those can include, but not limited to, client scores, compliant trends, client satisfaction survey, which we do that on a regular basis, third-party supplier issues list and compatible information and ask for opinions. So, we do...that is part of our Cerner post market surveillance tasks that we're doing on a regular basis.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, one of the things that we've talked about in the past is the need for safety event reporting, is there anything you're doing that particularly looks for things that would be safety issues discovered at customer sites?

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Yes, we evaluate all reports that come into us regardless of the method and those go through a process that we have to determine what we refer to as complaints and those can have a safety issue or a downtime issue, which also could be related to safety, but we have criteria set where we evaluate all points to see if they qualify then for a complaint at Cerner.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

And you're using complaints here broadly as really any kind of defect...

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Yes.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Reporting?

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Right, right and it may be...it may not be a code defect, it could be, you know, the client may have a question on a database setting and, you know, it wasn't clear to me how I should set this for the outcome I achieved, while there was really nothing wrong with the code the client needed to know exactly what should be set so they could utilize the software to support their workflow.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Right, okay. Any other questions from the Workgroup?

George Hernandez – Chief of Applications and Development – ICLOPS

This is George Hernandez I have a few questions.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Take it away George.

George Hernandez – Chief of Applications and Development – ICLOPS

All right. Back on slide 14 with the low-risk, medium-risk, high-risk and you mentioned that the high-risk has more bullets, is there a tendency to have more complexity, more expense and slower operations with having to in one sense implement more bullets?

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Well, I think the slowdown in that comes with the fact that we would then possibly have to submit some documentation whether it be a 510(k) to FDA, a technical file for CE marking, a technical file for registration in another country that's where the slowdown really comes, it's not...we try not to make it overly burdensome but there just are standards that have to be met before we can place markets safely and effectively...excuse me solutions safety and effectively on the markets and, again, I think with our use of the agile approach it does help not only the quality of the software but it also helps the timeliness of the software as well.

But, to be perfectly honest, if there is something that we have to do with a competent authority prior to placing it on the market there will be a lag time.

George Hernandez – Chief of Applications and Development – ICLOPS

Okay, so it does...there is a reporting aspect that adds time to it, but in making the product it adds to a complexity and expense that's transferred onto your client.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

I think other than the fact that they wouldn't be able to utilize it in a production environment until we would achieve clearance or CE marking, or registration, or licensure we don't pass along...we don't make the client pay for a licensing, we don't make the client pay for a 510(k) process, no that is absorbed as part of operational cost at Cerner.

Time-wise, I don't really know because I don't look at a lot of contracts, but I don't think that a line item for an actively regulated device is exceedingly more expensive than a line item for a non-regulated device.

George Hernandez – Chief of Applications and Development – ICLOPS

Okay, thank you.

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated

Hi, there, Robert Jarrin with Qualcomm; I particularly liked the slide that was just mentioned, I think it was slide 14, but I was wondering if Cerner also implements HE75 and 80001, and 80002?

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Yes we do look at both, all three of those with regard to, especially the systems and the integration, and we are keenly aware of interoperability and any risks of that.

It is interesting to me and I'm actually working on an interoperability committee right now with several other manufacturers and FDA and it's interesting because we've come to the realization that while those are great standards and they all make a lot of sense there is not one environment out there at a healthcare facility that looks like any other environment anywhere.

So, it's very important that Cerner work directly with clients and understand what is in their environments and help them identify risks and potential hazards using whatever it is they're going to be using in their environment and to help them understand how to mitigate any risks, and that also takes us working with other manufacturers.

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated

Thanks.

Bennett Lauber, MA – Chief Experience Officer – The Usability People, LLC

Hi, this is Bennett Lauber, I have a question regarding the size of your quality management team relative to the size of your development team. I see your user experience team has about 50 or so people and I'm looking at a picture of all them in their purple user experience T-Shirts, but I'm wondering, you know, what's the size and ratio of the quality management team to the user experience team and to the overall development team?

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Are you talking about...okay, so we...the quality management...the quality representatives utilize or actually take on a little bit different role and there is close to 75 of those across the company it's each group and location and then there may be multiples within locations and groups.

But there is also quality processes that are, you know, applied by engineers, test writers, test executors, strategists, architects, so there is not...we've tried to embed the quality into all of the steps and so each person is involved in a portion of that quality assurance so it's not really a separate team at Cerner, it's not a silo'd team. Does that make sense?

Bennett Lauber, MA – Chief Experience Officer – The Usability People, LLC

Yes, yes it definitely makes sense. But I was just trying to get an understanding of the ratio because in the CHPL site there are 30 or something pages of just products that come out from Cerner so I just sort of wanted to get a feeling for, you know, how many developers you guys actually have relative to, you know, both the user experience team and this embed quality across everybody.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

And I don't think I can give you those numbers I'm sorry.

Bennett Lauber, MA – Chief Experience Officer – The Usability People, LLC

Yeah.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

We look at numbers when we do our ISO certification we actually look at tasks performed at a location and the number of associates at a location but those associates may also be doing, you know, multiple things some of which are quality activities for solutions and services but they may...

Bennett Lauber, MA – Chief Experience Officer – The Usability People, LLC

Right.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

You know also do something else. So, I don't know that we really have a ratio or a number that we can provide.

Bennett Lauber, MA – Chief Experience Officer – The Usability People, LLC

Okay, well I just want to commend you on having a large user experience team and I just wanted to get a number because most companies have a very, very low ratio of user experience to developers and I hope that you guys have a more...

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Yeah, that area is definitely where we have been putting a lot of different focus in everything in the past few years in the user experience usability side of the business and definitely that team numbers are growing and we also spend a lot of time and effort in budget building a state-of-art usability user experience lab here at Cerner so we can...like I mentioned during my presentation, so we can bring that user...bring the best user experience to all our software products.

Bennett Lauber, MA – Chief Experience Officer – The Usability People, LLC

And I commend you for that, thank you, very much.

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Well, thank you.

Paul Egerman – Businessman/Software Entrepreneur

So, this is Paul Egerman, hello?

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Hi.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Hello.

Paul Egerman – Businessman/Software Entrepreneur

I have a question about actually the certification process not your quality process and my question is, do you have any idea of what it costs or how much time it took to certify what your quality process is so just the certification part of the process?

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Yeah, we don't really measure them by hour as much just because all our projects are different, you know, have different complexity, different size per see and every release has, you know, some releases are larger than others. So, I think it's harder to measure that by hour from our perspective, but I do have to say that, you know, our principle is always how much time you put in for development coding perspective which is the equal amount or more on the testing side. So with that comes a lot of...

Paul Egerman – Businessman/Software Entrepreneur

And again, I'm just...

Sharon Muehlmeier – Senior Manager – Cerner Corporation

What?

Paul Egerman – Businessman/Software Entrepreneur

My question is just the certification requirement was simply like describe your quality process and so I'm asking how much effort was it to meet that part of the requirement was that something simple that could be done in like 10 minutes or did that take hours or days, or maybe you're not the right people to know the answer to that question.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Are you talking about ISO certification?

Paul Egerman – Businessman/Software Entrepreneur

No, no the certification for ONC.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Oh, oh, oh, okay.

Paul Egerman – Businessman/Software Entrepreneur

I'm just talking about the ONC certification process where...

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Yes and...

Paul Egerman – Businessman/Software Entrepreneur

There is a description of something that you have to do to describe what your quality management process is...

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Oh, okay.

Paul Egerman – Businessman/Software Entrepreneur

And I was just curious was that just a very minor thing like checking the box or did it take an hour, or a day can you give me a sense of the effort involved for that?

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Yeah, I did work directly with the Cerner Associate who is John Travis who, you know, wrote all of our attestation and he actually worked with many associates across Cerner and I don't know exactly the time and effort put into that but knowing John it was done meticulously and extremely well. He worked directly with me and another associate in RAQA to pull our information together because it is an inherent part of our business and the quality management system at Cerner really can't be separated from anything else I would say it was not a lengthy process to get that into our certification because it was a matter of regurgitating what we do on a daily basis. So, it's part of what we've done starting back in 1997 and moving forward and it's unfortunate that I can say that because I've been here even longer than that so I've lived it, breathed it for a long time, but it...I'm not going to say it was a 10 minute project but I'm not going to say it was a 10 week project either.

Paul Egerman – Businessman/Software Entrepreneur

Okay, thank you.

Steven J. Stack, MD – President – American Medical Association

This is Steve Stack.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Hi, Steve.

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Hello.

Steven J. Stack, MD – President – American Medical Association

Hi, so I have a question specifically about the user centered design piece. I happen to be a user of Cerner in the clinical setting and when you create the electronic health record and you design the processes I can imagine the complexity that goes into designing all these different processes and the need to just get all the work in any form let alone, you know, the most user friendly form. How do you though...how do you incorporate considering how many, I don't know, how many click it takes to do certain activities?

So, like when I go to discharge a patient I can't just easily go to one spot and discharge I have to...it takes like seven different clicks and three different screens. And I don't think this is unique to your product so I don't...it just happens I use yours.

But, when you go through these process designs, one, what's your process for user centered design so that not only does the software tool perform the function required but it performs it in a way that is as usable, intuitive, least likely to cause error or extra steps, you know, for the actual end user so that's question one.

And then question two, is you've got a large install base across a whole array of different clients who I'm sure ask and require different things of you, what is your process on the back end as you get feedback from all your different client assimilating, if you will, best in class approaches to different problems so that you're generic install product, if you will, your base platform product incorporates as much as possible all the best learning that you've derived from all these different clients some of whom, you know, will figure out better ways to do things and work with you in partnership to do that?

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Yeah, yeah, definitely, absolutely from the development process perspective I know for our user experience usability team they actually come back on site observation for all the key clients they will go on site to actually sit with them, observe how they, you know, leverage and use a certain workflow, they actually...and also on the other end for your second question there is a client feedback loop that they're trying to reach out to as many clients as they can to gather those client's feedback. So, they're trying to understand the user by doing on site observation and gather those...incorporate those client feedback into our applications.

Then they, you know, trying to use and leveraging those defined in scope by defining the user stories so wire framing of the scope then that way turn that into a design user...then with design user interface and prototyping with a solution team the whole thing is a kind of ongoing iteration looping and again we do user testing and we actually do user testing with our partner and the design partner feedback then we will feedback into that whole entire scope and redesigning the scope to kind of refining, retuning that process and we validate that.

So, that's kind of our user centered design principle that we understand that, you know, we still have a long way to go, but especially some of our products, you know...some of our products they are pretty large in size and, you know, user centered design is kind of...we kind of measure emphasis in the past few years but it will take us a little time to kind of redesign everything even from, you know, 10-15 years ago. But we are working on those by gathering client feedback and on site observation.

Steven J. Stack, MD – President – American Medical Association

Well, thank you, if I could just follow-up. So, because there was no intent to imply any criticism there more to acknowledge the complexity. So, I'm in a health system that has, I don't know how many total, but over 80 facilities probably in close to 20 states and we have a contracted health system with Cerner and they install Cerner at a large number of their facilities but not all, I think at some of the really small ones they have a different vendor for the critical access hospitals, but even within this, even though...it's not like when I go buy the Microsoft Word Suite and install it on my Macintosh or my Windows-based PC, I buy that one application, I install it and it works.

How much custom effort does this require for each of these clients and recognizing that even one client is not really one client it's a multiplicity of clients because if you have a health system that has 80 hospitals in 19 states but all those different hospitals have legacy systems how much of this actually has to be custom coded, you know, based on your...you must have a core colonel of your product but then you've got to go and I imagine modify and tweak your product to be able to interact with all sorts of differing legacy systems and all sorts of discretely different settings or facilities. Is that a substantial body of work or have I overstated the complexity?

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

No, you have not overstated it.

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Yeah.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

It is a substantial body of work and we have a very large group of Cerner Associates that work on that. And one of the things that is very important early on in the client relationship is to understand how we are going to support their workflow so that when we go to install you may have, you know, a set installation look and feel but to support your workflow we have worked...it's usually weeks if not months prior to the software actually being live in that client's environment or environments to make sure that it is set up to support their workflows and then obviously we ask that they validate that it is working as they believe it should to support those workflows.

So, that is a substantial amount of work and it takes open and frequent communication among Associates at Cerner and at our client sites to make sure that we are getting, you know, operational value out of that software up front and that's done before the go-live as opposed to, you know, trying to rectify it after go-live.

Steven J. Stack, MD – President – American Medical Association

And so I'm sorry to...I go on some of these calls and I don't say anything but time I'm going to say just a little bit more Larry if you don't mind. So, the reason I dwell on this complexity issue is we had an issue with our install of Cerner at my specific facility where we were importing radiology reports and it was truncating the text document at a certain character limit and it took months and months, and months...because I don't talk to Cerner people I talk to my health systems IT people and then they have to talk to Cerner people, so, but that could have been unique to our site of install or our local clutch of hospitals based on an interface that they wrote a specific code for between the specific radiology information system, correct?

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Correct.

Steven J. Stack, MD – President – American Medical Association

I mean, so that could have been just unique to our specific install and had nothing to do with the broad-based Cerner code.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Correct, I'm not saying that was the case but that is...

Steven J. Stack, MD – President – American Medical Association

It's a possibility.

Sharon Muehlmeier – Senior Manager – Cerner Corporation

One possibility, yes.

Steven J. Stack, MD – President – American Medical Association

Yeah, I'm not building a forensic case, I'm not trying to lore you in like a lawyer here, I'm just trying to, for the sake of discussion...because one of the challenges is you clearly have an incredibly robust process that you are trying to comply with all sorts of different standards to manage risk, you clearly are taking a very serious and deliberative approach to this and it's a lot of work and time, and effort.

There is a disconnect though, if you will, between the robust elegance of what you're doing and then what the frontline clinician feels because there are so many layers to this process. So, I guess for the purpose of this kind of call for a FACA group for ONC I dwell on this to tease out that those of us who are using the tools at the frontline do not experience one, all of this process that you're doing, we just know what works or doesn't work.

There are numerous steps in the chain where things can either go right or go wrong and there really isn't much way for a frontline clinician to influence the system except through a lot of filtering. So, through the IT department at your local facility or the regional level, or national level eventually filtering up to the Cerner thing, so, I'll end on this final point, so the complexity of something like Meaningful Use and then the pace of change and how often these things evolve must add even more to the complexity and difficulty in having a consistently smooth and elegant usable and reliable product.

I don't know that I need...feel free to respond but I'm not trying to lore you into any kind of a, you know, specific response other than to say, seeing how much you're already doing but still experiencing the frustrations that we at the frontline have, and I tell people over and over I don't dislike Cerner but I do have real challenges just with the way it has interacted with our workflows and the need to do things and there are times we can't tell if it's Citrix went wrong, if it's Cerner went wrong, if it's my own IT, you know, server problem that's having problems that the hospital maintains we don't know all that, we don't see where the breakdown is, we just experience it as the end user using it and it's not quite where it needs to be and I think most people acknowledge it's not quite where it needs to be but nonetheless the pace of change continues seemingly unabatedly which adds further frustration and challenge. And so I don't know if you have any response to those observations, but don't feel obligated if you don't want to.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Well, I think, they are valid and true comments and it's something that we try to deal with on a daily basis and one of the reasons that we do want to have open and honest communication with the end users as well as the IT groups at the facilities and to try to understand what's coming in the future and how quickly do we have to meet it and how burdensome is it going to be for our end users to adopt and deploy, and so I agree with everything you say and I have to say I've been at Cerner for a very long time, I was 10 when I started though, so I just wanted to make that clear, that is something that we work on hourly, it's not even a daily thing it's something hourly because we do understand the challenges.

And again, as I mentioned earlier we try to remember that each and every one of us at Cerner could walk out this office door and become a patient and if you're at a site with a Cerner system or systems we want you to focus on us as a patient and not struggle with working with your Cerner tool to assist us. So, we do take that very seriously and it is something we are working on every single hour I would say of every day.

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Yes.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Because it is critically important.

Sharon Muehlmeier – Senior Manager – Cerner Corporation

And I think that I agree with Shelley 110%. I feel like we do try to learn from our mistakes and we're trying to constantly come up with different improvement items to make things better. Meaningful Use, you know, is a good example that we actually pulled the group together for all the Cerner internal key executives and stakeholders and tried to come up with multiple different improvement items that how can we make Meaningful Use Stage 3 implementation and releases more successful than 2 and we came up with a huge list of things we will do differently how we can gather the scope a little bit better, how can we actually add additional testing validation steps into the system to make it better. So, I think that I agree with you there is definitely a lot of areas that we can work on and improve on.

And like you said, it is just not easy when you talk about medical software and the things are so robust and complex. But, you know, definitely I think we're taking our quality and we'll use the experience very seriously so from everything that we do we try to constantly improve on all those areas.

Steven J. Stack, MD – President – American Medical Association

Thank you very much for your responses, I appreciate it.

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Yes, you're welcome.

George Hernandez – Chief of Applications and Development – ICLOPS

This is George Hernandez, I have another question. This is related to in one instance the concept there of implementation. Do you find a difference between say employed physicians versus independent physicians say there is a hospital with employed physicians, you have a top down install, implementation of the EMR versus a hospital with a lot of independent physicians the hospital still is responsible for the EMR but because each physician is independent they get a lot more say and therefore it's like a bunch of multiple installs of an EMR. Do you find a difference?

And clearly the top down is much easier to manage and to specify but do you find that having the independent physicians makes it not only more complex to manage but maybe also less safe because of the complexity of the system where everyone gets to say what they want...what their workflow should be versus another physician's workflow?

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Well, because I don't do installations or implementation I don't know that I can really address this very well, but we are sensitive to the fact that Clinician A may not work exactly like Clinician B and we are, you know, also very sensitive to the fact that we can't maybe serve every individual workflow because there would be a risk from a safety perspective or a risk to the outcome perspective if we did that.

And so, again, it's one of those times when the group that does do the installations and implementations as well as the post implementation support team working very closely with the clients to make sure that they've optimized as closely as they can in a safe and effective manner the various workflows that they may encounter at a single facility.

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Does that answer your question? Hello?

George Hernandez – Chief of Applications and Development – ICLOPS

Roughly, but you have no feel as far as like safety of one versus the other? Because in one sense as the system gets more complex it becomes harder to manage and harder to fix all the bugs.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Well, right and that's why we have, you know, a really well-defined change control process within our design and development areas, but understanding that it may not always be a cold fix that would address the situation, you know, clients have these systems and I'm not just going to say it's Cerner, but there are usually multiple systems that work within their environment to support their workflow and, you know, while we try to give good guidance and for lack of a better term, IFUs on how to use the system, once it is in their environment and in use with other systems in their environment there are things that can happen that we at Cerner do try to foresee and we do try to foresee them in working with other manufacturers that may live in that environment but there may be unforeseeable things and there may just be things that we would never recommend as safe but a client chooses to do it that way because it supports their workflow and they then apply the controls around that to ensure the safety.

George Hernandez – Chief of Applications and Development – ICLOPS

All right, okay, so certainly, someone can do whatever they want with their copy of Microsoft Word, thank you.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Well...

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So...

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

I'm not saying so much the software, I mean, they're likely not going in and actually changing the bits and bites of the code but there may be settings that they use or interactions that they have with other systems that, you know, could cause a safety issue or present more risk.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, this is Larry, let me jump in with what I'm hearing as sort of a recurring theme here. We heard a presentation on what Cerner does really mostly internally and including post market surveillance feedback on use of their systems and, you know, how their development process works and in many ways it's a big challenge and it's kind of reassuring and we appreciate the 10 or 15 almost 20 year maybe investment that Cerner has made in its quality systems.

But I think we're faced with the reality that when systems are implemented the environment is very complex, the number of interacting parts is really high and that there is a lot perhaps that is being asked of the provider organizations whether they're physician practices or hospitals, or other care settings that really create a very high load on those organizations to do, if you will, comparable work to have their own risk assessments, their own quality management system in place because there is only so much any one vendor can do.

And I guess I'm personally struggling with the implications of all this complexity and, you know, is the answer more probably structure or is the answer somehow simplify the whole environment or, you know, decompose it into subsystems because the whole system is too big or I'm not really sure.

So, let me toss it back to you for sort of more speculative comments maybe from our Cerner folks on having looked at many years of implementation and many years of use of Cerner product comments or observations about how the provider side might better manage the risk of the things they're taking on?

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Well, I guess, this is Shelley, I would say that, you know, having an overall risk management plan and approach, I think approach is probably a better word, for your institution is necessary, because as you say, I mean, we are one of many players in a lot of these healthcare systems and understanding the risks with working with multiple systems to support your daily business is critical to understanding that.

So, I think that leads us to the point where you're going to have to have a good and effective communication with the providers of these systems, services and/or medical devices to make sure that, you know, you have the right inputs to your risk management process so that if effective risk mitigations can be applied, tested and applied. And have, you know, the flexibility and capability to modify mitigations on a short notice.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Any comments or thoughts from the Workgroup members on sort of looking more broadly at kind of the risk management needs on the provider side?

Steven J. Stack, MD – President – American Medical Association

Well, Larry, this is Steve Stack, it's so tough because there is just tons of risk of all sorts and it's probably beyond what...it's not probably, it is beyond...much of it is beyond what the federal government and regulation can or should be doing.

I think...I guess I would think that a less is more approach to some of this would be better from this perspective, that it would be helpful to the system deploying these things to have a narrower array of items or a smaller array of items on which it specifies what must or must not be done to make sure those are really high yield and important that they can evolve over time but that whether that evolution or other evolutions need to allow for a little bit more deliberative pace of change not the pace we've been trying to keep up with.

And then hopefully in so doing that it will allow some of the vendor bandwidth to open up and to respond more to some of these things that, you know, I may only be seeing in my particular hospitals install but when Terry Fairbanks uses Cerner in a different deployment he's not having the same problems I'm having, you know, so it may allow a little bit more time to, if you will, solidify the ground we've already taken and make some improvements on just cleaning up stuff that we haven't had time to clean up.

As far as others risks, gosh there's so much, there were some instances posted on the KevinMD Blog where a judge apparently in a ruling said, you know, I don't know who is at fault whether it's the government or the software vendor at a hospital or the doctor but the only person on trial here today is the doctor and this medical record is simply unbelievable, you know, so I think there is a lot of frustration and this is not unique to Cerner this is just the current environment that there is a lot of frustration that clinicians feel they have no...we don't have any choice, it's not a feeling we really don't have a choice, we use the tool that an enterprise puts in front of us and then you have to try to somehow still get through your day and maintain your productivity, and in so doing that...apparently even the nurses at my hospital, in the emergency department cannot see the doctor's note that we're creating currently, so they can't even see our documentation in real time while we're collaborating on the care of a patient.

So, if things like that are happening then how in the world can we ever reconcile that the notes provided and created in parallel with each other during the same encounter are incongruent in their content, there is no way for us even to see each other's notes.

So, I think there's tons and tons of risk but it's...a good deal of it is probably not going to be within the ability of the federal government to respond to in the way the vendors and the installers are going to have to fix.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Yeah, so Steve, I appreciate your concerns about over regulating. I'm wondering though if there aren't areas where we can encourage providers and vendors to work on other things outside of regulation just surfacing issues, providing better education or, you know, there has been so much focus within ONC on the certification program and within CMS on the Meaningful Use program that I don't think there has been good learning from what's been done and good, you know, cycling back broadly to the community of what has been learned.

Steven J. Stack, MD – President – American Medical Association

I think there is though I think there is opportunity to do what you just said but look to simplify but also make perhaps more rigorous and smaller in a different way in a smaller number of ways the certification program.

And the AMA submitted a comment letter that I know got all sorts of discussion of various types on the certification program and then also what ways can groups like this, you know, the FACA groups and then just discussions kind of alert to the...I use as a surrogate the health systems of CIOs, like the CIOs who are deploying these systems and the vendors to say, hey, look we're not going to regulate this but boy it sure does look like this area is ripe for your attention to try to make better. To the extent we can make a rational list that's, you know, reasonable and high yield I think that would be of value, I think that may be of use.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, I'll go ahead...

Joan Ash, PhD, MLS, MS, MBA, FACMI – Professor & Vice Chair, Department of Medical Informatics & Clinical Epidemiology – School of Medicine – Oregon Health & Science University

This is...

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Go ahead.

Joan Ash, PhD, MLS, MS, MBA, FACMI – Professor & Vice Chair, Department of Medical Informatics & Clinical Epidemiology – School of Medicine – Oregon Health & Science University

This is Joan and I just wanted to put in a plug here for the SAFER guides once again because I was involved in that and the ONC produced them especially just for the reasons that we've been talking about and we were hoping as we developed them that they would be used by any sort of organization and hopefully plugged by the vendors, the vendors are out there trying to get the organizations to implement safely, right, and so if the vendors...and they were somewhat involved in the development of the guides, if the vendors would recommend the use they are fairly high quality documents themselves and that would be great. I understand that the Joint Commission is looking at having their inspectors familiar with the SAFER guides, so post market surveillance, you know, a softer way of doing it.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Joan thanks for pointing out some of the tools already in place to help the providers along.

Joan Ash, PhD, MLS, MS, MBA, FACMI – Professor & Vice Chair, Department of Medical Informatics & Clinical Epidemiology – School of Medicine – Oregon Health & Science University

Well, hopefully the vendors will find them valuable as well.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Any other comments from the Workgroup? Well, maybe we should open up the lines for public comment and I'll make a couple of closing comments while we wait for folks to dial in.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thanks, Larry.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

This is Shelley, I'm going to have to depart I have a meeting that I'm already late for, thank you again for allowing Cerner to speak today and we hopefully answered some of your questions and again our appreciation for being included.

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Thank you.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Thank you.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Yeah, thanks for the time you gave us it's been great.

Shelley Looby – Director Regulatory Affairs/Quality Assurance – Cerner Corporation

Of course.

Sharon Muehlmeier – Senior Manager – Cerner Corporation

Thanks.

Public Comment

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you. Lonnie, can you please open the lines?

Lonnie Moore – Meetings Coordinator – Altarum Institute

Yes, if you are listening via your computer speakers you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. If you are on the telephone and would like to make a public comment, please press *1 at this time.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, while we give folks a chance to dial in I just want to thank the Workgroup for the discussion today, we covered a lot of ground. We looked at both some of the vendor aspects of quality management systems, the possible role of ONC and the certification program and I'm glad to know that we can now get these off the CHPL it is part of the PDF document that's available so thanks for filling in that gap and my own information base of what's out there, hopefully these will be of value to folks as they go through their selection process or reviewing what they have with their vendors.

And also the very huge complexities of implementing these systems in the clinical environment, the variety of other systems we interact with and the risks introduced both because of the complexity of the number of moving parts, the robustness of the environments themselves, the wide variety of changes that were introduced both through Meaningful Use and through other changes in the healthcare system and the timelines many of which we've heard about in the past as well as today as creating a real crunch and that maybe now is a really good time to be learning from what's already been implemented and making the incremental changes that will really help us deliver value and improve safety. So, do we have any callers?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

No comments at this time.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Well, maybe we'll end this early today. I want to thank everybody for their time and we've got about a month until, maybe not quite a month, until we hear from the Policy Committee and maybe get a more detailed charge with respect to upcoming certification rules. So, thanks, everybody have a good weekend.

W

Thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you, Larry.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Bye, thanks a lot.

Joan Ash, PhD, MLS, MS, MBA, FACMI – Professor & Vice Chair, Department of Medical Informatics & Clinical Epidemiology – School of Medicine – Oregon Health & Science University

Bye-bye.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Bye-bye.

Bennett Lauber, MA – Chief Experience Officer – The Usability People, LLC

Bye.