Graded Approach: Not just Why and When, but How
Dr. Vince (Alois) Chermak, INL, USA

Berta Oates
Welcome everyone, to the Next Gen IV International Forum webinar presentation. Today's presentation on 'Graded Approach: Not just Why and When, but How' will be presented by Mr. Vince Chermak.

Doing today's introduction is Dr. Patricia Paviet. Patricia is the Group Leader of the Radiological Materials Group at Pacific Northwest National Laboratory. She is also the Chair of the Gen IV International Forum Education and Training Working Group.

Patricia?

Patricia Paviet
Thank you so much, Berta.

Good morning or good evening, everyone. It's a real pleasure to have Mr. Vince Chermak with us today. He is the Assurance Director for the Versatile Test Reactor at Idaho National Laboratory. He has enjoyed more than 20 years in Nuclear Quality Assurance that spans the Department of Energy, Naval Nuclear Propulsion Program, in the United States, United States Commercial Nuclear, ISO, and Nuclear Waste Management industries.

He is currently the INL representative to the IAEA for Supply Chain Management Toolkit development initiative. Mr. Chermak is also serving as a member of the ASME NQA-1 Subcommittee on International Activities. He earned his Bachelor's in Science and Physics and a Bachelor of Art in Education, in Mathematics and Physics from The University of Akron.

It's going to be I think a very interesting webinar. It's a first, maybe there will be others like this. Thank you so much, Vince for having this idea to make it very lively and have people we participating. Without any delay, I'm giving you the floor. Thank you so much, Vince.

Vince Chermak
Thank you very much, Dr. Paviet.

Today, we're going to discuss the graded approach, a way to choose the graded approach. The reason we chose this topic is because it's one of those topics that folks and companies seem to have an easy time with the difficult, and a very difficult time with the easy parts of grading an approach. Part of this is because the regs and standards address the difficult pieces

of identifying and executing a graded approach but they don't address the easy parts.

Today, we'll talk about the definitions of graded approach. We'll talk about why we grade our approach. We'll talk about what we consider when we grade our approach. What are the methods for grading our approach. And give some examples.

The first definition I am going to discuss is NQA-1:2015. The reason we decided to go with this version of NQA-1 is because it's the most recent version that's identified an NRC Reg Guide 1.28. If you look at Rev 5, which is the most recent Rev to NRC Reg Guide 1.28, you'll see 2008, 2009-A, 2011-A, 2011-B, right on up to 2015.

If you look in that particular Reg Guide, you'll find that their definition – and I'm going to read this one word for word so please bear with me, I won't do that with all the other ones. They say, 'It's the process employed once the applicability of the requirement to the scope of the organization's activity has been determined, to ensure that levels of analysis, documentation, and actions used to comply with requirements are commensurate with the following.'

What they want us to consider, what they want us to be commensurate with are the relative importance to nuclear safety, the magnitude of any hazard involved, the lifecycle stage of the facility or item, the mission of the facility, the particular characteristics of a facility or item, the relative importance to radiological and nonradiological hazards, and any other relevant factors.

Now in the next slide, we are going to talk about the DOE's approach.

The DOE actually codifies graded approach in the law. We might ask ourselves, 'Why does the DOD codify it in the law, where the NRC doesn't?' Okay. It's actually required in 10 CFR 830.7.

The origination of this – as I've been told, this is a seed story, so you have to take it for what it's worth.

If folks recall back in the '80s, there was a lot of discussion about the government spending $500 for a hammer, or $200 for a toilet seat, $700 for a small electrical fan that's in a facility. And if you think about over-specifying items that are used in a nuclear facility, or for a nuclear application, you can understand that if someone purchases a 12-ounce hammer, and doesn't put a tolerance on that hammer, it may take 75 or 100 hammers for a supplier to weigh before they find one that is close enough to spot on that they can send it to that government facility.

Along with that came a phenomenal increase that was passed along to that government facility. So that requirement actually says that you should upgrade your approach as applicable to the application, and in the order that supports that, they get very more specific. And it's very much like the definition that we saw in NQA-1:2015.

One of the differences is number 1 here, instead of relative importance to nuclear safety, they say relative importance to safety, safeguards, and security. All of the rest are very, very, very close. What you will find in NQA-1:2015.

Now this very definition is also found in NQA-1:2019; Part 2, Subpart 2.23, which is a DOE-specific subpart of NQA-1. So they have it in two places that are very well-known for folks who are contractors for the Department of Energy. And so that's what we consider when we grade our approach at a national lab or other folks do it in another DOE facility.

Let's go to the next slide.

All right. The next two definitions are examples that are provided by IAEA. The first one I am looking at is a little different than the second one because it's more waste specific. It's out of a Waste Safety Guide G.5.2. The header is very similar but the four things they are very concerned about, they get general in in terms of the magnitude of any hazard involved. The particular characteristics of a facility. That sounds familiar. The step within the decommissioning process, which is something you do consider when you're working with waste from a decommissioning facility. And then the balance between radiological and non-radiological hazards. That is very familiar with the others.

Let's look at their next one. Their next one is a more well-known, more widely used document. It is the application of management system requirements for facilities and activities. In Annex X, they talk about a graded approach. They have it in this paragraph form. I've broken it down. These aren't specific steps but I've just broke it down because it's much easier to parse this way.

I'll read this one verbatim as well. 'For a system of control, such as a regulatory system or a safety system, a process or method in which the stringency of the control measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, a loss of control.' This is the IAEA's widely used document and this is how they address graded approach.

Let's go look at the next slide.

If we look at this big picture, what do these four approaches have in common?

And I am going to ask – yeah, here I go – I was going to ask them to watch a survey. Go ahead and fill in all of those that you think these four approaches have in common.

What I am going to do is ask our host to watch and tell me when we are at about 75%. And when we are at about 75% of the people responding, she will go ahead and let me know, and we'll give you another 5-10 seconds to wrap it up.

So where are we right now, Berta?

Berta Oates
We are at 52%.

Vince Chermak
Okay. That's good. I like the participation. You are going to like to see the result. It's nice. They provide a bar graph that shows us percentage of folks who responded to what answers.

Berta Oates
We're at 65%, Vince.

Vince Chermak
That's wonderful. All right, so we'll give them another 10 seconds or so, and then we'll move on.

All right, so big picture, what do we have in common? Oh, this is interesting, this is really good. So consequence; probability of failure. Consequence you put 71%. And probability of failure – I know that everyone can see this, we got a little more than half. About 3/4th for significance. Characteristics we have a little less than 1/2. And application about 1/3rd.

Actually, you are all right. Every one of these fall into what we have in common. So, what those have in common. They all talk about the application involved, they talk about the characteristics of the facility or item, they talk about the significance whether it be to nuclear safety, personnel safety in some cases, safeguards, and security. They talk about the probability of failure, and the consequence.

But I have another question, and this one's not a poll. What do those five things have in common? And our host will pull it up. Right, there we go – it is risk. All of these things feed into risk. And so, when we grade our approach, we are really balancing the risk with any efficiencies we might get. And as we'll talk a little further, we want to make sure that we also

balance our grading with the idea of making things easier for our folks to perform, making things more efficient, and ensuring that we don't become non-compliant, ensuring that we meet the regulation or standard that we are implementing.

This next document that I want to talk about, it's a great document. And if you look at the bottom, there's a link. And that link will be in the version of this that's posted to the GIF website. This particular document was written by Gian-Luigi Fiorini and Luc Van Den Durpel. In this they talk about harmonizing safety and security while addressing risks. The title of this is 'A New Paradigm for International Standardization: Harmonization for the Design and the Assessment of Future Nuclear Installations.'

It is put up by Nuclear-21. This is the March '21 edition of their publication.

Let's go on to the next slide.

These graphs really jumped out at me when I read their document. After thinking about it for about a week or so, I asked them if I could use these. They were very generous. Not only did they allow me to use these but they let me set up telephone call just to make sure that I understood how the document was laid out and what were the important pieces of that document, and how this all fit in the integrated approach. Great folks to speak with, they are excellent.

One of the things that this document talks about is the difference in impact of one accident with 100 deaths. If we are looking at risk, the difference in impact of one accident with 100 deaths or 100 accidents with one death each. I encourage you to go out to their website and get this document and read it if you want to consider grading your approach, if you do design work in general, and if you are one of those folks who is part of planning, building, or even working in a nuclear power plant.

This first graph right here – oh good, my mouse is working – this first graph is called the 'Farmer Curve,' and they reference this in their document. This Farmer Curve is actually depicting the risk curves in conjunction with the ISO risk curves. The risk curves of the business and of the regs that you are implementing, they are corrected to better consider the possible societal impact of the severe accidents. We talked about accidents, one accident with 100 deaths or 100 accidents with one death each. The risk, the domain of tolerable risk is that curve corrected to better consider that impact. The residual risk domain is where we can grade our approach.

When we grade our approach, we consider this graphic which is a great graphic. When I was talking to Gian-Luigi, he said that – and I understand what he's saying here – that the deterministic approach circle, and the risk-based approach circle are really the foundations of this and that they are

the bigger, the more important circles. The deterministic approach is really what engineering does with the design basis, identifying and ensuring that their defense is in depth, calculating the safety margins.

The risk-based approach over here on the right, it includes realistic models that account for major uncertainties and so it's probabilistic risk assessment – it is those things that we consider. But you can't consider those alone. You also have to consider things like operational experience, best practices, lessons learned, industry standards – all those feed into this as well, and they are all based on the regulations too.

Let's go to the next slide.

Here's a question, 'Why do we grade our approach?' There's no wrong answer to this one. When you fill out this particular survey, what I am really looking for is, why do you grade your approach? Go ahead and think about that and start filling this out and submitting your answers. What will follow is why in the past I and companies that I've worked for have graded our approach. That doesn't mean that that's what you consider but it's something that we consider.

I will say that different facilities with different missions consider different things in grading their approach. A commercial company really does put a lot of emphasis on efficiency while meeting requirements. High-risk facilities that maybe aren't in the business to have a bottom line, or to provide a profit, their reasons for grading an approach may be very different.

Let's check, Berta, how far we on this? How many folks have responded?

Berta Oates
About 66%.

Vince Chermak
Wow! That was fast. You folks are doing great at this. We'll give it about 10 mores seconds and then we'll look and see what answers we have.

All righty. A lot of folks put in robustness, which makes me feel as though they are grading their approaches upward. They may be putting in extra steps, extra requirements to make sure that they are in a safe environment. Cost is another thing that the companies consider, especially ones that need revenue to be able to stay in business and save the company money that falls right in line with that. Costs might be what we are offered in the marketplace, saving the company money is what helps them ensure that they are able to keep the folks on that they have.

Regulations are something that we would consider. We don't want to overlook those as we grade our approach. We don't want to grade them out. Saving time – absolutely. If you can cut down the wait-time of a customer from 6 weeks to 3 weeks, that very well may help them out. And if that doesn't help your customer base, you may not consider that. It's very interesting what we got there in the spread of responses.

The answer that we used to use as a rule of thumb at a couple of the companies I worked with was in line with balancing the application of process controls, which are often identified in the regs, with business needs to provide an efficient and compliant – once again, we are considering the regs – work process. That's what I have in terms of why we grade our approach to quality. All the answers that I got were great.

Let's go to the next slide, Berta.

Okay. This one is a really important one although it's very brief too. If we look at the consequences improper grading, there are two ways that we may go wrong. One of them is imposing excessive requirements. And I've seen this in a number of cases. We identify controls that don't add value. They are unnecessary and they are not appropriate. These things can make a process take an unnecessarily long amount of time. They can cause employees to have to do things that they really don't have to. We have this requirement that stops them from being able to perform their job, and it's really not necessary.

We also talked about over-specification, and we talked about that with the hammers. Over-specification can reduce the opportunity for success. If they had a tolerance of plus or minus an ounce on that 12-ounce hammer, they may have just had to pull 6 to get 6 hammers instead of 75 or 100, and just measure those 6 and send them on their way with a certificate of conformance. This also can cause additional, avoidable, time and costs both for the company and from the customer – the person who is actually using these items.

Another space we don't want to be into is not imposing applicable requirements. It's very important to have someone who knows your regulations or knows your standards involved when you are creating your approach. Because if you don't have that person, if you don't have that subject matter expert, that can result in discrepant conditions, it can increase the hazard associated with the work, and it will generally cost more.

In some situations it can cause internal rework, which is the cost of poor performance. Now, the cost of poor performance is generally time or money. But it's internal and so you do have control of it. Returns, those are the cost of poor quality. And the cost of poor quality is not just time and money – the time you have to invest, and the money you have to spend

to fix that if it's returned. But also, there's a cost of your perception in that customer's eyes.

You have that embarrassment to deal with and your reputation, the company's reputation is on the line as well. And worse than both of those, internal rework or returns would be an item that's not compliant, it is discrepant, that makes its way into a safety-related application and fails in that safety-related application. So, those are the two ways, imposing excessive requirements and not imposing applicable requirements, those are the two ways that we can improperly grade.

Let's go to the next slide.

All right. What do we consider when we grade? If you think about this question, we've already talked about this. But I'm going to ask Berta to please launch another survey. Here are the questions we have, and I look forward to seeing what your answers are.

Okay, so where are we in the response curve, Berta?

Berta Oates
We're just about 40%.

Vince Chermak
Okay, give people a little more time.

Berta Oates
We're up to 70%.

Vince Chermak
All right. Let's go ahead and wrap up in about 5 seconds.

What methods are used to grade our approach? Now here's where I get a little bit tricky. When we talk about methods used to grade our approach that's where folks usually have trouble that's where companies usually have trouble. They are very good at the analysis upfront, identifying those five inputs that they need to consider as they grade their approach – identifying and quantifying the risk, they are very good about that. But when it comes to grading their approach, a lot of times folks will go out on the floor, see the process from a big picture setting, and start approaching it like a lean activity, which isn't necessarily bad. But what makes grading easier is if you consider that there are only two ways to grade your approach, and we'll talk about those.

Here we have some examples, like adding a peer review. That's something that can be performed. But we'll talk about why that's not necessarily as a way of grading, so that was a trick in there. Instituting annual refresher

training requirements, that might be a way to upgrade. But it's an example, it's not a method; along with utilizing vendors, outside the approved supplier list that's a way to downgrade in activities where we don't have to have an approved supplier. And maybe buying a hammer, we don't have to specify the weight, we can specify the item number based on what we know we are going to need to use the hammer for. That's a way to downgrade. But it's an example, it's not a method.

Let's go on to the next slide, Berta.

Okay, so what do we consider when we grade? All right, let's revisit the big picture. We looked at risk. The risk is those five items: the significance, the application, the characteristics, the probability of failure, and the consequences. Those are the things we consider when we grade.

Looking back at that survey, I have to say, all of those things are things you would consider when you grade. Good job. The level of rigor for regulated activities or personnel, if I wanted to add a peer review – those are things that you can consider. But let's talk about the methods. The methods are a little different than that.

I am making Berta jump all around, she's doing a great job here. On the next slide, we have some photos. Here we are, we have those photos. There are really only two methods to grade our approach, and if we think of things in terms of these methods, it makes grading much easier. The first one is this top line of pictures. Well, the top line of pictures are simply examples to illustrate changing the level of rigor for regulated activities.

We have a picture over here – all right, there we go. We have a picture over here of a micrometer. Does that micrometer have to be calibrated and controlled as M&TE? Well, it really depends on the application. If this micrometer is being used by an engineer so that he can get a rough idea, an input for reverse engineering something that's out of patent, then it may not need to be.

If this micrometer is being used for an inspection that's going to be documented in an inspection report by an inspector because it's of a critical characteristic of an item, then yes, I would say it does need to be calibrated and controlled as M&TE. The level of rigor for controlling this particular item is really dependent upon the application for what it's being used, right. That's a regulated activity in some cases and not in others.

The second one. We have someone using a microscope here. Does this microscope have to be controlled as M&TE? Does this microscope have to be a certain power? It depends on what we are using it for. Once again, if this person in the photograph is an engineer who is looking at a printed

circuit board to get inputs for a design, it may be able to be whatever power that engineer wants to use it for.

If the person in this photograph is using this to perform an inspection on solders and soldering joints in a printed circuit board that's going to be documented, and part of the final package in CFC – Certificate of Conformance – before it is sent out, then this not only has to be controlled as M&TE but there are standards that require it to be a specific magnification as well, when those are being performed. So, that's important too. Once again, it's the application that tells us the level of rigor that we have to use for this activity or allows us to choose what's best for our company.

Here we have a warehouse with wood. Does this have to be temperature and humidity controlled? That's a good question. It depends on what they are using this for. There may be applications where that wood does have to be temperature and humidity controlled and sent out in sealed wrapping so that it stays as close to that as possible, as it goes to its destination. If this wood is used by the company to box up products and send them out, then no, it can probably be in a building that's subject to the temperature and humidity of the surrounding environment, and that might be okay.

Let's look at the second method. The first method was change the level of rigor for regulated activities, and the second method is changing the level of rigor for regulated personnel. As you go through your process maps, once you decide, 'Yes I can grade this approach,' you go through the process maps and the regulated activities are the ones that really need to be looked at when you are grading your approach, to decide what needs to be more robust, what can actually be lowered in their level of rigor.

If you focus on the level of rigor for regulated activities, you'll see actions and tasks in that process map. You look at the activities, and look at where you have regulated personnel, inspectors, folks who are required on review, if there are particular assessments that are performed throughout the process – those are where you have regulated personnel. What do I mean by regulated personnel? Well, we talked a little bit about this person up under regulated activities. If this is not a regulated activity, say, this is a peer review, peers are not regulated personnel.

If you look, I'll use NQA-1 for an example. They don't talk about peer reviews. They talk about inspectors, and inspectors are regulated personnel. If this is just someone checking someone else's work before it goes on to the next process, simply a peer, that's not a regulated activity and so this person doesn't have to be a certified inspector. And it really changes everything associated with that particular activity. Not only does this person not have to be an inspector but this microscope doesn't have to be calibrated, it can be at the level that the person is comfortable to be

able to ensure that what they pass along is going to be the appropriate quality, and there's a lot more freedom in that.

Now, if this is an inspection that is required, once again, just like up above, or the certification package that we put together, and signed by that person, that person has to be an inspector. This is a critical characteristic that they are signing off on, you'll want an inspector who is fully qualified to perform that activity.

The second one, another example. Does this person have to be a certified welder? If they are just flattening something out to go to the next step in the process, they may not need to be. This might be a journeyman. However if it is part of the final grind before an in-process inspection, then that probably does have to be a certified welder. Now, it all depends on where we are in the process and what the application is.

For regulated personnel here, do both of these people have to be certified rigors? It depends on what we're lifting and where it's going. If this is something that is a heavy piece of wood or railroad ties, something like that that they're moving, we may just have one certified rigor and a spotter. If they are moving nuclear fuel, both of those folks have to be a rigor and one of them is performing the activity, the other one's inspecting it because they have to be certified that way.

Let's go on to the next slide.

This is a quiz and I am going to tell you, it's a trick question – I am going to tell you that in advance. This is 'Yes' or 'No.' Is adding a peer check in a welding process considered grading your approach? 'Yes,' or 'No.' Is it considered grading your approach to quality?

All right, so how are we in terms of responses, Berta?

Berta Oates
63%.

Vince Chermak
That was fast. All right, so let's give them about 10 seconds. Give everyone about 10 seconds and then we'll wrap it up.

All right, let's see what we've got in terms of our answer. Wow, we've got 50:50 on this one!

Okay, so this one's a trick question and it might make some people a little disgruntled but let's look at the answer here. All right, so is adding a peer check in a welding process considered grading your approach? Actually, it's not. And we have Rowan Atkinson here saying 'What?' It's not. But

see, a peer check is not a regulated activity, and peers are not regulated personnel.

Peer checks are things you can add or subtract without doing any of the analysis upfront. You don't have to apply the evaluation for a graded approach in order to add or subtract a peer check. That's purely a business decision. When we grade our approach, what we are really looking at are regulated activities in the places where regulated personnel engage. Those are the activities where we really do need to consider the significance the characteristics, the probability of failure, the consequences of the failure, those are what our standards are talking about when they have us perform an analysis before we either make them more robust or we remove them from the process. Those are the ones that they are very application and output-dependent from a regulatory standard.

Let's go ahead and look at that.

What examples of graded approach can we share? And if you have something to share, please feel free to put it in the chat, and we can read through these things. We may not get to all of them but we can read through these things as we go through the chats. Another thing we are going to do as we go through the chats are, we'll answer questions. So please put your questions in the chat. Now, I'm going to start by talking about three examples that I've had as I've gone through my career, and all of these are in commercial nuclear.

One of them was, eliminating an inspection and replacing it with a peer check. We actually eliminated the regulatory activity or what we thought was a required regulatory activity, we eliminated that and put a peer-check in its place. What are the advantages of that?

Well this particular inspection that was being performed was also performed at final inspection. It was something that wasn't covered up or wasn't in a place on the particular work pieces that we were producing that couldn't be reached and inspected at the end of the process. So, this particular inspection was redundant. It was added years ago because they were having problems at final inspection and they wanted to eliminate those problems earlier in the process because that would enable them to save time and money because they would not only be able to save the rework performed with that particular activity but also the rework associated with anything downstream that had to be fixed because of a problem earlier in the process.

What we did was we took out the QC inspection and we eliminated the need for fully-qualified QCIs at that point in the process. Since it was checked by a certified quality control inspector later on, this could be performed by a peer or anyone who was able to look at this and determine whether or

not it was acceptable – so, a supervisor, a manager, or an engineer. Usually, people just asked the person next to them. This decreased wait-time because fully qualified personnel, or fully-qualified QCIs I should say, there were only a handful of those in the facility, and they were running around doing all sorts of inspections. So this work piece might wait for a half-hour, maybe for half-a-day before it got an inspection.

If they turned and asked their buddy, their buddy could go ahead look at it and say, 'Yeah, I think this is good,' or 'No, I think you need to do this particular soldering joint over again.' And it could be taken care of in less than 15 minutes. It decreased the wait-time because they didn't need the full-qualified QCIs. And interestingly enough, it decreased the cost of poor performance. This could be a number of things. Maybe, people didn't want to be embarrassed in front of their peers. Another likely contributor to the decrease in cost of poor performance is QCIs would look at this with the magnification specified by the standard.

A peer-checker might look at it under a higher magnification and find something that maybe they just didn't like. But they may have identified a cold solder joint or something just because they didn't like it – and a cold solder joint is typically something you can't visually find. But if you're following the regs, you use the magnification specified. And if you are if you're doing something for yourself, you use what makes you feel comfortable. This had a twofold benefit and if it was wonderful. We were getting things out faster and we weren't having the internal rework.

The second one, certifying receiving personnel as receipt inspectors. Here was an example where we had fully-qualified quality control inspectors performing receipt inspections – all receipt inspections. And we identified that we didn't need to do that. We only needed fully-qualified quality control inspectors to perform receipt inspections that required specific measurements. What this did was it decreased the level of rigor for certification of receiving personnel – people who were receiving things in, and it decreased the wait-time.

This impacted the folks at receipt because they didn't have to wait for an inspection for about 85%-90% of the things that they brought in. It also, as in the above, impacted the quality control inspectors in a very positive way because it cut down on the work that they were performing, so they could actually spend more time on the things that were required.

Let's look at the next example. So the last one that we're going to talk about. This was a design question. We had QA signatures throughout the process, and we eliminated the QA signature after looking at the design process for a little more than a half a dozen design documents that would accumulate in their inbox until they had all of those documents, and then they would look at them together. Rather than have it on those individual

documents, their signature was on the final design package, and they would look at those documents together when they got the final design package, and everything else that went into the design.

This did not impact the quality of the final design package but it really shortened the amount of time that it took to put together that design package because other people in the process weren't waiting for these 7-9 documents that QA was holding in their inbox until they all accumulated. That was a real win as well. In all of these cases, we talked about things that appropriately lowered the level of rigor of activities that we had in our process that were regulated.

I think I am going to hand this over to Berta next. Do I have any more slides, Berta? References? Right, so yeah.

These are my references, and once again, they are in the final that will be posted to the GIF website, and you have that link, the Nuclear-21 document.

Please, I am going to ask everyone input questions into the chat while our host discusses upcoming Gen IV International Forum webinars. Give me some questions.

Thank you.

Berta Oates
Thank you, Vince.

Our upcoming webinars, in September we scheduled a presentation on 'Experimental R&D in Russia to justify Sodium Fast Reactors.' In October, we are expecting a 'Metal Fuel for Prototype Generation-IV SFR: Design, Fabrication and Qualification.' And in November, a presentation on, 'Geometry Design and Transient Simulation of a Heat Pipe Micro Reactor.'

If you do have additional comments, there are some in the chat. I'm going to see if I can open this up so you can. You can read it correct, Vince, you can see the questions in the pane?

There's a comment, 'It is nice to see the international community considering risk-informed and performance-based approaches. And yes, we've been promoting this for 30 years. Finally our regulators the NRC, are beginning to accept it. Follow US NRC 10 CFR Part 53: Rulemaking.' Thank you for that comment.

Vince Chermak
Thank you, Berta. All right. If we don't have questions in the chat, do you want to start with some of the questions we got before the meeting?

Berta Oates
Yeah that would be great. There's a couple coming in. 'Do you want to discuss changes to NQA-1 2021 or ongoing ballots in NQA-1?'

Vince Chermak
I can't talk about future changes to NQA-1. In terms of ongoing balance, if you could be a little more specific on that. I want make sure I answer your question, and I don't quite understand what's being asked there.

Berta Oates
Great. Steven, if you'll add some more input to that follow-up to your question, that'll help us.

'How do grading approaches apply different lifecycle stages for a facility, that is like design versus operation?'

Vince Chermak
In every case, the title of NQA-1 is the design and operation of facilities, might even have maintenance in there. So, you use that same process. The very, very, important parts of that process are the once that are specified in your regs and standards. Those identify what to consider as you are going through the process to identify, what it is you want to grade and how you want to grade it.

Those are the things that talk about risk. And as we saw, they are similar but different in every case or in most cases. NQA-1, which is endorsed by the NRC has its approach, the IAEA has its approach, so there are just different things you need to consider. DOE's is very similar to the one that is endorsed for 10 CFR 50: Appendix B. But a little bit different; it includes safeguards and security as well as safety.

So you really need to rely on the standards that you are using to implement your regs or your regs directly as you consider what you want to grade, and that would be whether you are in the design process or the operations process or performing maintenance or other activities. Those are things that you need to do in order to make sure that you are not grading out requirements. At the same time, you also want to make sure that you are not adding undue burden to your process. You want to increase the opportunity for folks to succeed and make your processes run as smoothly as possible.

Berta Oates
Thank you. What about universities, are there any examples or best practices of quality requirements graded to fit university research programs supplying validation data?

Vince Chermak

There is a document for that and I don't know the name of it off the top of my head. But I was working for a company that was providing products for medical research that were being performed in a university and we used that standard. I worked with that standard for about 6 months about 13 years ago. But it's out there, so I'd search for it on the web. It was something that was easy to get to, I don't think they had to purchase it.

Berta Oates
Great. Vince's email is also provided at the beginning of this slide deck, James. If you wanted to reach out to him privately and maybe Vince can help you find that standard to which he is referring, that would be great to do behind the scenes.

'Have you seen commercial-grade dedication be used within a graded approach, for example buying a test specimen [Unclear] validation data but not going to the final plant?'

Vince Chermak
Yeah, absolutely. We used to – I've got to think about this in a nonproprietary way. I worked for a company who had a pre-engineering process where they gathered inputs before they started officially documenting them.

And in that process – it was a messy but quick process. We would send unofficial items out to testing organizations and not require a certification with the testing because it was cheaper and quicker. And we would gather our inputs so that we had an idea of where we wanted to go before we officially entered the engineering process. That was an example where we graded downward to be able to have a better starting position in our design.

Some examples where we graded upward. There were some things that we might have tested and certified in two manners rather than just in one because we wanted to ensure that this item would perform for the next 60 years in a plant. The reg might have only required one set of environmental tests and we would have them done at independent labs. And both of these were with use of commercially-produced products that we dedicated for safety-related performance in a safety-related final workpiece.

Yeah, commercial grade dedication has a lot of opportunity for graded approach in it because it's a very – I don't want to use the word complicated but there are a lot of moving parts in commercial-grade dedication. And depending on what you are dedicating, it could be very simple or very easy or very difficult and complicated for that particular acceptance process.

Berta Oates
Thank you. 'It seems like the graded approach is another name for risk-informed approach. Are there some nuanced differences between the two?'

Vince Chermak
I would say graded approach is a subset of risk-informed approach. You are going to want to use your risk-informed approach for every part of your design and operations and identification of activities. Whether you are grading your approach or setting up an initial process or evaluating a current process, risk-informed approach is an input to graded approach is what I would say.

And then, your graded approach is something that you may use – you may use the graded approach process looking at your process map at this process that you came up with while you were developing it. And a risk-informed approach is definitely something that you want to consider – you want to consider all three of those circles on that chart. But as you are looking at that process map, you'll look at your regulated activities and where you are engaging regulated personnel and decide what to grade.

Once again, I feel like risk-informed is something that needs to flow throughout everything that you're performing, as you harmonize your processes. But you'll use that as you decide, is this an engagement point that I can eliminate, is it one that I can reduce to simply appear or change to an engineer or someone else who is more readily available than an inspector or other qualified/certified personnel? I would say that they are both very, very closely related. But there is a nuance between the two.

Berta Oates
Thank you. The follow-up to Steven's comment on the NQA-1. 'There's a lot of changes regarding signatures and signature authority and how these are documented, for example. You said I can look back through the 21 changes in balance. The intent is to be able to expand on what the NQA-1 priorities are for the group.'

Vince Chermak
I am not trying to dodge your question but I would say NQA-1 is a consensus standard that's put together and it's out there for folks to use as they see fit. When they put this together, in terms of an intent, the only thing I can offer is to provide a starting point for companies in the nuclear industry. I can't say that they intend for individuals to do things verbatim the way it is in the standard. It's not like, 10 CFR 50: Appendix B or 10 CFR 830 – it's not a Reg, it's simply a consensus a standard.

If you specifically have questions on intent, there is a process to submit a question to NQA-1, and they can give you an official answer that it actually goes through a rigorous process that's created appropriately. But it goes through a process where it is answered and evaluated by a number of people before the answer is given.

Berta Oates
Vince, maybe I am misunderstanding the chat pod, but my interpretation of what Steven has put in there is that – the intent of this question – is for you to be able to expand on what NQA-1 priorities are for the participants of today's presentation. And perhaps I've misread that but that's how I interpreted the input to the chat. But I actually you did that indirectly.

Vince Chermak
Yeah that's okay. I can't speak for prior use or intents of the standard itself. It's a consensus standard that's offered for people to consider as they implement the regs that they are required to comply with. The main thing that NQA-1 provides are the criteria for those upfront analyses. There are sections in NQA-1 that talk about graded approach specifically.

For example, there's a section on grading your approach to research and development. So you can get specific answers if they address it in there, but I can't provide an interpretation of intent or a purpose. You have to apply it to your application.

Berta Oates
Thank you. 'Are you aware IAEA just approved the publication of a TecDoc, an application of graded approach to regulating nuclear installations, including operating reactors research, and test reactors, and fuel-cycle facilities?'

Vince Chermak
I didn't know they released one of those. But I actually was looking through a number of IAEA TecDocs and I did see one on research facilities. The ones that I saw, all of them were paid products. You'd have to look on their website and purchase them through IAEA.

But there were a number of them. There were some that I was able to access information too, and I included two of them in here. But that's good. Yeah, if that works, if that's one that's good for you, I'd say, consider getting it.

Berta Oates
And then just some follow-up about the ex officio report, 18 changes in the 2021 for example, and it's the priorities for the upcoming year, the follow-up on the previous discussion on NQA-1.

Vince Chermak
Is that all right if I look at some of the questions we got beforehand?

Berta Oates
You bet! Yeah I have them on my fingertips but you are welcome to read them aloud.

Vince Chermak
All right. I've got a number of questions. One of them is – and this is similar to the risk-informed approach one. Risk-informed approach I think is something that should be used even when you are not grading your approach. And it is something that is important to use while you are creating your approach.

In this first question I have, it says, 'How is graded approach different from other forms of evaluation that use multiple-criteria decision-making (MCDM)?'

I would categorize MCDM as a method of going through the criteria as you grade your approach. So MCDM is a bigger thing than graded approach and it's something you can use as your graded approach. Just ensure that you include the criteria required by your regulations, your standards – the ones that you used to implement your regulations – or for other requirements that you have. Make sure you include those part of your multiple-criteria decision-making. That's the first one I got.

The second one, I did get a request for a link to the IAEA TecDoc and this one I did look up. Yeah, so it's the one you asked about Berta. It just sounded like more of a mouthful saying it than when I read it. 'The application of graded approach in regulating nuclear power plants, research reactors in the fuel-cycle facilities.'

I looked that one up. It's €29 on the IAEA website, and I can't provide a link to the document itself. I would just say, go to the IAEA website, and purchase it there. €29 is a pretty good deal. And then also remember the link for the Nuclear-21 harmonization document. That one's free. That's a good deal as well.

Let's see, another one. 'How does this apply to reactor design?' And this is similar to question someone asked already.

A graded approach can be applied to any of your activity, as long as you make sure that their requirements are not graded out. So, if you are doing design activities and there are things that are just used for collecting information or things that you don't necessarily want to go through all of their rigor, make sure those are pre-design activities. They might be something you do once you start the design but they are not part of the final design package. If there are things, activities/inputs that are required to be documented, make sure those are documented in the file design package, no matter how you collect them before you actually document them.

This next question is a really difficult one. It says, 'Japanese regulatory organizations are working based on graded approach. But Japanese regulation is very strict compared to other come countries. And I understand why.' So, the question was, 'What can we do to bring Japanese regulation closer to international standards?'

The only thing I can suggest is getting involved. I am involved in NQA-1, I am involved in IAEA, and it's very rewarding. You get an opportunity to work with folks who have been in the business long enough to say – if you ask him a question – 'I can remember when we put that in NQA-1 back in 1978 before we issued it.' And it's really interesting to hear the stories behind the 'whys' and the 'whats.' But then also, you have an opportunity to influence things.

I've had people say, 'Maybe it's time we consider changing that.'

And with respect to your regulators, there may be organizations that are similar, that are regulator-utility interface organizations, and so I would say get involved. That's really the most that I can offer to answer that question. Because when it comes to influencing regulation, there are some very well-defined processes involved in that that have to be observed.

Another question was with respect to the international consistency of graded approach. I would say that IAEA and Nuclear-21 provide international guidance for graded approach. However, regulations from country to country will impact our grading. And with IAEA being geared towards so many nuclear needs – they are looking at emerging nuclear countries as well as well-established countries that they are serving. They're very, very, very, general on many of the things that they offer.

If you are looking for something more specific, you would want to look at your particular country's regulations. And NQA-1, if that's applicable, is a standard that is working to get inputs from the international community, and so have established a subcommittee on international activities. But once again, one size doesn't fit all. So you have to consider what is it that I am required to do and how does this particular standard, whichever one you use, support that?

Let's see, I've got a few more than I'll go through and then we'll go back to what's happening live.

One says, 'This has been a mystery and a challenge for our organization.' Oh, I am sorry. That one's a comment. It says, 'Thank you very much for looking into this.' Yes, I thank you for saying that.

'Does a graded approach account for an organization's place in technology development (R&D versus construction or operation)?'

Hope folks aren't tired of hearing this – but I believe that a graded approach, I would actually assert that a graded approach can be applied to any nuclear activity, as long as the requirements are not graded out. And I think that it's important to look at your processes on a periodic basis. And most standards talk about this too.

But one thing that's very important is we often grade things upward – companies grade things upward without realizing it because of things that happened that were not desirable. It might be some sort of occurrence report or some other nonconformance that they don't want to ever see happen again. And over time, a process can become very overloaded with items that aren't requirements but are being treated as requirements and so to revisit those processes – and this is why it's very helpful to have processing maps for your processes – to revisit those processes and look at the things that you have in place and identify the things that we have identified as requirements that actually aren't requirements is very, very important.

A question that I got in my discussion with the Gian-Luigi and Luc was, 'Have you graded anything for VTR?'

VTR is the Versatile Test Reactor, and it's a project I'm very excited about. But the first thing I did when I hired on there about 1-1/2 year ago was I hired on as their contractor and quality assurance director. And so I looked at their contractor and quality assurance plans, and I noticed that we had some areas in our contractor assurance plan where we were very, very, rigorous in our approach and really didn't need to because we weren't at a point in our process where we were even working on final design at the time. It was all pre-conceptual and conceptual design.

We went through that particular plan and the procedures associated with it and we went ahead and graded a lot of that out. We took it out, grated it back so that we could proceed a lot easier under more appropriate controls for our phase, and put those in later when we needed to. So, in terms of does it account for our organization's place in technology, yes it does, and it can be used for any nuclear activity as long as you make sure that the requirements are not graded out.

I have, 'Could you give a list of standards related to graded approach?' So, I went ahead and included those in the references section. And, 'How do you prevent graded approach from not doing required activities?' And that is why it's key to make sure you have someone. If you are leaning out a process using [Unclear] to make a process more efficient, make sure that you have an individual who knows the regs involved.

If you're doing process improvements of any kind, make sure you have a person who knows the regulations involved. It's important that a process not be finalized without ensuring it's compliant. I guess the more clear way of saying that is, before you finalize a process, ensure you have a subject matter expert review it for compliance so that you don't eliminate activities that are required.

Then there was just one more question. This one said, 'The range of important systems and equipment differs between Japan and the United States.' And an example was given, 'Japan includes turbine systems and waste-treatment systems and so regulations differ in Japan because of that.' They asked me to mention the difference. And all I can say, the only difference that I know is the one that you've provided, that turbine systems and waste-treatment systems are included. But I am not familiar with the regulations of Japan. So, this comment will be included in the responses to identify the items you provided that I can't provide further clarification on.

Berta Oates
Thanks, Vince.

Vince Chermak
Yeah, sure.

Berta Oates
Before people log off, we are rapidly approaching that 90-minute mark but I do want to be sure that we share that the next NQA-1 meeting is October 25th through the 28th, if people want to get involved.

Steven, if you have a link or a meeting invite, if that's something that we can just Google – I didn't actually Google it while we were here today – I will post that as well. Thank you for that.

Again, thank you for joining today, Vince. Thank you very much, for sharing your time and expertise with us, practicing a new approach to engaging the audience with the polling. Other than I got ahead of you with one poll, I think it went really well. I apologize that but you did recover well.

Patricia, thank you also for all of your leadership skills and in putting these together and getting such great presentations.

Patricia Paviet
Yeah, thank you so much again, Vince. Like I say, it was something new, I think the participation of people, which makes this GIF seminar really great. Thank you so much, everyone.

Vince Chermak
Thank you, take care.

Berta Oates
Thank you, bye-bye.

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