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NUCLEAR REGULATORY COMMISSION

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NRC WORKSHOP ON DIGITAL INSTRUMENTATION AND CONTROLS (DI&C): LICENSING AND INSPECTION LESSONS LEARNED FROM RECENT DI&C MODERNIZATION PROJECTS

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WEDNESDAY,

MARCH 23, 2022

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The workshop convened via Videoconference at 9:00 a.m. EDT, Bhagwat Jain, Meeting Facilitator, presiding.

NRC STAFF PRESENT:

BHAGWAT JAIN, NRR/DEX/ESEB

SAMIR DARBALI, NRR/DEX/ELTB

DAVE DESAULNIERS, NRR/DRO

GREG GALLETTI, NRR/DRO/IQVB

BRIAN GREEN, NRR/DRO/IOLB/HFT

KIM LAWSON-JENKINS, NSIR/DPCP/CSB

SHIATTIN MAKOR, R-IV/DORS/EB2

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CHARLEY PEABODY, NRR/DSS/SNSB

RICHARD STATTEL, NRR/DEX/EICB

DINESH TANEJA, NRR/DEX/ELTB

JUSTIN VAZQUEZ, NRR/DRO/IOLB/HFT

MICHAEL WATERS, NRR/DEX/EICB

ALSO PRESENT:

RONALD L. BORING, Idaho National Laboratory

JACOB CHAMPAGNE, Entergy

JOHN CONNELLY, Constellation

WESLEY FREWIN, NextEra

PAREEZ GOLUB, NEI

JEFFREY C. JOE, Idaho National Laboratory

WARREN ODESS-GILLETT, Westinghouse

P R O C E E D I N G S

9:00 a.m.

MR. JAIN: Okay, we can get started, it's 9:00 a.m. Good morning to all, welcome to the digital I&C workshop. Today's public meeting is an information meeting with a question and answer session.

The workshop is posted by the NRC Staff by the industry and licensee to discuss licensing and inspection lessons learned from recent digital I&C upgrades, presubmittal activities, and regulatory and technical issues related to human factor engineering, or HFE, reviews.

The discussion and exchange of information today will assist the NRC in approving our regulatory infrastructure and in communicating the statutory expectations realized in the inspection of digital I&C upgrades.

My name is Bhagwat Jain and I am a senior Project Manager in the Office of NRR, along with me is Michael Marshall, and together we performed the project management function for all things digital in NRR.

I need to cover a few logistics points and then I will turn it over to Mike Waters, the INC Branch Chief, in the Office of NRR for opening

remarks.

The duration of the morning session is three hours or three and a half hours and it will include Staff's presentation on licensing and inspection lessons learned with a ten-minute break in between at around 11:00 a.m.

After one-hour lunch, the afternoon session is three hours long and it will include presentations on Staff's HFE reviews, NEI's approach to HFE, industry reflections on licensing and inspection lessons learned and then an opportunity for an open discussion.

In this public meeting, no regulatory decision will be made. This is an open public interaction and as such, we will not be discussing any proprietary or sensitive information.

We are using Microsoft Teams to conduct this meeting. Please ensure you are muted when you are not actively speaking and do not speak over each other.

To facilitate the question and answer portion of the meeting, we recommend that you utilize the raised hand feature in Teams so we can more easily identify who has a question or comment and call on the individual to ask their questions.

The presentation will be shown via Microsoft Teams meeting link that was provided in the meeting notice. You can also the presentation slides in our ADAMS system at accession numbers, for Staff presentation the ML number is 22077A409.

For NEI presentation, the ML number is 22080A021, repeating, ML22080A021, and for the industrial presentation the ML number is ML22076A191. Again, ML22076A191. Now, the slides have also been posted on the meeting notice on the NRC's public website.

Given the number of participants on the call, we are going to forego introductions. Instead, I would ask that as a person speaks, the first introduce themselves, please stand and speak.

Just for your information, today's meeting is being transcribed.

The Staff contacted stakeholders to provide comments and their feedback. If you have comments or feedback on any aspect of the meeting, please contact me or Michael Marshall and we will provide you the necessary forms.

Our contact information is provided in the public meeting notice posted on the NRC website. With that, I'll turn it over to Mike Waters for opening

remarks. Mike is going to make opening remarks. Mike?

MR. WATERS: Thanks, BP, and again to everybody, welcome to our 2022 digital I&C workshop. We are very to get everybody together again in this forum. We truly do consider this as an important aspect of our continual effort to improve our regulatory processes and our regulatory efficiency.

It has been a little bit more than a year since our last workshop and since then, there have been a number of accomplishments and let me recount them. NRC has made good progress in both exercising and honing the licensing and inspection guidance.

Entergy has successfully provided a sound design and licensing basis for the planned digital upgrade of Plant Waterford.

Both NextEra and Constellation have put a lot of energy and work into a major design license amendment request for Turkey Point and Limerick, planned to be submitted to the NRC later this year, and as we all know on a broader scale, industry, NEI, DOE, EPRI, IEEE, and other licensees have made some good passenger in the digital I&C arena, especially in developing statewide practices and standards from digital upgrades to support your long-term operations.

So, truly our goal today is for everyone to share these insights, build upon streams and experiences we have gained from a regulatory perspective, and of course, identifying challenge areas where more attention may be needed to address fact of life changes in how these digital I&Cs are implemented.

We are confident this workshop will succeed for a diversity of stakeholders that we have here today. Finally, because I am a regulator, I do have to make one disclaimer and fall upon what BP said.

No regulatory decisions will be made, we do have two pending applications before us in pre-application space. Indeed, part of this workshop is to discuss their experiences and lessons learned from the security application interactions.

However, we cannot use workshops to make decisions on specific issues associated with those applications that are coming to us. Those types of discussions of course will be made in separate application interactions.

So, again, welcome, we do have a packed agenda. There are some impressive presentations and I'm excited to get started. With that, BP, any issues

to communicate before opening remarks?

MR. JAIN: Yes, I'm requesting to NEI if they would like to make any opening remarks. Alan?

MR. CAMPBELL: Thank you, BP, can you guys hear me okay?

MR. JAIN: Yes.

MR. CAMPBELL: Good morning, everyone, I am Alan Campbell and I'm a technical advisor with NEI and we are the Digital I&C Work Group. I want to thank the NRC for hosting this workshop today.

I think we have a lot of great agenda items and great discussions to look forward to.

As Mike was just mentioning, ISG-06 Rev 2 and the associate alternate review process were a great step forward for the industry and really helped provide licensees with the confidence to move forward with a fresh wave of digital I&C applications.

These digital modifications are imperative for our industry as we continue to strive for safe and long-term operation of our existing fleet. As expected, we have learned a great deal through these initial projects using this approach.

And we appreciate the opportunity today to discuss the lessons learned using this process and garner insights from the inspections. In addition to

gaining a good understanding of the lessons learned, NEI and its members are looking forward to the discussion on human factors engineering, expectations during the LAR process.

We appreciate the NRC's efforts to communicate its concern with the availability of information and the potential path forward using multi-stage validation and earlier public discussions.

Our goal today is to further this discussion with an alternative approach that aligns with the intent of the alternate review process and uses a research-based approach that has proven to lead to successful integrated system validation results.

Ms. Pareez Golub will be presenting on behalf of NEI and its Members, and we've allocated part of the NEI timeslot for Idaho National Labs to present some research pertinent to the discussion.

Our goal today with that discussion is to identify any considerations or significant challenges to our alternative approach. We're also looking forward to discussing the NEI member comments provided to the NRC on the inspection plan 52003.

While we understand inspection procedures do not typically require public comment periods, we felt that it was necessary to identify key items that

we believe can be resolved generically to avoid any misunderstandings or misapplications in the future.

And we appreciate the NRC's willingness to engage with the comment resolution process on this matter. Again, I want to thank the NRC, specifically BP and Michael Marshall, for arranging this workshop. And we look forward to a great dialog through today's meeting.

MR. JAIN: Thank you, Alan. Now, I'll next introduce Samir Darbali, he's the Staff Team Lead for this morning's session on the presentations, licensing and inspection lessons learned.

Now, we have several other NRC Staff online and as they contribute to the meeting they will introduce themselves. Please wait for your questions until the end of each presentation.

With that, I will now ask Samir to make the Staff's presentation. Samir?

MR. DARBALI: Thank you, BP. My name is Samir Darbali, I'm an I&C technical reviewer in the Division of Engineering and external hazards in NRR. And I'll be going through the licensing and lessons learned slide.

Like was mentioned, we had the first lessons learned digital I&C workshop back in February

of last year, which although it was early in the use of the alternate review process or ARP, it proved to be very productive.

We have covered the background and history of ISG-06 before and so we're not looking to repeat that today. We can think of the theme for this presentation to be where we started, where we are, and where we're going when it comes to ISG-06 usage for digital I&C modernization.

So, following that theme, we'll start looking at what was the intent of the alternate review process when it was developed. We'll then move into some of the deviations we have encountered and how the overlap of the licensing and development schedules is somewhat shifting.

We'll also identify some of the lessons learned related to information submittals, licensing audits, the vendor oversight plan, and the VOP summary.

We'll also talk about the review scope of other NRC Branches that are outside of the INC grout, and finally, we'll look at some of the things that we can do to achieve licensing success path for digital I&C modernization.

As Mike mentioned, the current digital I&C

licensing activities that are exercising key portions of ISG-06. The Waterford III core petition calculator short-term replacement was the first application using the alternate review process and it was approved in August of last year.

The Staff also completed the inspections for the factor acceptance testing and set acceptance testing, SAT, and we're currently preparing for the site installation inspection.

We've also been engaged in pre-application meetings since 2020 with the licensees for Turkey Point and Limerick and we're expecting their respective digital modernization LARs to be submitted this year.

So, the main intent of the ARP was to allow for issuance of a license amendment prior to completion of the system's implement and test lifecycle phases. This would provide licensees with much needed regulatory certainty.

An application based on the ARP would focus on the system design, the development process for the system's software and hardware, a summary of the vendor oversight plan, and additional regulatory commitments for those lifecycle activities that take place after each license amendment.

And system implementation and testing including factor acceptance testing is subject to oversight through NRC inspections as well as the site inspections.

This slide shows the ISG-06 licensing re-process options provided to licensees for developing license amendment requests. Each lane is for a specific review process and there are prerequisites for using each lane.

The tiered lane provide the benefit of supplemental information as well as options for referencing a pre-approved topical report.

The ARP lane provides the benefit of an earlier approval but doesn't allow for supplemental information to be submitted and doesn't allow for deviations from the topical report.

That means that not all applications are suited for use in the ARP as it is described in the ISG. We typically compare the tried process with the ARP and the ARP shouldn't be seen as being easier for either the licensee or the Staff, it just means that it's packaged in a way that supports an expedited review.

So, for a licensee that wants to use a platform that hasn't been approved previously through

a topical report, let's say they identify a vendor and they want to use this platform that hasn't been approved, that's something that is accommodated in the tiered process.

They just need to provide details on that platform in order for the Staff to perform its review. For a Tier 2 application, we're looking at a licensee referencing an approved topical report but there are deviations in the application.

So, for example, it could be new modules, a change in technology, some new cards or a change in software that wasn't approved during the topical report evaluation.

So, the licensee would need to add that information into the application for the Staff to be able to review the system.

And then the Tier 1 process references the topical report without any changes. So, out of the three tiered options, that provides the more efficient review process.

And the Staff's focus in the evaluation is based on just those plant-specific aspects of the modification, including plant-specific action items from the topical report.

Now, the ARP also references a previously

approved topical report but like we said, it doesn't allow for deviations to that topical report.

So, you wouldn't expect an application that resembles a Tier 1 with some supplemental information or Tier 2 with deviations to the topical report to follow through or use the ARP lane.

So, the ARP lane does provide that expedited path but an application has to meet the prerequisites for using that lane.

And as we'll cover later, one of the key aspects and benefits of the ARP is the earlier issuance of the license amendment followed by inspections of implementation and testing.

So, the ARP was developed to provide licensing review guidance to quickly support upcoming digital I&C modifications.

This intent was that all information was to be provided in a single high-quality submittal, meaning that there would not be a need or room for RAIs or supplemental information.

The emphasis was given on determining how past one-for-one digital modifications like Oconee, Diablo Canyon, and Hope Creek could be reviewed and improved before completion at FAT.

Emphasis was not given specifically to

modifications that will be envisioned in the future like those that incorporated a combination of systems, the elimination of sensors, measure of control room changes, changes to plant defense in-depth and diversity, or crediting of self-diagnostics to eliminate surveillance requirements.

We knew those applications would eventually come but the expectation was that they would come in after the ARP had had enough run time and lessons learned.

So, we've covered the intent of the ARP and now we're going to look at what we're seeing currently, which is that actual applications deviate in some manners from the ISG-06 guidance in terms of the LAR contents, the use of supplemental information, and the licensing and development timelines.

The scope of LAR modifications is more expansive and goes beyond the one-for-one digital replacements that we were expecting.

And they include changes to plant architecture, operations, and tech specs, which requires added NRC resources to address more complex applications.

Now, minor or modest deviations are not necessarily impediments to the review if they're

addressed early in pre-application meetings. The challenge really is in attempting to apply a specific ISG-06 licensing process when the application doesn't align with that process.

To address these deviations and maintain regulatory certainty, the Staff and the licensee may need to adjust the licensing review scope and schedule, as well as their expectations.

This includes adjusting for the potential for additional information to be audited or docketed, changes to the licensing review and license amendment issuance schedules, and changes to the licensing audit and inspection scopes and schedules.

Flexibility on the part of the Staff and licensees will need to consider other aspects of the application, such as the level of detail in the vendor oversight plan, the use of regulatory commitments, and even the safety significance of the modification.

Now we're going to talk about the scheduling deviations.

The ISG-06 describes what can be considered as the model cases for Tier 1 and ARP in the sense that it assumes that specific licensee and vendor lifecycle development activities will overlap with specific NRC licensing review and inspection

activities.

The Tier 1 review schedule overlaps with the system design implementation and testing lifecycle phases, whereas, the ARP compressed the licensing schedule to overlap with the system design and early implementation.

What we're seeing is that the actual system development schedule appears to have also been compressed and so the implementation phase is taking place during the later half of the licensing review, also supplemental information submittals like equipment qualification summary reports have an impact on the review schedule.

And this has resulted in an overlap of the development and licensing schedules that are neither the ARP or the Tier 1 as it was envisioned in the ISG. So, this slide shows the model case for the ARP licensing and development timelines.

Most of you have seen variations of this timeline before, it keeps evolving as we gather more lessons learned.

But the top part in blue are licensee and vendor activities, going through the different lifecycle phases, and the bottom part is the NRC licensing inspection activities.

And typically, what happens is a licensee will identify an installation date based on a specific refueling outage, when they want to install the system, and that's going to determine, as we'll see in a later slide, when they really need that license amendment to be issued and approved and also that's going to determine when they're going to be able to submit the license amendment request.

As you can see in the model case, ARP supplemental information is not provided. The Staff performs the licensing review and regulatory audits based on the information in the LAR which includes requirement specifications and a level of detail of the system design in order to demonstrate that the regulatory criteria is met.

I do want to point out that the date when the license amendment is issued doesn't mean it's the time when the Staff completes our safety evaluation.

The Staff actually completes the safety evaluation a month or more before, which means that after the Staff completes their draft SE, that SE goes through internal reviews and concurrences, no legal objection review by OGC.

There may be ACRS meetings taking place in this time and of course, preparation of the license

amendment itself. So, there are other activities that take place after the Staff has completed their draft safety evaluation.

Because at this point, you could say the Staff has put their pencils down, they're not reviewing any implementation activities that are taking place so at that time, if necessary, we would expect vendor oversight plan implementation and vendor inspections to begin.

Those would be carried out until factor acceptance testing and they would be followed by regional inspection side activities, including side acceptance testing.

This slide shows how an actual ARP licensing and development timelines have shifted. There's no easy way of having this timeline show the effects of multiple deviations without becoming too complicated and hard to read.

So, these examples show the effects that multiple supplemental information submittals have on the licensing review schedule.

So, you can see supplemental information is being provided so that extends the licensing review schedule and compresses the VOP and vendor inspections.

Now, a similar effect may happen when the review schedule remains the same and there isn't supplemental information submittals, but the lifecycle development phases are compressed because for some reason, it doesn't take the vendor as much time to complete each lifecycle phase.

So, those would be compressed but it would have a similar effect that the license amendment is getting issued somewhere in the testing phase. Now, in both cases, that license amendment is still being issued before completion of factor acceptance testing.

So, this slide shows the factors that determine the licensing and development schedules. So, the factors are, like I mentioned earlier, when is the license amendment needed?

That is going to be determined by when the modification is going to be installed. That's going to feed into when the project starts and so when are the development lifecycle phases started and completed?

Some of the early lifecycle development phases like concept design requirements and early portion of the design phase are going to feed into the contents of the LAR.

So, the schedule for those lifecycle

phases is going to determine when the LAR is going to be submitted and depending on if additional information is going to be provided, when will all of the information be submitted.

These three factors are dependent on licensee and vendor resources as well as complexity of the design. So, once all that is incorporated and we have a LAR, then the question is on the NRC side, when can the Staff complete the draft SE?

And that's going to be determined on what is the time needed to perform the licensing review? Again, that's going to be dependent on NRC's Staff resources and the complexity of the design.

After the Staff has completed their SE, the question is when can the license amendment be issued? And that's going to be dependent again on those post-draft SE activities and those NRC internal processes.

So, what we do during pre-application meetings is the licensee will come in and say we are thinking of submitting the LAR at this particular date and we would like approval by this particular date.

So, we go through all of these exercises to understand the scope of the modification, the need for supplemental information, and looking at resources

that both the licensee, the vendor, and the Staff side.

And what we're trying to achieve during pre-application meetings is can the license amendment issuance date meet that license amendment request date? So, that's an exercise that we do.

This slide shows the first table of Enclosure B, which identifies the typical information to be submitted depending on the applicable review process. And it points to the respective sections of the ISG for the detail criteria.

So, the information in the Enclosure B tables is based on the applicable lifecycle information and outputs that are subject to Staff review and audit. The tables assume a model case application and did not account for deviations from the ISG-06 guidance.

So, given any deviations or application-specific aspects, we can expect the different information from that identified in Enclosure B may need to be provided.

In the end, the information submitted for an actual application and the timing of submittal may end up resembling something in between the ARP and a Tier 1 application.

So, for example, when it comes to the crediting of self-diagnostics for the reduction or elimination of surveillance requirements, there is certain information that needs to be provided besides what is identified in the ARP.

This is because even though such surveillance reductions had been approved before under the TR review process, this was not a review topic that was considered when the ARP was developed.

However, licensees do want to credit self-diagnostics for the elimination of some surveillance requirements and during pre-application meetings, we have identified that an FMEA needs to be provided to support a technical basis.

Licensees will need to provide analysis to justify the crediting of self-diagnostics for a tech spec surveillance requirement reduction and we'll need to perform periodic functional tests and the self-diagnostic features to satisfy BTP 7-17 guidance.

Licensees will also need to provide a description of plant administrative control that will provide assurance that falls are captured and investigated. And here are some lessons learned regarding the licensing audits.

During the pandemic we relied on virtual

audits of undocketed material and living documents like the VOP.

And this has proven to be very effective, using open items during audits and providing questions to the licensee in advance of virtual audit really improve the effectiveness and use of the audit time.

We did find that in-person audits of the vendor should still be performed during the licensee review and this helps Staff and inspectors familiarize themselves with the system and interfaces.

And the scope of the information to be audited should include those vendor and licensee documents developed during the licensing review.

If any audit information is needed to support the Staff's draft safety evaluation, then the Staff will ask the licensee to place that information on the docket.

Now we'll talk about the integrated licensing reviews, a digital modification encompasses various technical review disciplines, and depending on the application, the Staff responsible for these branches may be involved in the licensing review, the inspections, or both.

Each branch involved in the review will use the criteria found in the SRP for the respective

review area, the guidance in ISG-06 is the digital I&C portion of the review.

The ISG is structured in a way to reference or interface with other guidance such as the SRP, BTPs, and other disciplines such as human factors engineering.

And now I'll turn it over to Charley Peabody from the Reactor Systems Branch in NRR, who will go over the reactor systems review of diversity and defense in-depth. Charley?

MR. PEABODY: Thanks, Samir. Depending on the application, like Samir said, you can get either INC Branch reactor systems or human factors engineering staff involved in the defense in-depth portion of the review.

That involves a systematic approach used to analyze a proposed digital I&C system for common cause failures which can occur concurrently within a redundant design.

Branch Technical Position 7-19 discusses how you address those common-cause failures and provides three potential paths to deal with them.

You can either eliminate the common-cause failure from consideration, you can use diverse means to mitigate the common-cause failure, or you can

determine that the consequences of that common-cause failure may be acceptable and still be able to meet the requirements of the accident analysis.

Some of the reviews may require re-analysis of Chapter 15 accidents. Next slide, please.

For reactor system reviews, the following items are expected to be included in the D3 analysis, identification and selections of transients and accidents that are to be considered in combination with a common-cause failure.

So, basically, that requires addressing all Chapter 15 events, both anticipated occupational occurrences as well as the postulated accidents. Other critical events such as those initiated by spurious actuation that are not analyzed in Chapter 15 may also have to be considered.

Description of what systems are lost during a common-cause failure, either whether that's, for example, in the past reactor trip system or engineer safety features and then you identify and describe the credited diverse equipment which can be either existing or new equipment and doesn't necessarily have to be safety-related if you can show that it's of sufficient quality.

We'll also consider identification for

credited operator actions in lieu of systems that are lost. And like I said, that factors into the evaluation and analysis of each event.

Next slide, please. Actually, I see somebody has a hand up?

MR. HERB: Yes, this is Ray Herb from Southern Nuclear, I really had a question on the previous presentation. It can wait until you're done and when we get ready to go to break, then ask it. But it was on Samir's presentation.

MR. PEABODY: We'll circle back to that.

MR. HERB: Thank you.

MR. PEABODY: Like I said, that gets into the event characterization and analysis. So, when you're determining what level of detail needs to be provided, if the event where the CCF has no adverse effect, those events require no reanalysis.

If the events are terminated by a diverse system, you need to discuss what those diverse systems are and describe any changes or a side-by-side comparison of the diverse system actuation timing versus the original based timing.

And depending on the results of that, a new analysis may need to be performed if there's a significant time difference between the base and the

new case. Next slide, please.

If the event is dominated by another event, you can just refer to that, that for instance, in the past, an inadvertent steam generator relief valve opening may be bounded by a steam line break.

And other than identifying that it's bounded by the other event, it doesn't require any initial analysis, just the analysis of the bonding event.

The events that the analysis is required to demonstrate that acceptance criteria are met, these are basically what were not eliminated by other categories.

And they may be analyzed using either best-estimate methods or conservative methods. And an analysis must be done to demonstrate they meet the acceptance criteria in Section B3.3 of Branch Technical Position 719.

Next slide. The D3 analysis is considered for all relative events and then we're going to determine that they were categorized correctly, whether it's any of the three outcomes that were previously mentioned.

And we'll also verify that it has demonstrated the consequences of common-cause failures

remain acceptable, so should the common-cause failure occur, the facility will remain within the appropriate acceptance criteria for the limiting events applicable to the proposed digital I&C system or component.

Next slide. This is just an example of some previous ones that we've looked at and what methods are credited in each one.

I guess I'll either turn it back over to Samir or I don't know if you want to go back and address that question now, or whether you want to go onto human factors?

MR. DARBALI: We'll go on with Human Factors and we'll get your raised question when we finish. I think we're close to the end. Thanks, Charley.

MR. PEABODY: Thanks, Samir. I'll now turn it over Brian Green from the human factors team to give a high-level overview of human factors engineering review of digital modifications.

MR. GREEN: Thanks, Samir, good morning, everybody, can you hear me okay?

MR. PEABODY: Yes.

MR. GREEN: I'm going to just speak real quickly here because I do have some time on the agenda later where we'll go into these points in more detail

but just some observations we've had here related to the human factors engineering, a point to start with is ISG-06 points out the HFE review guidance area is not within the scope of ISG-06.

Instead, rather that's handled by Chapter 18 and that's in concurrence with NUREG 0711 Rev 3, the human factors engineering program review model.

One observation we've had is that some of the recent modifications we've been discussing have been more significant than what were considered at the time that ISG-06 was developed and revised. So, we're kind of adapting and working out ways to adapt to that.

We have also notice there have been some scheduling challenges with regards to the review of the integrated system validation testing, it's one of the key human factors points of contact and there are some challenges as far as how and when to schedule that in order to make the modifications to simulators while still maintaining the ability to do other functions in the simulator such as operator licensing training and other activities.

To address that, the NRC Staff have been considering some possible alternatives that may help provide a suitable regulatory checkpoint that's a

little bit earlier in the process to break the log jam at the back end there, so to speak.

One of the methodologies we're proposing for that is to use a multi-stage validation test program, which effectively spreads out validation activities throughout the course of the design work into different discrete steps.

And we believe we can, depending on how an MSB program were designed, we could probably find enough support for the design a little bit on the left of the schedule when the ISV would happen, and that may free up some scheduling opportunities there.

We've also been considering various alternative test beds that would allow testing to happen without necessarily modifying the plant simulator. At the same point, one of the really promising tools for that is the glass-topped simulators.

But our discussion has not been limited to just those, there are other methods that may also be acceptable to use within an MSV program. And I mentioned earlier that I'm going to discuss this in detail later so I think that's all I've planned to cover this morning.

Back to you, Samir.

MR. DARBALI: Thank you, Brian. I'll now talk about the secure development and operational environment and the cybersecurity considerations. Clause 5.9 Control of Access of IEEE 603 1991 is the basis for SDOE reviews.

Section D8 of the ISG discusses the SDOE reviews and refers to the guidance in Regulatory Guide 1152 Revision 3. And so the ISG also provides guidance to NRR Staff to coordinate with NSIR Staff on matters related to cybersecurity.

Now, the licensing review of a digital I&C modification does not include a cybersecurity review for compliance with 10 CFR 7354, which is the cybersecurity rule.

The regions with NSIR's support perform cybersecurity inspections of the digital INC modification and the licensing review is independent from the cyber inspections and the cybersecurity inspections did not impact the licensing review schedule.

And so NRR, NSIR, and Regional Staff worked together to ensure adequate coverage and understanding of the SDOE and cybersecurity aspects of the modification and this includes security requirements for controls to be implemented by the

vendor, supply chain requirements of the cybersecurity plant, and security impact analysis of the modification.

So, the combination of SDOE and cybersecurity programming provisions address the secure design, development, and operation of digital I&C safety systems.

So, you can see in this table that there is a difference when it comes to the focus of SDOE and cybersecurity, the focus on SDOE is on safety, and we're looking at aspects that are non-malicious acts where cybersecurity is focused on prevention of radiological sabotage and malicious acts.

Regulations are different for SDOE. It's 10 CFR Part 50, for cybersecurity 10 CFR 7354, and the Regulatory Guides are different. Again, for SDOE is Reg Guide 1152 Revision 3 and for cybersecurity it's Reg Guide 571.

And almost all licensees use NEI 0809 Revision 6 as the basis for their cybersecurity plants. And I'll now turn it over to Deanna Zhang from the Vendor and Quality Inspection Branch to talk about the VOP.

Deanna, are you there? You might be on mute. Just give us a minute, folks.

MR. JAIN: Is Greg going to do the presentation?

MR. DARBALI: Greg was doing the inspection portion of the vendor inspection presentation. So, hopefully Deanna can join us and I'll go over the VOP slides.

So, the Staff recognizes the need for guidance for developing the VOP and VOP summary. This is not just an industry comment or feedback, we also understand these internally.

We do plan on developing this guidance after the licensing actions for Turkey Point and Limerick and use those lessons learned in the development.

For the Waterford III review of the VOP, the Staff evaluated the licensees' oversight activities as described in the VOP summary.

And we did that again following the criteria for Appendix B 10 CFR Part 50, Criterion 3, inline control, Criterion 5, instruction and procedure on drawing, Criterion 7, control of purchased material, equipment, and services, and Criterion 16, corrective action.

The VOP framework should supplement the licensee's overall QA program descriptions with

specific system, hardware, and software development activities, including a description of the proposed development lifecycle, development documents to produce, and management activities that will be implemented in the design and the development of the I&C safety-related systems.

The VOP and VOP summary should address how the licensee's oversight activities will verify the software development processes and the lifecycle design outputs meet the software development process descriptions that are summarized in the LAR or any reference software program manual.

If the full VOP is not a lengthy document, it may be beneficial for a licensee and the Staff if they submitted the full VOP in the LAR instead of a summary, that of course is up to the licensee.

Engineering procedures that are used to implement the VOP should be described in the VOP and VOP summary, including how they fit into the overall QA program for the site.

The critical characteristics that will be verified by VOP activities should reflect system and architecture design that is specific to the application being reviewed.

Identification of all documents that will

be reviewed and approved as an engineering design document should be identified. And identification of all lifecycle activities including V&V activities should be described.

And the VOP and VOP summary should describe the VOP changed controls. So, we need to understand what is the process and the controls the licensee has for changing the VOP after the license amendment has been approved.

Regarding the VOP audits, they serve several purposes. First, if the full VOP hasn't been submitted in docket, then the VOP provides for the Staff to review the full VOP and this can be done as part of a virtual audit.

VOP audit also helps the Staff to verify how the licensee is implementing the VOP and to determine if there is reasonable assurance that the licensee will implement the VOP after the license amendment has been issued.

For Waterford, the VOP audits were conducted throughout the log review timeframe. The focus was on VOP activities described in the VOP summary plus details of implementation provided in the VOP itself to ensure consistency.

Like I mentioned, the pandemic required

these activities to be performed virtually.

A lesson learned or some feedback that we got internally is the VOP audit should take place after the audit of the vendor or if a vendor inspection does take place during licensing, then after the vendor inspection.

And this helps the Staff to focus on specific items that will be audited. The licensee's implementation of VOP activities may not occur sequentially in accordance with the development lifecycle.

This is something that should be explained in the VOP. For example, oversight activities or the implementation phase may take place after completion and observance of the factor acceptance test phase.

One thing we also notice is that the licensees' oversight audit reports may lack the actual observed vendor activity by as much as a month or over a month.

So, this creates a challenge to the Staff reviewing the licensee's VOP audit reports as they are seen as issues identified months in the past and may not be aware of the resolution in a timely manner.

If the licensee's VOP audit report will be issued after completion of the draft ANC, the Staff

may need to consider if an NRC audit of the vendor is more practical to support the licensing review.

So, we've gone over the intent of the ARP, we've gone over some of the deviations that we're encountering, how the overlap of the licensing and development schedules are shifting, and we've gone over some of the lessons learned and some of the human factors engineering and reactor systems' radioactivities.

So, now how do we apply these lessons learned and move forward to achieving a success path for digital I&C licensing?

If an application comes in and follows the tiered or ARP guidance according to the ISG, then great, this is going to maximize the regulatory certainty and the certainty of the review schedule.

But if an application doesn't follow the tiered ARP guidance according to the ISG, then the Staff and the licensee will need to consider what the licensing review schedule is going to look like.

And what is a reasonable review time and does the schedule support the requested installation date?

What information needs to be submitted and depending on the modification and the review schedule,

it could be a mix of the ARP Interior 1 and what's going to be the availability of the information, what is going to be submitted and when.

This way of moving forward provides for some efficiencies and flexibilities that allow both the Staff and licensees to navigate through licensing process deviations.

Both the Staff and licensees need to be flexible to allow for consideration of other aspects of the application such as the level of detail in the VOP, the use of regulatory commitments, and safety significance of the modification.

It's likely that moving forward in this manner can result in a license amendment being issued before it would have been issued under the Tier 1 process. And when compared to the ARP, it's likely that some inspection activities will be covered instead through licensing audits.

Now, the goal for industry is to get the digital modifications license approved in time to be installed and to do so with regulatory certainty.

The goal for the Staff is to have all the necessary information to make a safety determination on the adequacy of the digital modification.

If the necessary information can be

provided in a timely manner to support the licensing review and the license amendment is issued in time to support the planned installation date, then I think we can consider that to be a success.

But in order to do that, the Staff and licensees have to be flexible and adapt to the licensing process deviations and be accountable for those changes.

We have to continue having productive communications during pre-application and licensing review meetings, maintaining openness on the scope of the modifications and what the deviations are, and having realistic expectations of what the licensing review process is going to look like if the application doesn't meet the guidance in the ISG.

Finally, we have to continue to leverage lessons learned, the use of innovative tools like open items or virtual audits, and licensing successes we've had both using Tier 1 and ARP.

And with that, I think we're ready for the questions so we'll start with you, Ray.

MR. HERB: This is Ray Herb from Southern Nuclear and first of all, I want to say I appreciate the NRC's willingness to be adaptable and flexible in the licensing process, and I think this works out as

a great idea.

But I had a question back on Slide 11. I wasn't sure if you were taking questions in the middle of the presentation or if I had to wait until the end, so that's why I raised my hand.

But here I seem to have heard that you say those vendor oversight parameters and vendor inspections and activities could not really start until the draft SE was complete.

And my question was if some of those activities in my VOP happened to happen before that draft SE is complete, would the NRC still support those? Would those move into a different phase?

Or would we be sitting around just waiting to hold those activities before you guys are done?

MR. DARBALI: Now, those would be part of the VOP audits and I'll jump back to the VOP audit slide. So, like we said, there's a few purposes for the VOP audits.

The first one is to review the full VOP and then to see the implementation of those VOP activities that take place during licensing.

And the idea of performing those implementation audits during licensing review is for us to get a better idea of, hey, the licensee is

implementing the VOP, they are performing their inspections with being able to audit the licensee oversight audit reports during the licensing review.

And that gives us a level of assurance that, okay, we feel confident they're going to maintain that same level of vendor oversight after we've completed our draft safety evaluation.

MR. HERB: That makes me feel much better because I was thinking that we wouldn't be able to even start those activities on our end until after that green box was complete, and the yellow box.

But they would still happen, they would just be in a different space for you guys, and because those activities may be planned out years in advance.

MR. DARBALI: Right, and to add to that, the licensee's vendor oversight activities shouldn't depend on when the Staff is reviewing them, whether it's on licensing or it's on inspection.

That's your oversight, you control that, what you're providing us is the vendor oversight planned summary and a lot of the plan itself and the implementation, what takes place during the licensing review ideally becomes a licensing audit.

And what takes place after that would go into inspection.

MR. HERB: Thank you for clearing that up.

MR. DARBALI: Thank you for the question.

MR. JAIN: I see another raised hand.

MR. CAMPBELL: Good morning, Samir, this is Alan Campbell. Back on Slide 6, it stated that the ARP is intended to have no RAIs or requests for additional information. This seems to be some new information or a new expectation.

Even when I'm reading through ISG-06, it acknowledges the RAIs as part of the ARP process. Can you help provide a better understanding or a basis for that?

MR. DARBALI: So, when we were developing the ARP, again, we're looking at what was reviewed and approved before under the TR process and the idea is how can this be reviewed and approved in a shorter timeframe, get that approval before completion of factor acceptance testing?

And what was looked at was, well, we're going to need an application that's complete. And the time that was being requested was much less for the Staff to perform their review.

So, we had these conversations with industry during the development of the ISG. If we're looking at adding RAIs, that's going to push the

review schedule and it's not going to be as early as what was being requested.

Now, I'm curious to see which section of the ISG, you say it's referring to RAIs for the ARP?

MR. CAMPBELL: Yes, it's Section C.3.2.2. It's a fairly generic statement that just alludes to an RAI process.

So, the NRC Staff should draft the safety evaluation and issue RAIs for information or clarifications necessary to finish the review of the docketed material.

MR. DARBALI: So, we understood that it might not be realistic to have an application that's perfect but the goal for that LAR was that it has to be as complete.

RAIs should be the exception, not the expectation, in order for us to meet that schedule.

MR. WATERS: Hey, Samir, this is Mike Waters, I do want to supplement. And I think, yes, RAIs are part of the licensing process, no doubt about it, but our goal at NRC is never to have RAIs, right, but that does happen.

I think the point being made is based on the history of previous digital I&C modifications, there's a mentality and thought process on both sides

that multiple-phase submittal, NRC details what we need later on through an RAI process.

We'll plan to have an RAI, we'll plan to have a supplement to address these gaps that we know exist today. So, the more fundamental point for ARP is no, the idea is to submit everything up front.

We've aligned clear expectations of what's needed up front.

There are no plans to supplement later through an RAI process for example, and that was the paradigm we had before the ARP and I think what we're trying to communicate is the ARP paradigm now is the idea at the time was to submit everything at once.

We're not playing at supplements later, we're not playing to purposely ask RAIs because we'll know a supplemental meeting later. We know what we need up front and I think that's what was meant here.

MR. DARBALI: Right, the flow chart for the alternative process does incorporate RAIs. I think the intention was to -- again, this is guidance for the reviewers to understand.

You always have the option to ask RAIs but I think Mike explained it well.

MR. CAMPBELL: I think just my understanding here is through the presubmittal phases

and through the communications up front, we want to aim for the best and highest quality submittal possible.

We just wanted to make sure that from the expectation point of having a perfect submittal every time, that's a really high bar to achieve but our intent is to minimize the RAIs as best we can to keep within the review windows that we're aiming for.

MR. DARBALI: I see Rich and then Ted?

MR. STATTEL: They key point here is the supplemental information and I also want to explain that when we first developed ISG-06 in the previous revision, the NRC and us worked together and we recognize that we're performing these evaluations in parallel with the systems being developed so it's a moving target.

So, back in 2007, 2008 timeframe, industry asked us to have this two-phase submittal process to accommodate that. And in a sense, we're evaluating a moving target because the system is being designed and evaluated at the same time.

So, that was the original premise of ISG-06. What happened with the revision was when we created the alternate review process industry also asked us to provide this early issuance of the license

amendment.

And that basically threw the whole process out of whack because in order to do that, in order to accomplish that, the early issuance, prior to testing of the system, we really needed to have a once-and-for-all submittal right up front.

And we could no longer adopt the Phase 2 submittal that was later in the process, we just couldn't do that. So, that's how that evolved to where it is and that's certainly being challenged with the applications we're receiving today.

MR. DARBALI: Thanks, Rich. Ted?

MR. QUINN: Samir, can you hear me okay? Good morning, and thank you, NRC, for doing this and providing this workshop. It follows up on the February one that I thought was so well done.

It's Ted Quinn from Paragon. My question relates really to the Vendor Inspection Branch. And there's a second question on eRoom that may have to be done at a later time today.

On Vendor Inspection Branch and the VOP at Slide 27 and 28, that series that you presented, Samir, I wanted to talk about the division of responsibility between NRR and the Vendor Inspection Branch.

I think it's a great addition to the Staff on this new process to us relative from after Diablo Vendor Inspection Branch but the ideas on, say, Slide 28, do you have lessons learned on the division of responsibility between vendor inspection and NRR in, for example, software development activities?

Did you during, say, Waterford or previous license reviews address that the Vendor Inspection Branch focused more on procedural guidance and that the NRR focused more on evidence, on did that incorporation -- what did you see of this overlap, how it was handled?

MR. GALLETTI: Samir, this is Greg, I'll try to respond to that. This is Greg Galletti with the Nuclear Regulatory Regulation. I'm in the Quality Assurance Vendor Inspection Group and was responsible for leading some of these inspections.

Ted, to answer the question, what typically happens when we engage a vendor on a vendor inspection, we're going to have a combination of quality assurance personnel staff from the NRC as well as some of the technical staff that we're responsible for doing the licensing reviews.

So, those individuals would have an in-depth knowledge of the systems being modified or

changed and the processes being used, the technical requirements for those systems.

So, when we would go out to do the vendor inspection, it would be a combination of the two things that you brought up.

One is we would be looking at the vendors, Appendix B quality assurance program implementation, looking at the procedures and implementation of those procedures and focusing more primarily on those important system requirements that the technical staff has identified and evaluated as part of the licensing review.

So, that's typically how we would go about doing these. Does that answer the question, Ted?

MR. QUINN: It does, I guess you would sit side by side with NRR and as they do their reviews of, say, the different documents that are being developed in the software lifecycle, for example, then you perform your review and they perform their reviews as well?

MR. GALLETTI: Yes, and it's a collaborative effort, quite frankly. We, the vendor group, are in NRR also. So, they are a sister branch --

MR. QUINN: Sorry, you're right.

MR. GALLETTI: No problem, but as we go through the licensing review, we and the quality assurance staff also have people involved in the licensing amendment review.

And so we are familiar with the VOP, the VOP summary, the application in general and we work together with the technical staff to develop RAIs and open issues, open questions and we support and are involved in the auditing that goes on before the safety evaluation is drafted.

So, there's a very, very strong collaborative effort.

MR. QUINN: Thanks, what I should have said is the I&C branch and I like what the VOP is doing. So, let me go on, Samir, to the eRoom. Where today are the potential benefits of eRoom?

It was discussed well in the February workshop so is that on the agenda today?

MR. DARBALI: What do you mean by eRoom, Ted?

MR. QUINN: So, the eRoom is the post-LAR acceptance and the start of review process, and the integrated actions we did, say for example, during Diablo where there was the exchange of information between the utility and the NRC on the many documents

that were available for the review cycle.

It was very detailed and there's many documents on the order of 40 or 50 documents. And there was an eRoom discussion that did occur during the workshop in February and I'm wondering if that's on the agenda or is that a separate item?

MR. DARBALI: I'm understanding you're talking about the acceptance review that we do once we receive the LAR.

MR. QUINN: No, it's beyond that.

So, the issue is there are docketed and undocketed items and the issue part of ISG-06 Rev 2 was the streamline the process so that it would be clear on the availability of information to NRC and the three potential docketed audits and inspections.

And the purpose of an eRoom was to help optimize that so that the NRC would request specific docketed information. But it would be done in a tailored manner to the information you really need in order to write the SER.

So, the eRoom was a clear access of information to the Staff in all of these many, many documents that are developed as part of a hardware or software lifecycle. Is that clear? Is that not clear?

MR. DARBALI: So, you're talking about the virtual portal?

MR. QUINN: Yes.

MR. DARBALI: We don't have digital information on this presentation from what we provided in February of last year but for Waterford, we used that virtual portal throughout the licensing review.

So, we used Certrec and what we did is we developed an open items list similar to what we have done for the Diablo Canyon review and we developed and tracked those open items.

And those open items were carried into Certrec.

And we were able to look at those living documents that were being developed and then we would perform virtual audits to determine if this is something that we need to have docketed or if it just becomes part of the audit scope.

But yes, the eRoom or the virtual portal has been tremendously useful for the Staff and licensees in reduction of docketed material and just speeding up the process of getting that information.

MR. QUINN: That was tremendous, thanks.

MR. WATERS: This is Mike again, I just want to add on just for everyone's awareness, that

open IM process and portal that was formally done in our licensing auto process.

We had a long process and procedures and we had I believe a consumer-defined audit plan that defined that process. So, it's transparent and open to everybody what we're doing here.

Of course, a lot of it is proprietary but that was technically under the licensing audit process and how we defined that.

It did take a lot of effort for us to get started, I'm looking forward to Entergy's comments on that because I know the first few months was hard to get the fireworks on.

But once it all got going, it was extremely beneficial, Samir.

MR. QUINN: To us on both sides as well. I'm really appreciative for both of your discussions here. Thanks.

MR. DARBALI: And Ted, going back to your question on the VOP activities and interaction between licensing and inspection, in the slides for last year's workshop, I believe there is a table that identifies the VOP activities during the licensing review and that falls into inspection.

MR. QUINN: Thank you.

MR. DARBALI: I see Ron Jarrett, go ahead, Ron.

MR. JARRETT: Can you hear me?

MR. DARBALI: Yes.

MR. JARRETT: There was a trigger word in one of your slides on VOP, the word all. I don't know what slide number it's on but it said something about listing all the engineering and approved documents.

Could you I guess be more specific on what all means?

MR. DARBALI: We'll ask Greg if he can take it.

MR. GALLETTI: Sure, this is Greg again. I guess all is probably not the proper term to be used there but the intent of that comment is in the VOP summary itself it talks about various vendor oversight activities of the licensee.

And what we have learned from the experiences is that the implementing procedures that you're using for various activities and typically, these are your 10 CFR Appendix B quality assurance program criteria implementing procedures are needed by us to understand how you're going about doing these oversight activities.

So, what we saw in the past is the VOP

summary didn't have that level of detail in it, and then when we looked at the VOP itself there was some additional detail.

But again, it wasn't a complete picture of the various activities that you were performing, the criteria of Appendix B that you were using and leveraging to perform those activities, and the governing procedures to do those activities.

So, that's really the intent of that bullet.

MR. JARRETT: Thank you for the clarification.

MR. DARBALI: Thanks for the question. Any other questions?

MR. JAIN: Any more questions on Samir's presentation this morning? We've got a question from Waterford.

MR. ODESS-GILLETT: For the Waterford license submittal, they submitted a draft LAR before the actual LAR. Did you find that improve the licensing review process?

MR. JAIN: I'm going to let Mike Waters take that one.

MR. WATERS: Thanks, Samir. We tried to use a different approach.

I think it was helpful, in one aspect I think it gave us an early jumpstart of the VOP and I think there's been a lot of effort on that because Entergy is the first one to develop the VOP and summary.

And I think it jumpstarted on asking questions there. It is a struggle because the review of that draft was a very short period of time and it was always any significant red flags.

But as a regulator, it's not part of the formal review process and we didn't communicate any findings to that degree. It did give us a jumpstart in looking at it but we are rethinking does that make sense from a regulatory standpoint, from that standpoint?

I look forward to hearing your comments and Entergy's comments on that as well. It's a lot of effort for a licensee to put together a draft and then have to resubmit it a month later. I think that's what Entergy said.

We have to balance regulatory process uncertainty with the benefit of something that may be provided for us.

MR. JAIN: Are there any more questions to Samir on the presentation? Hearing none, Samir,

should we continue because our break is almost a half-hour away?

Maybe you want to continue with your presentation on inspection lessons learned and then we'll break in the middle?

MR. DARBALI: I think maybe we should take the break first because we do have a series of presentations and different presenters who might not be ready until a bit later.

MR. JAIN: Okay, that'll be fine so we'll break for 10 minutes and this is 10:22 a.m. so we'll restart at 10:30 a.m., everybody. So, a 10-minute break. Thank you.

(Whereupon, the above-entitled matter went off the record at 10:22 a.m. and resumed at 10:32 a.m.)

Hello, everyone, now we will start the Staff's presentation on inspections lessons learned and Greg will lead the presentation.

MR. GALLETTI: Good morning, everybody, again, this is Greg Galletti from the Office of Nuclear Reactor Regulation. I'm one of the inspection team leaders in the Quality Assurance Vendor Inspection Branch.

And I was responsible for two of the

inspections that we've performed to support the Waterford digital modifications. Next slide, please.

So, I just wanted to give a quick background. As we discussed back in February, the intent was for the NRC's inspection framework to really be focused in two areas, the first being the vendors' development activities and design outputs.

Again, the inspection framework was really twofold, the first area was looking at the vendors programs for the development and the activities and support of the design itself.

And the second area for inspection is looking at the licensee's implementation of their vendor oversight plan activities and that, as you'll see, will be covered in a later presentation by our regional representative.

As I mentioned, we had an opportunity to implement the inspection framework for the Waterford Digital I&C modification project and I'd like to go over -- sorry, Joe, that you can't hear me -- some of the lessons learned from the inspections as well as originally we were going to go over the lessons learned here for the audits but you've heard that earlier from Samir.

Next slide, please.

So, we conducted two inspections at the vendor's facility, one was actually a virtual audit, unfortunately, due to the pandemic but that occurred back in March of 2021.

It was a virtual audit and we focused on the requirements phase of the development process that the vendor had been implementing.

We issued an inspection report with no findings on May 10, 2021 and I provided the ADAMS accession number for you. Just to give you a little bit of background, for both of these inspections we used our routine vendor inspection procedures that we have in place.

The first procedure is 43002, which as titled is a typical routine vendor inspection procedure that we use that covers the applicable portions of the 10 CFR Part 50 Appendix B requirements.

And the second more focused inspection procedure is IP 35710, which again, focuses more on the software development lifecycle and the quality assurance application to the development of that software.

In concert, we used both of these procedures typically whenever we do a digital I&C or

software-related vendor inspection. So, further requirements phase inspection, we focused primarily on looking at both the software and hardware requirements phase lifecycle development documentation.

We verified adequate translation of the design information provided in the LAR into the hardware and software requirement specifications, we looked at and we evaluated the traceability controls that the vendor had in place to ensure the requirements were incorporated directly into those specifications and carried through to later phases of the development lifecycle.

We looked at their configuration management and design control processes specifically to address these areas and we also looked at the independent verification and validation processes that the vendor had in place to evaluate the outcomes of the various phases, and in this case the requirements phase.

And finally, we focused on the non-conformance reporting system as well as the corrective action program reporting system that the vendor used during the development lifecycle phase in order to capture any non-conformances or discrepancies, evaluate those, and disposition those.

The second inspection that we performed was the factory acceptance testing phase that was done in July of 2021. Again, we issued the report about a month later, September 10th, the ADAMS accession number is provided there.

Again, as a result of the inspection, we did not have any significant findings. Again, for this particular inspection we focused on and reviewed documentation associated with both the design and the implementation phases as well as the factory acceptance testing phases.

So, as part of that, we looked at design documentation and verification reports associated with design and implementation, we looked at the inspection and testing procedures that were being performed.

And in this case, we had an opportunity to physically be on site to do the inspections so we got to look at the test facility, the system as developed for the testing, and then observe certain aspects of the testing that were going on during the week that we were on site.

Next slide, please. What did we learn from all of these things? I'll characterize these five or six bullets in three simple terms, coordination, communication, and scheduling.

And those three areas were the ones that were the most challenging for these particular types of inspections and things that as our opportunity to do these sorts of inspections continues, processing will be more mature and we'll get better results.

So, if we go through some of these, certainly depending on what type of process you're in, whether you're using the alternative review process or a traditional Tier 1 process, those will dictate when and what types of information are going to be available to the inspection staff to conduct those inspections.

And that'll be based on the maturity of the design at the time of the submittals. Secondly, the I&C systems as we've seen, the development activities don't necessarily follow the traditional Waterford lifecycle phases.

What we had noted when we did these inspections is that certainly, certain design changes may occur during the lifecycle that would affect the design and therefore, require some additional regression analysis that may not actually occur until after our inspection was completed.

Additionally, during the inspections of the testing, whether it be factory acceptance testing

or at the site level, site acceptance testing, those may trigger some additional design changes that again would occur after the inspections had been completed.

Regression would have to be done by the licensee and the vendor and then subsequent evaluation may need to be evaluated by the NRC at that point.

What we also noted was that the expectation when we went out and we were looking at the fact testing, our expectation going in there was that the implementation and design phase activities would have been complete at that point in time and then we would have been looking at the result reports in concert with the FAT inspection that we were doing.

In fact, what we found out is that there were certain design artifacts associated with both of those lifecycle phases that were not completed at the time we were on site for the FAT testing and so again, that made the inspection somewhat limited and we had to evaluate what to do in those cases and move that over towards the system level reviews that were done.

The scheduling, this comes down to that the scheduling really needs to be somewhat dynamic.

As you're approaching the design, the vendor is implementing the various lifecycle phases and we have to have formal communications between

ourselves, the vendors, and the licensees so that we understand what's going on with the development lifecycle, the dynamic aspects of that, and any potential changes or delays or accelerations to that lifecycle activity.

The frequency of the vendor inspections also, as we pointed out back in February, will probably be dependent on both the complexity of the digital I&C system under development as well as potentially our expertise in understanding experiences with the vendors and the licensees that may have already gone through digital modification upgrades and we have some familiarity with their programs.

As I pointed out, probably the most significant thing that came out of the inspections and certainly the FAT inspection is that there needs to be really strong coordination between the vendor inspection group, the licensees themselves, and the vendors in order to ensure that adequate coverage can be accommodated at the testing facility.

In the case of Waterford, we've had the vendor inspection team, we've had the licensee oversight team. Obviously, we had the vendors testing team and we also had support from our regional inspection team.

So, there's a lot of moving parts to these inspections and coordination is really extremely important to ensure that we have effective and efficient inspections.

And communications, it's clear that as early on in the development lifecycle that the earlier we can open up the channels of communication between the licensees, the vendors, and ourselves in terms of developing schedules for doing inspections, establishing the resource allocation that we need internally to support the inspections as well as the vendors staff in terms of being able to support those types of inspections is really critical.

I think that pretty well sums it up in about 10 minutes or less. So, I'll open it up for questions.

Was there a hand or did it go away?

MS. GOLUB: There was a hand, it was me, it's Pareez Golub. First, thank you, Greg and the NRC of course in general, for doing this workshop, we really appreciate the opportunity to hear the lessons learned.

Greg, on your Slide 4, I didn't quite understand when you were talking about something that was not complete at the time of FAT.

MR. GALLETTI: Yes, when we were out at the facility looking at the FAT testing that was in progress, one of the areas that we wanted to focus on was to look backwards as part of the lifecycle development activities.

And I should preface this by saying when we did the FAT inspection we also had support of the quality assurance vendor group, we had support of the technical staff that's responsible for the LAR review and approval, and we had a member or members of the regional staff that were performing vendor oversight inspection activities in parallel.

So, while we were out there looking at some of the activities associated with design and implementation, certain of the oversight activity evaluations that were done by the licensee and IV&V-related activities done by the vendor were not completed at the time we were there on site.

And so we couldn't obviously evaluate those final reports associated with those development lifecycles.

MS. GOLUB: Thank you.

MR. JAIN: Any more questions for Greg?

MR. GALLETTI: Ted?

MR. QUINN: Thank you, it's Ted Quinn. I

wanted to ask and again, I'm going to focus in on docketed and non-docketed, and it has to do with your request.

When you go through the procedure lifecycle at a vendor and you have a set of procedures, are you able to address that in the inspection process or do you have to docket those?

I didn't know what lessons learned you've had from past work.

MR. GALLETTI: I should say in this case the vendors' implementing procedures that implement their Appendix B program typically are not at a level of information that we need docketed.

So, we will review those implementing procedures typically during the inspection itself, looking at whether those implementing procedures carry out the requirements that are documented in their quality assurance program manual, and then looking at the implementation of those procedures to ensure that they were implemented properly and the results of that implementation were documented properly.

And the fact that we can review that documentation to see what the outcomes of those activities were.

MR. QUINN: Perfect, end of comment.

MR. JAIN: Samir, do you have questions?

MR. DARBALI: Yes, I just need to reiterate something that Greg had mentioned earlier, the fact that Greg and Deanna were also part of the licensing review team, I think that made the transition into performing those inspections much, much easier because they were already familiarized with that modification and the contents of the LAR.

So, I think that's something we need to continue to do in the future.

MR. GALLETTI: Samir, I fully agree.

I think the continuity between understanding the design and looking at the VOP and the VOP summary and following that through to the completion of the LAR documentation, and then carrying that beyond into the inspection is important, absolutely.

MR. JAIN: Any more questions for Greg? If not, then we can move to regional inspection lessons learned.

MR. DARBALI: Thanks, Greg, so Shiattin will take over.

MS. MAKOR: Yes, I'm going to take over. I'm going to switch it to mine, give me one second. Is it showing now?

MR. DARBALI: Yes.

MS. MAKOR: Good morning, everyone, my name is Shiattin Makor, and I'm the team lead for the regional inspection activities associated with the Waterford III core protection calculator system, better known as CPCS and, what I'll be referring to it as throughout the rest of this presentation, digital upgrade.

And I will be presenting our lessons learned regional processes and the application of the inspection procedure.

As I just mentioned, Waterford III is implementing a digital I&C modification to upgrade their CPC and their CEAC system using the previously approved common-queue platform, This Spring.

Because Waterford III volunteered to be the first site to you the alternate review process, which relies heavily on vendor oversight and is inspected using the revised inspection procedure 52003.

Region IV of the NRC Office has the privilege of being the first to implement the revised inspection procedure. To organize our assessment we used key inspection milestones marked by the completion of major deliverables.

So, for this presentation I will cover how we implemented the new inspection procedure, how we inspected the alternate review process, and the lessons that we've learned so far.

The first area that I would like to discuss in the regional inspection process that we chose to employ is how we decided to go about this inspection. So, what we did is we divided the regional project into these manageable steps to easily control the inspection project.

We wanted to make sure we were able to control the quality of the output and identify major deliverables. So, the initial phase, which you see blocked in the red was more of a familiarity-type activity for us.

This is where in the licensing review process we had to obtain regional administrator approval.

And so for this part, during this phase, NRR evaluated the proposed license amendment by reviewing the design and capabilities of the modification as part of the normal review process.

The region during this phase reviewed specific documentation to gain familiarity with the system which made it easier downstream to perform

documentation and functionality review once the system left the vendor.

And it allowed us to be familiar with the licensee's administrative programs for designing, installing, testing, and maintaining modifications. So, for the license review process, we would sit in on the meetings, we weren't active participants, we were very passive in it.

We listened in, we saw the type of questions being asked with the request for additional information. We saw the discussion for safety evaluation and pretty much just shadowed the approval of the license amendment.

For the regional administrator, we had to obtain approval because this is, especially, an infrequently performed activity and so this required approval. So, for us to be able to get approval we had to be able to brief management and stakeholders at each phase and to get approval to do the project as a whole.

So, in order to do that, we had to be familiar with what the modification was. The next phase of the regional process is the planning and scoping essentially.

So, for this phase, the team used the

inspection procedure requirements to identify what documents were necessary to perform the inspection.

We use the license amendment review in the inspection procedure to be able to determine our inspection scope, and due to the dynamic nature of these inspections, the team had to be flexible.

So, pinpointing dates, team composition, and inspection in some cases was a moving target. Our request for information was heavily based upon the inspection procedure requirements.

And in our inspection planning and scoping we identified our team composition, we used objectives in the inspection procedure, scheduling we obtained from the licensee for their master scheduling to see when major activities were occurring.

And then specific activities and assignments, those were based upon our team composition, which as was mentioned before, we want to maintain some of the continuity so our team composition included a lot of the individuals who were involved at the beginning.

So, the vendor inspections, the technical reviews, our team had team members from that, so they had an idea and understanding of what was already going on.

The next part of the process is the implementation phase and what this essentially is is the licensee was doing a factory acceptance testing, the site acceptance testing, and the CPC modification installation.

So, for this phase, the inspections are all conducted by inspectors knowledgeable in the areas of digital I&C and operations.

But because these inspections occur over several weeks, actually months, the decision was made to perform the inspection in phases which allowed the team to keep track of what was assess and afforded a level of transparency.

So, for our factory acceptance testing, that was performed in July of 2021, and we were there at the same time, as mentioned before, as the vendor inspection. And so we were providing oversight of the licensee, who was providing oversight of the vendors.

So, it was a lot of watching one another. But there was value added in that phase because it allowed us to see the equipment at the vendor facility and started to get familiar with the process, the testing, everything that we would need to address it.

If we would have waited until the very final activity, which is installation, we wouldn't

have some of the lessons learned and the awareness that we do have.

In January of 2022, we performed the site acceptance test activities and that was performed at the facility. So, that was performed at Waterford and then in May of 2022 we are preparing right now to perform the installation inspection activities.

At this point, I want to pull up the inspection procedure application and the two major updates that affect and apply to regional inspections particularly. So, Inspection Procedure 52003, digital instrumentation and control modification inspection, was issued July 1, 2021.

There are two major updates in here that particularly affected us.

One of them was the revision allowed for the confirmation of the digital I&C and software development, integration, and testing to be stripped from licensing activity to inspection activities as a result of the ultimate review process.

So, under the new guidance, the licensee has an option to use the alternate process or traditional approach. Under the traditional approach, the license amendment review would be completed after the completion of a system design.

Under ARP, the license amendment approval relies heavily on vendor oversight and allows approval prior to the completion of the design. This update shifted some activities that fell under the licensing activities to inspection.

So, in the past, digital mods such as Oconee, Diablo Canyon, the FAT did not fall under regional purview but this time it did.

Because of the reliance on the vendor oversight plan, when using the ARP it's important to note that when executed the VOP can be used to ensure the vendor, one, executes the project consistent with the LAR and, two, uses an adequate software or quality assurance program.

The VOP when executed helps ensure the vendor will meet both the process and the technical regulatory requirements. But one thing to note is that execution of the VOP is the responsibility of the licensee.

So, this includes performance of oversight activities on the design artifacts and development activities for the requirements, design, implementation, integration, and factory acceptance test phases of the system.

So, as I mentioned before, this was

something that was different in my previous experience.

I was usually more of an observer during the factory acceptance testing for the other two facilities that I mentioned whereas this time around, our team, we were active participants and it was an actual team.

Usually, it was just the team lead that participated in the FAT but now you'll have a full complement that's actually providing oversight. Those are the two major -- I did leave out the second one, I apologize.

The second major change to the inspection procedure 52003 was the formal inclusion of the verification of commitments in the licensee's cybersecurity plan.

So, I'm going to talk about that a little later after I talk about the applications and I do have my cybersecurity team member who will also add to that, because we did feel there was some value in talking about that a little bit more since it is one of the major updates.

When it comes to the application of inspection procedures 52003, it's divided into five major areas that are listed below. Here I just

included major or key takeaways for each of the sections.

For the inspection objectives, the expectation is that the licensee has performed and will verify that the licensee has performed enhanced vendor oversight activities as defined by the vendor oversight plan.

So, as I mentioned before, the vendor oversight plan is very significant and very important. That's something that we're looking at to make sure that it's being applied and performed correctly.

The next part that we wanted to point out is the inspection requirements, 52003 Section 2, all requirements are not needed to be completed.

The team lead has the autonomy to look at the applicability of items that are in the inspection procedure and then if we're unable to do it, then they don't have to be completed.

So, that section, Section 2, was pretty extensive but some of the activities it may not apply to the site.

So, that depends on the particular inspection. For the Waterford inspection, what we did is if it didn't apply, we note that so that there's no wondering or no confusion later on.

That was an important aspect for us. For inspection guidance, I did say see the reference page. I have a reference page at the end of my presentation and some resources that will include the ML extensions for all of the FAT and SAT and all of the documents with ML numbers so that you can go back and look at that.

But the main thing that we wanted to make sure was emphasized when you look at the inspection guidance section is that this is guidance for inspectors. So, the reason why we wanted to emphasize this is because we were in a training class for DGE and there was an impression that this was the requirement.

Section 3 is not the requirements, the requirements are found in Section 2. Section 3 is just guidance for inspectors, it includes references and things that you can look at and use to inspect the requirements in Section 2.

The next section in Inspection Procedure 52003 is in regard to resource estimates. So, the resource estimates is 120 hours onsite activities and if you're doing the ARP, then it's an additional 120 hours.

So, 240 hours total if it's using the ARP

process. I'm going to discuss this later in lessons learned so I won't go or delve into it right now but I did want to point out that information.

And then the last section discusses procedure completion. And so it's conducted to demonstrate the modification is implemented in a safe manner.

So, satisfactory review of documentation verification, testing, operations and training, and plans for maintenance and repair are in accordance with the inspection plan, and that will constitute completion of this inspection procedure.

There's two things that I did want to point out, one is that it may be completed over similar inspections so there may be concern or wondering why do we do it over several inspections.

And the inspection procedure does allow for this. The other thing that I wanted to point out which I'll talk about later is how do we call the inspection or procedure complete?

How do we call it good? And so for this, we have looked at using the major activities such as the FAT, SAT, and installation as our methodology for saying, okay, this portion is completed and moving on from there.

As I mentioned before, formally including cybersecurity requirements in Inspection Procedure 52003 was another major update that did affect the regional inspection team's inspection scoping, planning, and composition.

Additionally, there are sections of the cybersecurity plan that are particularly applicable to the digital equipment upgrades and things the inspection team saw during the FAT and the SAT.

So, my cyber team member, Kim, will specifically discuss this area. Kim?

MS. LAWSON-JENKINS: Hi, I'm going to briefly discuss the cybersecurity area where we participate in these inspections and the factory acceptance testing, and we will be participating in the upcoming installation inspections.

The basis for almost all of the site security plans and also for Waterford, which includes Waterford, is NEI 08-09.

Appendix A, which talks about Section 313, with identification of critical digital assets, specifically in there it discusses technical security requirements for security controls.

And those security requirements are usually sent to the vendor because then the vendor

implements those security requirements and the licensee will take credit for those as a part of the cybersecurity plan.

So, one of the main things that we were looking at as we went into the inspections were the requirements that were sent down to the vendor and the vendor received this information and it will be information that is sent back to the licensee.

Also, we look at NEI 08-09, which is Appendix E of 08-09 security impact analysis 10.5, and that is verifying when the vendor determines that they're going to use a new CDA or system, what would be the impact to the security posture of the plant?

And that may be an ongoing process documenting this information but most certainly it should be done as you're sending those requirements down to the vendor that certain mitigations are put in place and technical requirements are implemented.

And that comes back up into going into the overall CSP. But we looked at the security impact analysis to get an idea of how the licensee is looking at implementing this new equipment from a security aspect.

A lot of the controls may leverage safety protections that are put into the system but they are

very specific security impacts that we are looking at because as Samir mentioned earlier in his presentation, we're looking at malicious harm that may occur with the system, not just safety impacts.

Also, we looked at a series of controls and in NEI 08-09, there should be Appendix E11 for controls for the supply chain.

There's five controls that are in there and specifically for the vendor, we were looking at the security test and evaluation plan, which says how did they test these security requirements that were implemented based on the instructions they've gotten from the licensee.

And the last control that we look at is NEI 08-09, which is Appendix D 1.4, information flow control, because when you install the new equipment, there's going to be attack pathways that have to be analyzed and addressed and mitigated if there's a possible way to attack the system.

And that control, Appendix D.1.4, is very important in the cybersecurity plan when you're implementing new equipment.

The plan covers many more controls than these but these are the base, I would say the foundational controls that we look at going into a

cybersecurity inspection.

So, the plan isn't in place until the equipment is installed but the actual requirements, especially when it comes to technical security controls, have to be relayed to the vendor so they are properly implemented.

And then that information is, like I said, sent back to the licensee and then we will come and perform oversight to verify that the complete cybersecurity plan has been implemented for this digital system.

That is patient in this. In the early phases, this is for the factory acceptance testing and the site acceptance testing, we may have had observations but that wasn't the formal inspection.

The actual inspection will occur at the installation when the plan is actually in place. That's all I have today. Later on if there are any questions I will be definitely glad to answer any questions.

MS. MAKOR: Thank you for that, Kim.

MR. JAIN: Are there any questions for Shiattin or Kim on inspection lessons learned at this point? A question from Ted?

MR. QUINN: Hi, I'm really pleased at the

reissue of the 5203 and the expanded role in the region. The first question is does Region II take care of all of them in the country or is it spread out among the regions?

And then the second question is you have what's called site-specific follow-up items that are part of a safety evaluation report and they come from the different divisions.

They come from I&C, they come from the Vendor Inspection Branch, they come from Human Factors Branch, they come from NSIR.

And I just saw what Kim did is a great job in presenting the overview of where the cyber is done in the breakdown between the role of I&C and the role of NSIR in evaluating. You have a funnel and all of your items come into the Vendor Inspection Branch, is that correct?

Do you see your role as closing those items in addition to completing your other actions in 5203?

MS. MAKOR: Yes, that would be an accurate statement. We're more of a confirmatory follow-up-type activities so I think your first question was in regard to -- there was three of them, I lost the first one.

MR. QUINN: Region II did it for new reactors and I was wondering are they also doing it for current fleet?

MS. MAKOR: Region II, as far as it would go in regard to Inspection Procedure 52003 and the implementation, that's done regionally for your plant. So, Region IV has everything west of the Mississippi and so our facilities that are doing digital I&C, we would implement IP52003 for it.

We would implement it for there and Region I and Region III.

MR. WATERS: Region II there's construction specifications for new build, I don't know if that's where Region II gets involved often.

MR. QUINN: Right, that's what we saw earlier.

And then the second one, really, was you're a compendium, a collection of those site inspection follow-up items and you relate what each of the NRC divisions that have open items to close.

I assume you do that, right?

MS. MAKOR: What we do to handle that is our inspection procedure or scope comes from the IP52003 and then input from the technical reviewers from the safety evaluation. So, items that weren't

closed, they're not required for us to do it but these suggest items to follow up on.

In our case, a lot of it was already items that are in our requirements in the inspection procedure requirements and then our team also has a complement of an inspector that was in the vendor group, an inspector who was the technical reviewer on this, and then we had the cybersecurity role.

And then operations is followed up by using our regional onsite inspectors. So, our complement is how we maintain continuity and make sure that we capture everything throughout this process.

So, we've built a team that included people who were very aware or involved with the other areas.

MR. QUINN: Thank you, you answered my question. As more utilities go through SLR and modifications, this is really a benefit that you're expanding your role. Thank you, end of comment.

MR. JAIN: Samir?

MR. DARBALI: Yes, I just wanted to add to what Shiattin was saying. What we do is we provide the region with recommended inspection activities, and like Shiattin said, those are optional.

So, they're not technically open items

from the review. Our review stands on itself and we don't depend on inspections or inspection results to determine the acceptability of a modification.

So, when Shiattin develops the inspection plan, she's going to use IP52003, which is the inspection procedure, and she's also going to use those recommended inspection activities that we provide as more targeted activities for the review.

And also I think Shiattin might cover this in the lessons learned. She was involved throughout the review so she was aware of the types of modifications that were being performed.

So, it's a combination of different factors that go into that inspection plan.

MR. JAIN: Jarrett, I saw your hand raised?

MR. JARRETT: Yes, I know you haven't performed the inspections for Waterford as far as installation, but we have detailed outage schedules and has there been the thought of planning and integrating with the plants outage schedule and that interface during the outage?

Has there been any thought on how to interact during the outage? Because it's critical for the plant and so how that will actually occur and what

will you all be looking at?

MS. MAKOR: We do this just like any other inspection process, what we've done is we've been communicating with Waterford since the FAT.

We found that communication was really important and so we communicate frequently, we have a master schedule so we know what is going on during the outage, and then when we put our inspection plan together and do our request for information, we essentially announce our inspection with request for information and that'll give an idea of where we're going to be looking at.

And then also, with the inspection plan for this part of it, the plan is to go ahead and have that actually formally issued.

So, the inspection plans for the factory acceptance testing and the site acceptance testing was not formally issued but we figured this would be a good resource not only for Waterford, but also for other plants that this is coming down the pipeline for.

So, we've been in communication with Waterford, it's not an unannounced inspection, they know we're coming. We're not going to disturb work or bother them in those ways.

We understand it's critical to have them and we're making plans as we speak to be able to perform our duties, our regulatory requirements, without interfering with implementation and installation.

Does that answer your question?

MR. JARRETT: Yes, thank you.

MR. JAIN: Ted had a follow-up question?

MR. QUINN: After Samir spoke, I just wanted to ask a follow-up, in the back of the Diablo LAR there was a section called site inspection follow-up items and I just wanted to clarify, I assumed that is a continued process for NRC that is part of the SER so that those are followed up.

And I didn't quite understand if those are followed up by Headquarters or if they're followed up by the region, are you able to clarify?

MS. MAKOR: They're followed up by the region. There was a change in how those items were documented, so it was decided we would no longer put it into -- since it's optional, we would not put it in or recommend it, we would not include it in the license amendment.

Because the license amendment should standalone, it should be a standalone document.

And Samir, if I'm misspeaking please correct me but the decision was made to do it how we're doing it now versus having it in the license amendment.

So, there are changes from Diablo Canyon until now.

MR. WATERS: This is Mike Waters, I'll just jump in, you're absolutely correct.

There are some intense changes at Diablo Canyon and stakeholders were concerned that having the recommended inspection items, just having even the optics of somehow being a basis for licensing decisions.

So, we decided not to do that anymore and it's not going to appear in the SE.

What we do is internally communicate in a similar manner with the region and recommend inspection items like Samir did to help on the inspection plans.

MR. QUINN: So, the licensee, Mike, would hear that in a different manner than was done for Diablo, is that correct?

MR. WATERS: As part of the inspection planning from the region, or if there's been inspections after the license issuance, that could

possibly happen, we don't know but that's where you'd hear it from, yes.

MR. QUINN: Thank you.

MR. JAIN: Dinesh, do you have any comments to make?

MR. TANEJA: No, I'm just unmuting.

No, I think Ted's question and concern, I think it's been addressed. What I was going to say is when a LAR is issued, licensing is complete, we made our safety finding.

And so the follow-ups and inspections are confirmation that the implementation is being done in accordance with the approved LAR. And there is not really part of the ongoing licensing act and I think Mike just clarified that, and that's what I'm going to do, that's why I took my hand down.

MS. MAKOR: Yes, and if you look at the Inspection Procedure Section 2 it's very general. So, the information that we're provided is just more specific.

Instead of it saying digital equipment, now it's saying the CPCS, make sure the CPCS is doing X, Y, Z versus make sure the digital equipment is doing XYZ.

So, it just specifies what's already in

the requirement section and it gives us a little bit more pointed or detailed information.

MR. JAIN: Thank you, Shiattin.

MS. MAKOR: You're welcome, are there any other questions? I can't see the hands.

MR. JAIN: Are there any more questions on inspection lessons learned?

MS. MAKOR: I do have two more slides.

MR. JAIN: Go ahead.

MS. MAKOR: I broke the next two slides down into one on lessons learned and the other on best practices, so I'll try to get through this pretty quickly. I see that we did take a little bit more time.

But the first lesson learned is not really a lesson learned, it's more of a challenge that was only specific to the region and Waterford. So, Inspection Procedure 52003 was actually not issued until July 1, 2021.

And then the LAR was not approved until after the FAT inspections. So, the challenge that it presented to us was that, one, we didn't have an inspection procedure until we were on site.

So, it was actually issued I think the Friday before the Monday we were on site.

And so I think that presented some challenges to both the inspection team and to Waterford, just because there wasn't the level of detail or understanding of what's in the inspection procedure.

So, for instance, the vendor oversight plan expectations for that also just the licensee didn't have that inspection procedure yet so you had an inspection team come on site that's using the inspection procedure and they didn't have the opportunity to prep with that inspection.

So, that's really something that just happened, it was the artificiality of having the inspection procedure issued at that time but it was a challenge and a lesson learned for us.

So, the three main lessons learned that I wanted to cover quickly is, one, all the work is in progress and documentation reviews such as test results, procedure changes, all those are going on throughout the entire process.

And it doesn't really catch up until the installation and even at installation, there was not any regulatory hooks or anything that we can address. All we can do is observe and so until we return to service, there's not going to be violations, only

observations at this time.

So, I wanted to point that out, that is a challenge for us but it puts the onus to stay on top of everything and get everything done because at the end, when you return to service, then any issues or concerns that we express that we had been looking at can actually be addressed once you return to service.

The next item that I think is a really big lesson learned is just inspection scheduling, how to account for when to be on site, what activities we're looking at, a lot of times we're not speaking the same language, terminology is different between the licensee and the region or just the NRC in general.

So, we struggled because initially we saw the factory acceptance testing and the site acceptance testing as when the testing is complete that's it.

So, we can call everything good and so we struggled because what we tried to do initially was call everything good or complete for that inspection phase based off of the inspection report. Not the inspection report, but the report that's performed by the licensee.

So, Waterford would do their report after the FAT was performed. They looked at the test data and everything but we were trying to be complete

immediately when the testing was done.

And so that afforded some challenge and so for the installation, the team is going to consider return to service as complete. So, our inspection won't end when the testing is done whereas for the FAT and SAT, we did end when the testing was done.

Since we didn't see any anomalies or major anomalies or issues, we were able to feel confident that we could go ahead and say, okay, for the factory acceptance testing this is done when testing was completed and the same for SAT.

Whereas for installation, we'll be using return to service as our metric for marking it complete. And that's not clarified or detailed in the inspection procedure so that's something that we learned and decided to implement as a result of doing the FAT and the SAT.

The other item lesson learned is inspection procedure resource estimates. So, the estimates, as I mentioned before, it was 120 hours plus an additional 120 for ARP.

What we found is that with the team composition that we have, one, it's a struggle to stay under 240 hours.

If you have five inspectors in operations,

a vendor, a technical reviewer, a cybersecurity, and a team lead for even just one week that 40 hours or 30 hours for 5, 6 people, that already eats a big chunk of your 240 hours.

One thing that we did notice is during the factory acceptance testing, since it's more of a familiarity activity, we didn't need as much resource during that as far as time.

A lot of it we were able to charge to prepping and just getting familiar with the system, which I think the inspection procedure had it in reverse, where the expectation is that you would spend a lot of time and charge more during the FAT and during the all the time less.

But we found it's the opposite. Because everything is in progress and still being worked on and changed, we just weren't able to call anything done. So, we're going to be able to look at most of it during the installation.

So, those are the later lessons learned. For best practices, some of these I think the vendor inspection, and Greg mentioned, but we found the phased inspection approach is a better approach for us.

It allowed the team to divide the project

into manageable pieces and then also it allowed us to identify lessons learned and best practices as we went along.

So, when we did the factory acceptance test, we learned a lot and we were able to implement that with the site acceptance testing.

And then now we're able to combine what we've learned and practices to the installation that's upcoming.

And we wouldn't have had that value or that opportunity if we would have just waited, not documenting and not formally doing it and waiting until the installation.

During the FAT, the next best practice that we notice is that during the FAT, I mentioned this slightly before but for the major milestones, it introduced overlapping priorities and it required significant coordination from the licensee.

So, this is one of those things that brought awareness for the licensee because during the FAT you'll have both the vendor and the regional inspection teams on site.

And so the regional team really tries to focus on their interaction with and observations of the licensee. We're not really trying to interact

with the vendor.

If we are asking quality assurance questions, they're questions that are going directly to the licensee, not the vendor. So, it may look like we're providing oversight of the vendor but our focus is really on how the site is interacting with the vendor and providing oversight.

And one of the themes is just that awareness so that you know when we're on site, that's what we're doing. Because I think there was some confusion on the roles and a little lack of clarity there.

The next item is that best practice for the SAT, we found that during the FAT our observations weren't as substantial whereas during the SAT we did Pareez substantial observations.

And so the documentation for that area, the documentation in the FAT, is really just a summary of the team's overview.

The documentation for the SAT will include observation so if there are any significant observations or things that we expected to already be in process or completed, then we would document it in the SAT.

It's not a finding, it's not a violation,

it's just an observation and that way, we're able to look back at that report and the previous one and see what we've looked at and prep for the installation.

And the last best practice is just the communication between NRC, all of the groups, that was very significant and valuable. So, regional, licensing, vendor and cyber, all of that interaction helped to make this go smoothly.

And then communication with the licensee is also critical just because of the dynamic aspects and the fact that the biggest thing is this is a long evolution, we started way before July of 2021 and we won't be near completion until, essentially, June of 2022.

So, communication, staying on top of it is very important, very significant and one thing that we did is as we got closer to inspections, we would have meetings with the site every two weeks.

And so we would have a biweekly call and just a status, this is where we're at, this is what we're doing.

And that helped to facilitate our inspection activities.

So, those were best practices and the key messages from our regional inspection activities is

that, one, I mentioned this before but Inspection Procedure 52003 had two notable changes, so that's in adding the ARP option, and formalizing the cybersecurity plan which we discussed earlier.

The next key message that I wanted to emphasize is just that the execution of the VOP is the responsibility of the licensee. And that's the focus of what we're looking at, the inspection team.

So, this includes performance of oversight activities on the design artifacts and developmental activities for requirements, design, implementation, integration, and factory acceptance testing.

And so this is the crux of it, this is pretty important and significant and the focus of inspection procedure 52003.

And then the last key message that I wanted to deliver is that lessons learned during the FAT, the SAT and installation are used in real time in our inspection planning and scoping.

So, once we get enough run time from Waterford, Limerick and Turkey Point, we can combine lessons learned to improve their process, procedures, identify best practices, learn from missteps, and make overall improvements.

So, everything that I did cover I try to

keep it focused on Waterford and the regional inspection activities because we do have the NEI comments and some of the observations and recommendations and lessons learned that we had also fall under there.

So, some of that will be covered. Is there any questions or comments about my presentation? And I apologize for taking up a little bit more time.

MR. JAIN: Ted has a question.

MR. QUINN: This is Ted, very good presentation and I liked all of the work that's been done to increase the coordination, for example, between yourselves and NEI and C Branch, the Vendor Inspection Branch, the Cyber Branch, there have been real improvements.

Now my question is to the next phase which is currently underway, the Human Factors Branch. How do you see your interface? You just described the FAT and the SAT and your activities, which in some of the larger modifications will include a significant role in cyber.

I know it will be addressed by Brian and Pareez this afternoon but I wanted to ask how you see it in your increased role in that area.

MS. MAKOR: So, I would say the way I see

that we are implementing is not formal but we went ahead and we added our resident inspector as a team member so you get that operations, that human interface.

It ties it together.

And so even though we're not formally performing those assessments, like the whole human factor engineering looking at the procedures in that way, we are looking at it from an implementation aspect.

So, operations being included I think covers it.

MR. QUINN: Thank you.

MS. MAKOR: And if anyone else on the team has a comment contrary to that?

MR. WATERS: Shiattin, this is Mike. I would offer I think for those human factors, the regional coordination would be similar to the coordination with I&C or other technical disciplines.

So, we would expect it to continue and I think that's maybe part of your question, Ted.

MR. QUINN: Yes, thank you.

MR. WATERS: Samir, is that what you were going to say?

MR. DARBALI: Yes, I was going to add that

for Waterford there wasn't a major human factors modification. We do have some recommended inspection activities related to the operator modules and some signals that are trained.

But it wasn't a major part of the review, we do expect for the upcoming LARs that would be much more involved as far as our recommended inspection activities.

MR. JAIN: With that, Samir, do you want to continue with your presentation and response to NEI comments on Inspection Procedure 52003?

MR. DARBALI: Yes, Shiattin, you're done, right?

MS. MAKOR: Yes, I am. Thank you, everyone.

MR. DARBALI: I think that's a good segue from Shiattin's presentation. We're going to take a look at some of our responses to the comments that NEI provided on IP 52003.

And Shiattin already talked about the development of the revision -- let me turn my camera on -- to IP52003 which was issued in July in 2020, just in time to support the factory acceptance test inspection of Waterford.

Now, public comments, like Alan mentioned

in his opening remarks, are not really part of the IP development process but NEI felt the need to provide those comments in August of last year and we're going to be going through those comments in the following slides.

Some of the key things to understand about the IP, and Shiattin already went through some of these, is that IP52003 is strictly for modifications associated with a license amendment request, which means it's only for safety-related modifications and does not apply for modifications performed under 5059.

Like Shiattin said, Section 2 is inspection requirements and identifies the inspection activities to be performed as applicable. That means that if there's a specific inspection activity that doesn't apply to the modification, it doesn't have to be performed.

And Section 3 is inspection guidance for the inspectors in preparation for the inspection. So, if there is an activity in Section 3 that calls for review of a specific document, it is for the inspectors to become familiarized with the modification.

So, what I propose is as I go through each individual comment, we can take questions on each

comment or comments. That way, we don't have to wait until the end.

So, Comment 1 refers to the IP activities that may have already taken place during the licensing review, like activities that refer to the requirements phase and the design phase, which again, they are parallel with the licensing review.

So, why does the IP refer to these activities?

Well, although a specific vendor oversight activity may take place during the licensing review, for example, the licensee could be performing an audit of the vendor during the design phase, that audit report from the licensee may not have been completed until after the license amendment has been approved.

In this case, the licensee's audit report is something that can be part of the VOP inspection. Note that the inspection activities that rely on direct observation will be as applicable and they will be detailed in the inspection plan.

So, we don't see a change made to the IP on this comment. Any questions or feedback?

I'll jump ahead and let me know if I need to go back. Comment 2 has to do with SDOE and there's two parts to the comment.

The first part notices that there are two sections in the IP that are related to verifying the adequacy of a secure development in operations or environment.

And NEI recommended these two sections be combined. And the second part of the comment notes that the wording in Section 22B8 ties SDOE to cybersecurity requirements instead of software quality requirements.

And NEI recommends the wording be clarified to reference other quality requirements. So, we agree with the intent of the comment, in particular, Item 22B8. We think it fits better under Subsection A rather than under Subsection Bravo of the IP.

So, we'll consider rearranging that in the next update to the IP.

Regarding the second part of the comment on the term secure environment, as used in Section 02.02.b.8, the term being used is secure environment, not SDOE and secure environment could apply to both SDOE and cybersecurity requirements.

So, the way it is used in Section 02.02.b.8 is specific to cybersecurity. We'll try to make that clear when we eventually merge those

sections.

I'll go to the next one. So, Comment 3 has to do with the inspection activity related to power quality, which focuses on the verification that harmonic distortion is measured.

NEI notes that plants don't typically measure harmonic distortion and recommends removing this criteria from the IP and instead refer to DGC 17 or an applicable IEEE standard.

We'll consider this comment in the next update of the IP. I think the focus here is that it's for the inspectors to verify how the licensee has performed power quality measurements.

We'll consider that comment. On Comment 4, this has to do with two sections of the IP that deal with the VOP and NEI recommends the two sections be consolidated into a single section to avoid duplication of inspection activities.

So, we don't see a change being made based on this comment because Section 21C is focused on inspecting the licensee's oversight of the lifecycle activities, so more of a direct observation.

Whereas, Section 22E is focused on inspection of the documentation generated by the licensee as a record of their oversight activities.

So, for example, their audit reports or their letters reviewing vendor documents. So, we do see those as separate activities that don't overlap.

So, moving onto Comment 5, this one refers to some inspection items related to site acceptance testing, installation, and startup plans that are phrased using future tense.

And it gives the impression that the NRC is approving the test plants, the comment also points to some language that is some subjective, like using terms like sufficiently or adequately.

And it calls for objective criteria for inspections to be provided. So, regarding the future tense, this is used because it's referring to the inspection review of the planning documents which have yet to be implemented.

The inspectors are not acting as approvers of the plan, that's either a vendor or a licensee activity. We are reviewing the plans to verify that the plans are detailed and clear enough to perform those activities.

This also helps the inspectors to confirm, once the plan has been implemented and completed, that the plan was carried out accordingly.

Regarding the use of the term sufficiently

and adequately, which could seem to be subjective terms, they provide a range of acceptability but please note that the inspections are performed using an inspection plan, which is besides the inspection procedure.

So, like we mentioned earlier, the inspection plan is going to be more detailed, is going to incorporate some of those detailed recommended inspection activities and so the inspection plan will carry the acceptance criteria for what needs to be accepted and their acceptability.

So, we don't see a need for making an update to the IP based on this comment. So, Comment 6 through 9 are regarding Section 3 of the IPEE, which we already clarified is guidance for the inspectors to prepare for the inspection, and they're not really activities to be performed during the inspection.

So, Comment 6 reads the ARP was intended to disconnect the license amendment, request approval from completion of the factor acceptance test, and that to a degree, the IP reconnects the factor acceptance testing to the modification.

So, please note that the LAR approval is still independent from completion of FAT under the ARP and the sentence in question, what it does, it points

to inspection activities of FAT which are independent from the licensing review.

And again, this is for the inspectors to be prepared for the inspection. So, we don't see any changes to the IP based on this comment. Comment 7 notes that a software development capability maturity model is readily used in the U.S.

And it asks what would happen if such a document doesn't exist? If it doesn't exist, it doesn't exist. Again, this is in Section 3 so it's one of the many documents listed for an inspector to be aware of and familiarized with as they prepare for the inspection.

So, if it's not listed specifically as an item, it's not listed specifically as an item that is going to be inspected. So, we don't see a chance of the IP. Comment 8, it infers that the language in Section 33B inserts the NRC into the implementation planning activities.

Again, this is guidance for the inspection team to help with the inspection planning. So, understanding of the licensee's implementation schedules helps the inspection team to prepare for and schedule the inspection activities and balance resources.

So, we don't see a change to the IP based on this comment. Comment 9 refers to another preparation activity calling on the inspectors to review the human system interface design as part of their familiarization with the digital modification.

The comment points to this as an example of the risk of combining non-safety-related, safety-related, LAR and 5059 inspections all into one IP. Again, this is guidance for the inspection team to become familiarized with the modification.

And again, this IP is applicable to the modifications associated with license amendment requests only and only to safety-related modifications. So, we don't see a change to the IP based on this comment.

Comment 10 is a general observation and refers to the terms verify and inspect. The comment notes that ARP is inspection guidance and should be mostly be used in the word inspect instead of verify.

So, a couple of things to note here, the first is that the IP is inspection guidance for the inspectors. The IP does not contain any licensing review guidance and inspectors don't perform licensing reviews.

So, any guidance in the IP, regardless of

the term used, is referring to the inspection activities. And secondly, the term verify is a confirmation activity so all NRC inspections are verifications.

So, the word verify doesn't imply a licensing review. So, if we are reviewing a document, we review a document to verify but if it's all done under an inspection, you're reading a document to confirm something.

You're not tying that to the licensing review. So, we don't see a change being made to the IP based on this comment.

Comment 11 is a general observation that the structure of IP52003 combines IP52001 for digital modifications that require a LAR and IP52002 for digital modifications that do not require a LAR.

And it combines them into a single procedure. And the comment states that the IP doesn't differentiate between safety-related and non-safety-related and doesn't differentiate between modifications that require a LAR or those that are under 5059.

So, please note that IP52001 and 52002 are no longer applicable and IP52003 only is used for modifications associated with a LAR. And we'll

consider making this more clear in the next update.

Comment 12 is a very good comment that ISG-06 Revision 2 provides limited guidance on what constitutes an acceptance vendor oversight plan.

And that given that the IP contains guidance for performing VOP inspection, the IP effectively establishes what the VOP content and acceptance criteria are.

And so NEI recommends the Staff develop regulatory guidance on the expected content and acceptance criteria for a VOP.

So, we are considering developing VOP guidance after we've completed the review and inspection of these first few applications so that we can incorporate those lessons learned.

The VOP guidance in whatever shape or form it is developed, it will not be included as part of the IP and therefore, we're not making changes to the IP based on this comment. But it is well taken, we understand the need for VOP guidance.

MR. CAMPBELL: Samir, this is Alan. I just wanted to thank you for acknowledging that and, you know, this is one of the more significant comments that we had, and so appreciate the consideration there and understanding our intent was not to have that

included in the IP. It would be a standalone.

MR. DARBALI: Thanks.

MR. CAMPBELL: Thank you.

MR. DARBALI: Okay, thank you. Comment 13 is a general observation that the IP provide specific cybersecurity criteria to be inspected and it requests some clarity regarding the scope of cybersecurity inspections specifically when using the ARP.

So, the cybersecurity inspection items in the IP are there to verify the licensee's implementation of those applicable cybersecurity controls that are providing their cybersecurity plan associated with acquiring a digital safety system.

Earlier, Kim described the NEI 08-09 appendices that are applicable to digital upgrades, so it's just a confirmation that those cybersecurity controls have been implemented according to the cybersecurity plan, so we don't see a change to the IP based on this comment.

Comment 14 is a general observation regarding the use of terms like effective, properly, and correctly, which the comment notes are subjective terms and it recommends that a reference or objective acceptance criteria be provided instead of using such terms. This is similar to an earlier comment.

Again, terms like effective, properly, and correctly do provide a range of acceptability, but again, the inspection plan will be containing the detailed criteria for the inspection, so the language provides that range of acceptability in the inspection procedure. The plan will contain more detailed criteria, so we don't see a change to the IP based on this comment.

And then the last comment is a general observation that calls for training to be provided to regional inspectors on the intent of the ARP and it's a comment that's also well taken.

You know, as we discussed earlier, you know, Shiattin has gathered all of these great lessons learned, but she's only in Region IV. You know, what about the other regions? So, we understand the need for training and uniformity for when those inspections are carried out.

So, an introductory training was provided to inspectors when the IP was revised and we are considering providing more detailed training to the regional inspectors, both on the intent of the ARP and the use of the IP, and hopefully licensing and inspection lessons learned helped to shape that training.

So, again, the comment is well taken. We don't see a change to the IP based on this comment, but we are considering that more detailed training. And that is it for the IP comments. Any questions? Alan, you still have you hand up.

MR. CAMPBELL: Yes, Samir, again thank you guys for acknowledging the comments and responding as you did. I think just the one, we had those two comments regarding the subjective terminology there.

Our intent here is at the highest level possible to kind of tighten in the bands of that range of acceptability. When we get into regional differences or differences with inspectors, you know, that's what we're trying to minimize to the extent practical.

As we move forward and as we have more runtime with the inspection procedure, this is something that, you know, we're sensitive to and will be tracking, and as it matures, we'll continue to be communicating with you as we see either examples or additional comments.

Otherwise, you know, again, thank you for acknowledging these. We just got the hard copies of these with the meeting material, so if there's any additional follow-ups that we have, we'll communicate

that to you.

MR. DARBALI: All right, thank you, Alan.

MR. CAMPBELL: Thanks.

MR. DARBALI: So, if we don't have any other comments, I'll turn it over back to Shiattin. Oh, Ted, go ahead.

MR. QUINN: Okay, thank you, Samir, and I hope -- this was a very good summary. I'm sure NEI will review and provide feedback.

Okay, so my question needs to go back to the turnover of the SER to this 52003 series, and maybe the word turnover is not appropriate, but what I want to address is the lessons learned from Diablo.

One of them was that the site-specific follow-up actions had a tracking mechanism, and I heard what Mike said and what you said, and I'll take a very simple example.

The very first one from Diablo said ensure that a new key switch used for setting subsystem operating mode is added to the key control procedure, so there is an interface between the design team and the site construction team that is also changing station procedures.

If I just use that simple example, Samir, how would that be tracked by the NRC as a turnover

from SER to, you know, to the inspection branch?

MR. DARBALI: Right, so what we did for Waterford, we had similar recommended inspection activities, and so we created that table, and I think it was like an internal memo we sent from the technical group to the respective region, so it went to Region IV and said these are the recommended inspection activities.

Now, what happened also is we were also involved in the development of the inspection plan. So, we provided feedback and input into the inspection plan, both for FAT and SAT, for those activities we had identified as recommended inspection items, and that's how we've been able to maintain tracking, that all of those recommended inspection items made it to those plans.

MR. QUINN: Are those visible to the licensee?

MR. DARBALI: So, for Waterford, those were shared as an internal memo. It wasn't a public document or a letter to the licensee.

MS. MAKOR: And Samir, can I add? The plan for the installation is to share that with the public, so we did recognize there is value in sharing that publicly.

So, typically for regional inspections, we don't share our inspection plans, but for this one, we're going to share our inspection plan for the actual installation, so that will have the recommended items as an attachment in the inspection plan.

MR. QUINN: But for the future, I really think it's a tool that is of benefit to the different portions of NRC staff. I think it's a valuable tool and the question is how your licensees know what is on those items so they can address them in a formal manner.

(Simultaneous speaking.)

MR. DARBALI: Go ahead, Mike.

MR. WATERS: This is Mike. This is a good comment to consider, and again, it's a multi-dimensional thing here. One is, you know, the wording, we don't want to imply that, again, that the licensing decision is somehow dependent or even linked to those specific recommended inspection items.

Now, the licensee has already committed to do those, right? That's part of the plan and part of the design, so they're obligated to do everything you say, right?

But we didn't want to word it in a way that made it sound like it was, you know, like ITAAC

or, you know, like a site-specific action item you see in topicals. We wanted to get away from that because the licensing decision is independent.

But we do communicate those recommended items, and as Shiattin noted, those are considered by the region and directly incorporated into the inspection plan.

And your example of, what was it, key switch, and I think when we recommend things, hey, we know the design and we know what attributes, features, elements of the plan that are more significant to us, more important to us, more significant to the extent we can do that, and those are the type of things we tell the region that given your inspection times, here is what we recommend the focus to be on.

Ultimately though, it is a region's decision on what the scope is and how to inspect it, but we are, as we've communicated, highly integrated and we communicate on this and, you know, the I&C is usually part of that inspection team to some degree.

MR. QUINN: Thank you. End of comment.

MR. DARBALI: Thank you, Ted. All right, so, Shiattin, I'll turn it over to you.

MS. MAKOR: Okay, so this is just, it's one slide, so I'll just go ahead and jump into it

because it goes in line and kind of parallels the conversations that we've been having as far as lessons learned and then the NEI comments, and then this area, I wanted to just briefly touch on it just because it has a relationship.

So, with the implementation of digital technology and safety in security systems, it's been useful in resolving Ops lessons issues, but it also presents challenges.

So, this workshop focused on inspection procedure 52003, but there's also digital upgrades that do not require a license amendment and those fall under regional reactor and resident inspector baseline inspections.

So, there is a working group that is out there that's working on digital instrumentation and control operating experience smart sample.

So, the purpose of this is to recommend inspection activities and provide support for baseline inspections. The working group has members from the regions, headquarters, and we all came together to try to work on drafting this guidance.

So, it kind of parallels IP 52003, but it's more used with Inspection Procedure 71-111.17, which is evaluation of changes, tests, and

experiments.

So, the modification inspections are typically where the regional team will go and look, and so we're having more and more digital activities come up.

So, when we review them, one thing that we are checking for is that should this have had a license amendment, you know, request, or is this something that the site can do on their own?

So, we're working on additional guidance and, you know, resources to help inspectors, regional inspectors, resident inspectors understand the differences between digital I&C as it would be under baseline Appendix A versus digital I&C in the inspection procedure, the non-routine type inspections that fall under Appendix C.

That's really all I want to emphasize with that since we had a lot of conversations about training for inspectors. This is another tool that inspectors will have. And that will conclude my comments on that. Any questions or comments? Ted?

MR. QUINN: Do you have a schedule?

MS. MAKOR: So, we don't have a schedule. We were trying to get it out I would say late last year, but we have had some delays in trying to include

lessons learned. You know, we just did the Inspection Procedure 52003, so that's one that -- I think that the focus shifted to that.

And so, the working group is still in process and I think we'll have to revise the expected date because we did want to try to complete it before the end of last year, but that didn't occur.

MR. QUINN: Okay, thank you.

MS. MAKOR: You're welcome. And then I think there was a question that I saw pop up on the inspection procedure, and the inspection procedure is 71-111.17 and that's evaluation of changes, tests, and experiments. That's typically where digital modifications that don't require a license amendment are covered.

One thing to note is that it could fall under design basis. Just depending on what inspection is being done, it could be covered in other areas, but the main core one is the evaluation of changes, tests, and experiments that we usually look at digital upgrades or modifications, sorry. Any questions? That would conclude that portion.

MR. JAIN: If there are no more questions for Shiattin or any of what we have covered so far, we are slightly ahead of our schedule. We will take an

early lunch break for one hour and reconvene at 1:05 this afternoon with a session on HFE. See you then. Thank you.

(Whereupon, the above-entitled matter went off the record at 12:04 p.m. and resumed at 1:05 p.m.)

MR. JAIN: Hello, everyone. Good afternoon. We'll start the afternoon session with a presentation by the NRC staff on HFE reviews. Brian Green of the NRR Operator Licensing and Human Factor Branch will lead the presentation. Brian?

MR. GREEN: Thanks, BP. Hi, everybody. Good afternoon. I'm Brian Green. I'm the team lead for human factors.

Dave Desaulniers, the senior technical assistant for human factors, is on the line with us, and I know my branch chief, Lauren Nist, will be joining us shortly, and I believe Jesse Seymour will be here as well from the human factors staff.

I look forward to having a productive discussion today so we can continue to keep making progress with regards to human factors for modernizing control rooms. Next slide, please.

So, here is a quick overview of what I plan to present on this afternoon. I'm going to give a kind of a rundown of some of the challenges we've

seen from our pre-application interactions with a few licensees at this point.

I'm going to present a few potential solutions, including a brief description of multi-stage validation, it's a relatively new concept, and also a discussion of using alternate test beds in that process.

And I'm also going to discuss some of, you know, our expectations for how the application will come together in an LAR submittal and kind of go through some of the guidance about what we have available and what the expectations are there. Next slide, please.

So, Chapter 18 of NUREG-0800 provides the staff with guidance about how to conduct various types of human factors reviews. Chapter 18 references several guidance documents to consider when doing various sorts of HFE-related reviews.

And of particular relevance to large-scale control room modifications is NUREG-0711 which describes a risk-informed and performance-based approach to human factors design which is based upon the systems approach to engineering.

So, in accordance with the guidance in 0711, the integrated system validation, one part of

the human factors process, has been the accepted means for validating the HFE of significant control room modifications.

ISV is typically conducted on a full-scope, high fidelity plant-referenced simulator, such as those used for licensed operator training and examination.

And ISV is perhaps, some of us would argue, the most important aspect of the 0711 process because it includes the use of performance-based metrics to demonstrate that the HFE design is an effective and safe means for the operator to monitor and control the plant.

In addition, the ISV presents an opportunity to identify issues with the HFE design, and any issues that may have safety implications can then be resolved in the final design. Next slide, please.

Maintaining the availability of a simulator meeting ANSI and ANS 3.5 for operator training and examination limits the availability of a modified simulator to use as a testbed for HFE validation. So, one of the big challenges we've seen is the timing of when the modification to the simulator can actually occur.

This is complicated when we look at the design development and testing schedules that place ISV near the time at which the actual control room will be modified and it may provide insufficient time for the NRC staff to consider ISV results when making a safety determination.

It's really back loading -- it had the potential to back load things a lot. And this is something that's kind of come to our attention in the last, you know, several months or so as we've seen the more detailed schedules, and when we compare it to the staff, the planning events that we do internally to figure out how we're going to actually conduct our review, we find that, you know, the timing of the ISV is just not necessarily at a time when we can look at it and conduct that.

So, that's -- the key challenge we're finding is finding an ability to look at validation results that works for both of the schedules for the licensee and for the NRC. Next slide, please.

The alternative review process discussed in ISG-06 is intended to be used if the NRC staff will decide whether to issue or deny the license amendment before completion of the detailed design, implementation, and/or testing activities.

And this poses a challenge where HFE is concerned in that ISV testing would likely not be performed until after the NRC would be expected to issue a licensing decision, and the ISV results typically relied upon would not be available for the staff to consider while making their decision.

So, in other words, delaying the ISV until after the staff needs to make a safety determination robs the staff of key information needed to make that safety determination.

And I'd just like to take a quick little aside here to note that the NRC staff have substantial experience conducting license reviews in which detailed design of the control room is not complete at the time of licensing.

The staff successfully licensed the AP1000 using DAC or design acceptance criteria, a special form of ITAAC. Staff also completed a review of the NuScale control room using a similar process, but was able to avoid using DAC because the applicant completed the design work while the staff was conducting the licensing review.

So, in that case, the applicant submitted a series of supplements, or result summary reports in this case, that superseded and/or supplemented the

implementation plans that had been docketed with the application.

In both cases, the applicants and the NRC staff were able to utilize the flexibilities inherent in the NUREG-0711 process to evaluate the detailed design while still providing the NRC staff an opportunity to review final results.

Unfortunately, Part 50 does not have a similar provision for the use of ITAAC. However, the staff has been working to identify solutions that will support the needs of the industry while still providing a meaningful regulatory checkpoint for the NRC to review human factors validation results needed to make a determination of reasonable assurance of safety.

Next slide, please. I think we can move onto the next one and we'll discuss some solutions here.

So, one potential solution that the staff have identified to address this challenge is called multi-stage validation or MSV. Multi-stage validation entails a staged approach to validation testing where results are obtained at stages throughout the design process. ISV is still a part of MSV. It's just the last portion of it would be the way we typically think

of just the final stage.

So, MSV incorporates successive, coordinated validated efforts performed at multiple points or periods during the development of a control room design or design modification.

So, we think that MSV may provide an opportunity to collect that performance-based data that we would normally get during ISV earlier in the process by looking at other testing that a licensee is already planning throughout the design process.

So, in other words, using MSV may help to move the opportunity for regulatory oversight to the left and would make it more likely that the NRC could support the types of project schedules that we're seeing requested.

And I think it's important to point out here that the goal of MSV is not to really make, you know, a significant more amount of work. We're thinking that there are lots of design activities that are happening with the designers that typically do not have the, you know, the regulator doesn't necessarily look at.

But if we were to reconceive of it, we might say hey, you know, we're going to run this usability testing early on and maybe we can use this

as -- a licensee could reconceive that and say hey, we can start to use the results of this test to start building our safety case to convince the NRC that things are going to be safe as we progress through.

So, we're hoping to find those, you know, those correct checkpoints where we can find those efficiencies without creating a lot of extra work in there as well. Next slide, please.

So, this is just a little, a picture of the standard. The IEEE standard 2411 was released in 2021. So, if you need this as a reference, feel free to look that up, but I want to point out that this standard was based on the work conducted by NEA, and several NRC staff were involved in a series of workshops that were supporting the NEA work and Dave Desaulniers was one of the key players in developing the IEEE standard as well.

So, our staff are fairly well familiar with the concepts in here and we do see this as -- we're well aligned that this is a valuable tool even though it's not necessarily called out by name in our guidance yet such of 0711. Next slide, please.

So, this slide summarizes at a high level, and I don't want to dwell on this too long here, but the defining characteristics of multi-stage

validation, and these key points include, you know, the following considerations here.

The activities that comprise the MSV are validation activities as opposed to simple tests and evaluation, so there is some sort of goal to provide a validation result at the end of it.

The thought is that they're conducted in series and that they are constructed and coordinated in a way that they build upon each other to support a final validation conclusion.

We can come back to that more if we need more discussion on that, but it kind of helps to frame the concept of MSV to see some of these characteristics. Next slide, please.

The IEEE standard describes a series of guidelines, which you see on the slide here, that we think may be suitable as acceptance criteria. We may need to have some more additional discussion on that, you know, that this may work in lieu of more specific criteria.

So, let me read through these real quick. The first one is that validations are conducted from early, AKA conceptual, to detailed stages of the design development and operations.

B, the subjects of validation comprising

an MSV include design concepts. Examples are operations and automation, system elements such as subsystem designs, and the integrated design.

C, results from each validation stage contribute to an accumulated body of evidence for the validation of the final design.

D, design changes made subsequent to a stage of validation are addressed through testing or analysis in the subsequent stages.

E, at each stage, validation methods, controls and rigor are commensurate with the intended use of the associated results and findings, and Annex A of IEEE 2411 gives some examples of that, how that can be done.

And validation testing of design elements that are novel, complex, or critical to safety is initiated early in the design process and confirmed in the integrated testing.

I know from some of our discussions, you know, that there is not an NRC guidance document that describes how to do multi-stage validation, so in lieu of that, this may be our best guideline. And we recognize that there is some consternation about how some of these criteria could be filled and I think that would be an area we could have, you know, some

further discussion on.

You know, my thought is personally that point B here, the validation methods, controls, and rigors, that's certainly one that I think, you know, licensees would want to have some more discussion on, and I believe we have the tools to do that within pre-application meetings.

You know, NUREG-0711 currently has lots of validation information in it about how to do it, and I think one of the guiding principles is that to --

We are not necessarily insinuating that every validation activity should be controlled the way ISV is described in 0711, that there is room for some reasonable grading, and we think that that would be something that we could have more discussions on perhaps in pre-application meetings so that we can avoid any sort of misalignment between the expectations of a licensee and the NRC. Next slide, please.

So, some things to consider when we're thinking about the early-stage MSV results, recognizing the constraint that ISV testing can place on the scheduling for significant and complex control room modifications, staff sees that the potential to leverage early-stage MSV results in evaluating an LAR

submittal for a proposed I&C modification.

Assuming we have sufficient information, it's possible the NRC could reach a determination to support approval of a proposed license amendment based on the early-stage MSV results without the availability of final results from ISV testing.

So, we would consider these results in congruence with the final ISV testing. However, the review of ISV testing may be relatively, you know, relatively brief on the back end, assuming that we had the opportunity to build the confidence using the MSV data earlier on. Next slide, please.

To be considered as providing a sufficient basis for the NRC's safety determination, early-stage MSV testing should provide a reasonable assurance that the eventual ISV testing will be successful.

Here are some examples of things to consider, the conformance to the MSV guidelines that I discussed earlier, the sufficiency of the testbed scope and fidelity to support to the validation objectives, the adequacy of the test scenarios that would be used should address both the normal scope of operations and emergency operations for which any HSIs are to be used, and the extent to which the results demonstrate the changes to HSIs will not have an

adverse impact on the ability of operators to safely conduct the risk-significant activities. Next slide, please.

So, I just want to reiterate here that, you know, if we move forward with an MSV approach, it does not eliminate the need for ISV testing. It would still be necessary within the program to show that the final system actually performance as it's described.

However, we're just going to build our case based on the implementation plans in addition to the MSV data, so we still have kind of a method, a balance between methodology and results to rely on here.

We may also elect to conduct follow-up inspections of the final ISV testing results along with the resolution of any identified HEDs. Those might be of particular importance if the ISV were to run and any significant issues were to be addressed, we would want to make sure those are closed. Next slide, please.

One of the tools that we expect, you know, that we have heard a lot from different licensees about and we think that many will probably follow suit, is an interest in using an alternative testbed.

So, alternatives to full-scope, high-

fidelity simulators as validation testbeds may be acceptable depending on the stage of the validation being credited towards the NRC's safety determination and the nature of the control room modification.

The glass top panel, the glass top simulators are one that we think are going to be particularly popular. However, I want to note that with MSV, there are -- you know, you can define different stages in different ways.

So, you may be doing some sort of conceptual, validation during a conceptual stage of design in which, you know, a glass top simulator may be overkill or may be unnecessary or unavailable. So, in that case, you may use mockups, and given that it's early stage, you know, that very well may be an appropriate testbed.

So, we'd want to have some level of alignment just to make sure we're not heading towards a misalignment later on, to make sure that the scope and fidelity of the testbed are adequate for the purposes of the particular validation that we're looking at in any particular stage. Next slide, please.

If the credited validation testing will not be performed on a traditional full-scope, high-

fidelity plant-referenced simulator, we think that some justification should be provided as to why the alternative testbed being used is adequate.

So, again, this would be an area that we would probably want to have additional discussion, perhaps in pre-application space, just to make sure that we're aligning on what some of these tools are and how they might be used.

If certain components or subsystems within the testbed will be modeled using a low-fidelity simulation, without full haptic fidelity per se, sufficient justification should be provided to conclude that the performance is not to be expected to be adversely impacted when operators are interfacing with the actual components or subsystems within the integrated system. So, those are the sorts of considerations we might have in that discussion. Next slide, please.

Okay, so some things to consider, you know, as a licensee puts together an application that uses MSV is that staged testing, if it's used, should be consistent with the MSV guidelines we discussed earlier.

And the remainder of the HFE program activities should be conducted consistent with the

0711 process and the Standard Review Plan Chapter 18 with one note in that NUREG-0711 does not describe MSV. However, we believe that MSV is consistent with the validation activities described in that document, and we believe some level of grading would be acceptable, you know, based on the particular plan.

So, reading through that guidance would provide, I'd say, some breadcrumbs about how to put together an application that has MSV if you were to pare down the ISV material to a level that was sufficient to prove, sufficient for the objectives of a particular stage of MSV, I think we would find ourselves in the right place.

And the validation activities and results should be assessed within the context of other HFE program activities. Next slide, please.

So, this table here is a summary of -- in the first column, you see a description of various human factors program activities. These are described in the 12 elements of 0711, and NUREG-0711 describes basically two types of submittals.

There's an implementation plan and there is a result summary report. An implementation plan as we see it typically describes a methodology to conduct one of the analyses, or design activities, or

evaluations described in 0711.

And an RSR is, the corresponding RSR that goes with an implementation plan describes the results of that activity when it's carried out, and usually has some level of summary of the process as well. And 0711 describes that a licensee has a couple of different options as far as how to put the submittal together.

The first one, and this one may not be practical, but I'll start with it because it's the easiest to explain, is that the licensee could come in a result summary report at the time of a license amendment and say hey, we've done the design work. We have the design work. This is the results of that design and the supporting analyses. Review it, NRC, and move forward.

That is the easiest path through because it is the most descriptive and it's easiest for the staff to wrap their head around. However, we don't expect we're going to see a lot of license amendments that come in with that path given some of the challenges and the timeframes needed to design these sorts of mods.

So, the alternative approach is to submit the implementation plans with the license amendment

which describe the methodologies about how the analyses and design work will be done, and then follow at some later point in time the RSR that describes the outcome of those activities.

And that's how we end up closing the loop here, and the real challenge, as I described before, is that the human factors verification and validation activity tends to occur outside of the time when the staff will be conducting the license amendment review.

So, the challenge is how do we get an RSR into the hands of the staff in the time they can look at it? And that's why we think MSV allows us that opportunity, to give the opportunity to the staff to look at that data of the results of that important element to us.

Let me see. There are a few exceptions. Not all IPs have RSRs and those are dictated here. I don't want to go into those a whole lot. If we have questions on that, we can have those later. The ones that we do see RSRs are clearly marked here and we can get into that if we need a more specific meaning or in the question section if we want to here. Next slide, please.

So, this slide basically summarizes some of the key points from the table on the previous

slide, so I'm going to run through these real quickly verbatim here.

In accordance with NUREG-0711, applicants should include within their LAR submittal an implementation plan for each of the 12 elements of the HFE program review model.

IPs, and I know we, the NRC likes to use IPs as the inspection procedure, so I apologize for having an inconsistent acronym here. When I use it, it's implementation plans.

The implementation plans should describe the methodology for conducting the activities associated with that program element. The IPs are subsequently expected to be followed up with a result summary report once the activity is completed during the licensing review period.

Alternatively, if the applicant already has a completed RSR for a program element at the time of the initial submittal, they should include that in their LAR application. Next slide, please.

So, if an application relies on early-stage MSV results to inform the NRC's safety determination, the IP discussing the verification and validation should include details as to how early-stage test results will provide reasonable assurance

that subsequent ISV testing will be successful and will not result in HEDs with safety consequences, so that would be an appropriate place to put that level of description.

Also, we should be confident that any HEDs that come out of this process are going to be resolved, well, any HEDs with safety consequences. Not all HEDs necessarily need to be resolved, not according to the 0711. Next slide, please.

If an application relies on early-stage MSV results, information should be provided to describe that those early-stage results are performed under a sufficiently robust test program to ensure credible results from early-stage testing.

Applicants should consider providing a discussion of their program's conformance with the six guidelines for effective MSV testing address in the IEEE standard, and applicants should consider discussing the 0711 criteria for ISV testing that are applicable to the MSV program being used.

I said it before, but perhaps I wasn't real clear about it, but the ISV criteria in the staff's opinion are a very robust method, so if you were planning an early-stage validation and you wanted to scale that down, that would be one way to do it

would be to pick those criteria that are of particular importance.

For instance, the ISV criteria have some discussions about the qualifications of the human factors team, and maybe there is some early design work where maybe you don't need a human factors expert to be involved in it, or perhaps you don't need a licensed operator to do some early testing, that you might be able to do it with somebody who is not licensed to do some early, you know, HSI usability testing or something like that.

So, there may be some arguments to say hey, we're going to reduce to a subset of these ISV criteria, and we think that these particular ones help to ensure that the results of the test are credible in the long run. Next slide, please.

The initial LAR submittal should provide an estimated timeline regarding when the V&V information will be available for review.

After I looked at this slide, you know, it says here they should be in the LAR submittal, but really it would be preferable to have these discussions in pre-application space at the earliest point possible.

I know there is some frustration that this

topic is coming out as late in the process as it is, and, you know, I think that had we had more discussions, substantive discussions about the contents of the human factors program and how and when those things would be submitted, we might have found that earlier.

So, I just kind of want to undercut what I have on this slide here to say the pre-application space is really the best option to start this discussion.

But we should have some consideration about a timeline that clearly demonstrates what information will be available at what points throughout the NRC review period because we may need to get in and do an audit or to look at some of this, and with the short timeline, you know, we're shooting at a very small window typically, so anytime we get to plan is preferable.

The submittals should also discuss contingency planning and expectations is there are possible delays in the completion of validation testing. For instance, you know, if a late-stage MSV stage identifies a safety-critical HED or human engineering discrepancy, that would be something that we would expect to be fixed.

Now, there's lots of ways to fix HEDs, but in some cases, it may cause a design change, so we would be looking to make sure that there is some sort of ability to do that. Now, not all HEDs, you know, warrant design changes. Sometimes they can be fixed with procedures, or training, or other methods, but sometimes design changes are necessary.

So, there is a concern that if an HED comes up real late in this process, it's going to ruin a lot of schedules, and clearly our position will be leaning on the side of safety in those cases.

Such a discussion will help to support the NRC consideration and acceptance of the proposed approach discussed within the LAR submittal and development of the NRC review timeline, and licensees are encouraged to discuss the timing as early as possible. Next slide, please.

So, this final slide here on, you know, the LAR submittal is that the RSRs submitted for NRC review should include the information indicated throughout the 0711 for each of the associated HFE review program elements.

As discussed in 0711, RSRs may include summaries for the indicated information, provided that the references given are for more detailed documents.

Sometimes RSRs, you know, if there was an implementation plan submitted, you know, on the early side, an RSR can say hey, you know, refer back to the IP. We followed everything in it, or, you know, we had to modify it. We went through a change process and made a change to the IP and this is what that change was.

So, the RSR should have some level of the final methodology tied to it, but if that's incorporated by reference, that's typically okay.

And I know there was some discussion about the electronic reading rooms. You know, to the extent possible, the IPs should be on the docket. If there are supporting documents, and this very well may be the case, that other licensee procedures or documents are to be used, you know, certainly those would be things that we would look at in electronic reading rooms.

We are open to finding appropriate documents to be in there, into an electronic reading room. One that is, you know, quite typically looked at in there is the detailed scenario guides for running validation testing tend to be things that the licensees put a lot of time and effort into, are usually proprietary, and they're often under exam

controls, so there is a lot of good reasons not to docket that.

So, we have in the past been willing to look at those in an ERR, and we can consider other expectations, but typically the IPs themselves and the RSRs would be something that would be docketed. Anything aside from that, we would take under consideration and willing to have that discussion.

So, those were the key points I wanted to bring up. I want to just open the floor for Dave or Lauren, if there was anything that I missed that they wanted to add before I open it up for questions here.

MR. DESAULNIERS: Thanks, Brian. I don't have anything to add. I'll just wait for questions.

MR. GREEN: Great, I see we've got a hand here. Sorry, my computer is a little slow loading the names here for some reason.

MS. GOLUB: Brian?

MR. GREEN: Pareez, yes, hi.

MS. GOLUB: Hi, first, thank you for your presentation, appreciate that. I guess one of my questions is we appreciate all of the dialogue on multi-stage validation, but from an industry perspective, it's difficult just looking at all of the slide material and the NEA document to really

understand what would need to be done.

You know, it feels a bit overwhelming, frankly, and so I guess I'm wondering is there any examples of precedents or anything out there that industry could take a look at so that we would have a sense of what is necessary if anybody wanted to go this path?

Is there anything out there or is it really just guidance and then, you know, folks are going to have to take their best shot at it?

MR. GREEN: So, I'll start to answer that and Dave may want to jump in. I don't know of a particular precedence where this has been applied yet. I do know that, I believe it was the NEA document, and Dave, correct me if I'm wrong on this reference here, provides some examples. I know there was one example about how the MSV stages might be considered.

When we were putting that together, we were hesitant to prescribe what stages should be used because we recognized that different designers approach design in different ways and we did not want to, you know, tell a designer that uses one approach that their approach is somehow not adequate or not appropriate because it's inconsistent with the prescribed stages that we had put together.

So, we chose to put an example in that report and that particular one, it was kind of a four-stage MSV that started with a conceptual design stage, moved to a subsystem design stage, and did some integrated system design stage, and then, you know, worked itself into a deployment and operation stage.

And then, you know, as we would envision it, and my memory is kind of rusty about how this gets built out, would be that, you know, the designers would consider the objectives within those stages and propose the validation tests that would conclude each of the stages.

So, and that, you know, that particular example, I had suggested, you know, the integrated system design stage might be a test very similar to the ISV that we see, but in the stage that precedes that, the subsystem design stage, there might be, you know, perhaps the full simulator is not available yet, but large-scale or large semi-functional level simulations of different systems might be available and you might be able to run some desk tests, or, you know, maybe not with a licensed operator.

Maybe you've only got some design engineers at that point or, you know, so there is some kind of wiggle room to make those determinations about

who the appropriate people are and what that test looks like.

And, you know, I think the guiding principle as I see it is to understand what the objective is within the defined stage that a licensee makes, and then to, you know, design an appropriate test to conclude that stage, you know, using some of the ISV tools that are available or similar.

You know, it doesn't necessarily have to be the ISV criteria from 0711, but put that together in a way that creates a creditable, sorry, not creditable, a credible result.

You know, from a regulatory standpoint, when I go and look at one of these stages, I want to believe the results and I want to see that, you know, if you say that, I don't know, the updated rod control system works, I want to see a test that gives a good flex to that using whatever simulation or tool is available at the time, and I want to understand what limitations there are to that test.

You know, maybe the rod motion doesn't go all the way or you don't have all of the interfacing systems connected yet. You know, if I understand some of those limitations, I can say okay, well, this is a good early-stage test. It might not be enough to

convince me that, you know, we don't need to look at anything else down the line.

So, you know, it's a matter of do you have enough control that, you know, a reasonable person is going to look at it and say, yeah, I believe the results that came out of that test because you controlled the methodology that went into it.

I know that's still a little vague and I'm going to turn to Dave here to see if he has a better or maybe a more concrete example to answer your question.

MR. DESAULNIERS: Okay, sure, Brian. Well, I think that an example that we can point to, while not identified specifically as multi-stage validation, may not have all of the, meet all of the check boxes of multi-stage validation, but I believe is just really quite consistent with what we're, the notion that we're trying to put forward here is a recent review example we had with NuScale and the design certification for their small modular reactor where early on in the process, NuScale engaged with us on their staffing and it was a unique staffing approach.

And therefore, they undertook efforts to do preliminary testing to show that indeed the

staffing concept that was being used there was a viable approach and gave confidence for both the applicant and the NRC that we were proceeding down a path towards success.

So, you know, those tests were being conducted, not with licensed operators and with their fully developed procedures, but they were robust tests consistent with the level of design development that was available at the time and controlled in ways, as Brian noted, such that the individuals going through the scenarios for the staffing validation didn't have prior knowledge of what those test scenarios were going to be.

And so, I think if you're looking for an example within the NRC and, you know, that's been reviewed, within the U.S. that's been reviewed by the NRC, that, you know, I think gives some indication of the type of thing that is done under a multi-stage validation type approach.

There, we're not talking about a subsystem, but really it was a staff concept that was being validated, and it aligns with, you know, the early-stage validations of design concepts.

MR. GREEN: Yeah, that's a great example, Dave. Thank you for bringing that one up. I should

point out that NuScale provides a unique approach that may work for some licensees in that they submitted the implementation plans with the, along with the license application.

And there was an agreement that we had come to with them at one point in pre-application space where, you know, they were not interested in having a lot of DAC as part of their strategy, and their proposal to do that would be to provide an implementation plan with a license amendment, but then conduct all of the validation activities, all of the design and evaluation activities before the staff would be done reviewing that implementation plan.

So, it occurred within the scope of a licensing process, in which case the staff were able to go and audit the validation testing that we saw, and it provided a high level of confidence and was relatively easy to move forward with.

Now, that may not work for all licensees, but it might work for some and it was a fairly successful strategy, I think.

MR. JAIN: With that, I see three hands raised. I will go with first Bill Hannaman. Please, go ahead with your question.

MR. HANNAMAN: Hi, can you hear me?

MR. GREEN: I can hear you, Bill. Thanks.

MR. HANNAMAN: Okay, thank you. I was really impressed with your slide 17 where you actually kind of laid out all of the 0711 activities and then you can kind of see a pathway in there depending on the complexity of the design and so forth, but it looks like if you put the IP plans in with the submittal, with the LAR submittal for a change, that that would allow you to do the approval of the LAR at that point in time, and then I don't know the role exactly of the regional inspectors, but would they do something related to the HFE plans?

MR. GREEN: Yeah, see the challenge that we have with what you say about making the licensing determination on the IPs alone, you know, that's kind of -- Bill, I've never had you over for dinner, but I'm not much of a cook, but if I showed you a nice recipe, you know, you may or you may not get a good meal out of it, and so that's why this validation part of it is a key part. Sorry, we're getting some -- we got somebody on the line, Mike. Okay, there we go. Thank you.

So, yeah, you know, that's why the verification and validation activities has always been a really key part of our decision, and that's one of

the challenges here is that for the staff to write a safety evaluation, we have to make our conclusion with the information we have in hand, and we have a -- we can't really bump that into the regional inspectors to confirm that. It leaves us lacking on a key bit of information needed for the safety evaluation.

So, I mean, I think, you know, NEI is going to give a presentation here about how, you know, perhaps a license condition might work. We have had some discussions on that and, you know, we're skeptical, but we'd like to hear it through and see if there is a path there, but that's generally been, you know, something we've not been able to pursue, to delay --

MR. HANNAMAN: Okay.

MR. GREEN: -- that part of the decision into that level of inspection, but I appreciate your question.

MR. HANNAMAN: Okay, well, thank you.

MR. GREEN: Thanks.

MR. JAIN: The next question is from Richard Paese. Richard?

MR. PAESE: Yes, can you hear me okay?

MR. GREEN: Go ahead, Richard. Thanks.

MR. PAESE: Yes. Thank you. So I'm not

sure if this topic has come up before, so my apologies if it has, but my question is related to the basis for the LAR expectations. So my understanding in reading the rule for 50.34(f) is that this regulation isn't applicable for many of the operating plants that are doing these plant upgrades. And as I understand it, NUREG-0800 Chapter 18 and NUREG-0711 were largely written to give guidance for review and compliance against this regulation of 50.34(f). So what's confusing to me it's not clear why NUREG-0711 is expected if 50.34(f) doesn't strictly apply.

And the reason I ask this is because many utilities' licensing basis say don't reference NUREG-0711 or 50.34(f) but they go into a lot of discussion about the orders and generic letters that were issued to them back in the 1980s and how their design complies with those orders and letters including things like NUREG-0737 Supplement 1. For example, many of them go into a lot of detail about how they address the control room design review requirement from NUREG-0737 Supplement 1, but these types of requirements from their license and from these orders and generic letters, they're not really specifically discussed here in this LAR expectation.

So my question is how these two ideas are

being addressed together, namely, the expectation to use 0711 and the commitments that were made in the licensing basis for these plants which don't specifically include NUREG-0711 or have expectations to meet 50.34(f).

NUREG-0711, obviously, is a good process and I'm not advocating for -- for not using it, but my question is really going back to the actual regulatory and licensing requirements that are -- that we're using to tie back to the safety case. This seems to be a slight disconnect to me. So maybe the assumption is that 0711 is to be used to show how these licensees are determining the acceptability of the changes that they're making to how they previously -- to the previous requirements that the orders and letters that they have referenced in the license. But this idea isn't clear to me. So that's my question.

I was wondering if you could speak to that?

MR. GREEN: Dave, do you want to take a first stab at this or would you prefer for me to?

MR. DESAULNIERS: You can go ahead, Brian.

MR. GREEN: Okay. So, yes, it is -- it's a great question, Richard. So the first place I would start is GDC 19 does say that they have a control room

where they can safely monitor the plant. Not all plants are GDC plants, but those that are, you know, that is another -- there is a position, I believe it's -- I believe we wrote in the advanced reactor world, but you know, these principles are the ones that help us confirm that the operators can, and safely, operate the plant under the normal and emergency conditions.

50.34, as we know, does have some limitations about the dates in which the applicability is there. I know there is some rulemaking going on to fix that. I'm not sure what the correct interim answer is to those that fall outside of that scope though.

MR. MARSHALL: So Brian, would you mind if I took a stab at this? This is Michael Marshall.

MR. GREEN: Oh, yes. Please do, Michael. Thanks.

MR. MARSHALL: You're right about the applicability of 50.43(f), but the thing to keep in mind and you're also correct in pointing to the TMI orders as being the basis for the requirement for the many of the operating plants being the human factors requirements there.

50.34(f) wasn't backfitted on the existing fleet because of the TMI orders that are in place.

And in some ways, depending on the plant, the TMI order might be a little more restrictive or -- not restrictive -- has more specifics in it than 50.34(f). But generally, the NUREG and the guidance that NRC staff is using applies equally to both 50.34(f) and the plants to have TMI orders as to requirements for human factors activities.

Dave, Brian, did I get that correct?

MR. GREEN: I appreciate you jumping in with that, Michael. Thank you.

MR. MARSHALL: Okay.

MR. PAESE: Just a quick follow up. So the way I understand it is that -- so these licensees have committed to these orders, these generic letters, these are the -- these are their actual requirements. These are the things that are referenced in their license. They've performed actions according to those orders and those letters.

And the idea here is that 0711 is the document that is expected to be used to show how their changes to those -- to their compliant -- potential changes to the compliance to those requirements, 0711 is being used as the means to show why those changes are acceptable.

MR. MARSHALL: Yes, but one thing to be

mindful of, even though most of the plants got similar TMI orders, there might be some uniqueness and an individual's plant TMI order that might bring into question the NUREG applicability, but generally the NUREG-0711 should be applicable to the plants that received the TMI orders.

But again, there was a lot of correspondence after the initial order, I would say modify what licensees are expected to do or required to do. But you would have to recreate that paper trail to make a determination that the NUREG-0711 wasn't applicable.

MR. PAESE: Yes, I guess the concern that I have is that I think -- it seems to me that we might be getting lost in what the actual requirements are in focusing so much on 0711. Again, I'm not saying 0711 isn't an important document and a good document to use, but I think it's important to always remember to go back to what the licensing and regulatory commitments are and how 0711 might be used to satisfy showing continued compliance to those -- to those regulatory licensing requirements.

MR. MARSHALL: Yes. I agree. And again, it's good to acknowledge that even though the orders went out to everybody, again, there was subsequent

correspondence that might have customized how individual licensees responded to the requirements in the order.

So that would be wise for licensees to make sure they understood what their human factors' requirements were with regards to the TMI order, as they're assembling their amendment packages for submittal to the NRC.

MR. JAIN: Okay, with that, the next question is from Jacek Nowakowski.

Jacek, you can unmute.

MR. NOWAKOWSKI: Yes, good afternoon. Yes, this is Jacek Nowakowski. I'm with Framatome, Inc. And my question was regarding the definition of validation in your 0711 and in IEEE 2411.

Does the staff consider that word validation means the same thing in both documents and it will be interpreted the same way, meaning it can be used interchangeably as meaning as used in integrated system validation and as used as part of the multi-stage validation where it's broken up into somehow, substance of a validation. Is that word -- would you advise that we use that word when referring to the components of MSV or would you advise that we use a different word like analysis or test or something of

that sort?

MR. GREEN: I would have to go back and compare those definitions. I don't have them in my memory enough to contrast the two of them right now. And if maybe Dave is more familiar with them, but I guess I would question is this -- is it a matter of -- I'm trying to understand like the nature of the question. Is it that they perceive there to be some difference between the two of them? And you think we may be getting disaligned or is this more so a matter of how to communicate with the staff?

MR. NOWAKOWSKI: I think it's mostly about how to communicate not to cause any problems, you know, during the process. So just the question up front -- the validation definitions are slightly different. One of them kind of reads, it's kind of leading you into a degraded system validation and the IEEE one it talks about, like you said, components, subsystem, and system, so implying that there is multi-stages to validation.

So it's kind of a -- can we assume that the word validation is well understood and it's kind of colloquial at this point and we can use it for components of MSV, as well as we can use this for ISV, or would you advise that we use alternative words for

that?

MR. GREEN: You know, there might be something worth some more discussion. I'd want to think on it a little bit, but Dave, if you have anything to say -- I mean I don't see a problem with it, but I've not had a chance to digest it either.

MR. DESAULNIERS: Right, unfortunately, I haven't had an opportunity actually to bring up the differences in definitions, but as I seem to recall, I believe, 0711 provides a definition for integrated system validation whereas the IEEE standard provides a definition for validation.

MR. GREEN: That's right.

MR. DESAULNIERS: Am I correct? And so I guess where you see the differences in the definition may be that -- I think we're getting a little feedback there.

Okay, integrated system validation is a specific type of validation. So the IEEE definition I expect was written to be broader and incorporate ISV whereas ISV is going to be more specific to a particular stage of validation where your focus is on validating integrated operations.

So the bottom line is probably would not want to consider the two definitions -- I would want

to pull them up again to be certain on this, but I wouldn't necessarily see them as interchangeable in that ISV, or integrated system validation, is a more specific concept than validation.

MR. JAIN: Are there any more questions for Brian on his HFE presentation or the staff?

MR. NOWAKOWSKI: Sorry, I was muted and I was trying to reply to the answer if that's okay.

MR. JAIN: No, you go ahead.

MR. NOWAKOWSKI: Okay, so if I understand it correctly that the two definitions of validation should not be understood as interchangeable? I guess that was my question. So thank you very much for that answer.

And I have one more quick question regarding slide 18 that's currently up on the screen. Does staff have any preferences to seeing individual implementation plans or is it standard practice to combine them into documents that include multiple elements and multiple implementation plans in one?

MR. GREEN: That's a great question. It is convenient for us to have them separate, but there's nothing that requires that. And to some extent it may make good sense to combine some of them. For instance, and I'm just speaking off the cuff here,

this isn't anything that anybody has to do, but the HFE program management one, that's one that really stands off well by itself and I think from what I hear from licensees, that seems to be a stand-alone document.

It's unclear to me if we're going to get a single document that's going to -- to submit the operating experience review function analysis and allocation, task analysis, staffing equals, and treatment of important human actions. It could be -- this could be separated into six documents or in a single document. There's not a big difference to us. However, given the tight time lines that industry seems to have, it might be better to send them individually and get them into the staff's hands to look at them as quickly as possible. If they're all going to come at once, then I don't know that it makes a big difference though.

MR. NOWAKOWSKI: Okay. I appreciate that. Thank you.

MR. JAIN: Pareez, you can go ahead with your question.

MS. GOLUB: Thank you. Just on this same slide, I guess I want to make sure I understand what the expectations represented on the slide are. I had

thought from reading 0711 that the IPs being submitted with the LAR was sufficient. If you could address the V & V element to make sure that ISV was addressed either as part of the -- during the review stage or after the review stage if you had a sufficient argument for why that was so and your MSV was being one example of that argument.

But when I look at the slide, it almost seems like the RSRs are still required prior to the staff issuing the SE. I just wasn't clear on the answer that was provided when that question was asked earlier.

MR. GREEN: Yes, so thank you for the question if that was not clear. So the staff would expect to -- we need to come to a determination of a reasonable assurance of safety. And within the validation aspect, you know, we're still having the discussion right now on if -- let's just say, you know, a licensee was going to conduct a relatively sophisticated multi-stage validation and they were going to say, Brian, come out, you can watch us do the testing. I can go and watch that and I can write an audit report that says, you know, I saw that they were using the good controls, the right sorts of controls, and the results that I saw were positive and support

safe operation. And I can cite that in my safety evaluation. So that gives us the performance-based part of the process.

Now it would be preferable to have the RSRs that has the licensees' perspective on that. We're still discussing internally can we live without that and the answer is maybe right now. But I don't know that we've determined that.

One of the reasons, the justification behind that is the licensee would run their tests and draw their conclusions and their conclusions might be different or there might be some HUDs identified that we don't see in the week that we're there. So it's just a matter on how much of that information -- how much confidence do we have at the time that we make that observation.

And you know, if we go in and we see a test that has lots and lots of issues come up, and the operators can't safely control the plant, then we're not going to have lots of confidence at that point. But if we get in there and we do see that things are working as expected and the HSIs are conforming with the guidelines and things like that, then perhaps our audit report is enough to get us across the finish line. That might be something for some additional

discussion on both sides, but we are considering that right now.

As far as for the other elements go, you know, we can get in and audit those. We don't necessarily look at all of them. For instance, task analysis is one that we typically find to be an important part of that process. Specifically, because it feeds into the verification and validation activities real nicely. It tells exactly what the operators have to do and those get built into the procedures and those procedures are the ones that the operators tend to run in the V & V. So there's a direct nexus there.

You know, function allocation could be really important if a particular modification is going to be automating lots of things that were not previously automated or vice versa, making lots of manual actions instead of things that were automated. But it may not -- you know, depending on the mod, it may not be as important. So we would have to figure out how we would handle that RSR as well. So those discussions there.

I don't think those are necessarily going to be challenging ones, but there is some room for discussion there.

MS. GOLUB: Okay. Thank you.

MR. JAIN: Are there any more questions for the staff on HFE? If none, then we can ask NEI to make its presentation on HFE.

MR. GREEN: Jacek has one more.

MR. JAIN: Go ahead.

MR. NOWAKOWSKI: Sorry to be monopolizing your time. Just quickly, do you understand that HFE analysis elements of NUREG-0711 to be prerequisites to the human system integrate design element? And then also to the MSV components or do you think that MSV components can happen prior to the completion of HFE analysis, you know, like its function analysis, task analysis, and all those other elements?

And do you think is there a precedence of going through the HFE analysis as the design of the project matures or is it something that should be locked down before any kind of MSV element is attempted?

MR. GREEN: That's a great question. I'm really happy you brought that one up. I probably should have put that on the slides although I didn't think of it. So this is how we've handled this in the past because this is meant to be an iterative process. So, for instance, let's say you're going through your

design process and you know, you identify some issue with the way the operator is interacting with the automation. You may need to go back and revisit the function allocation and make changes to it so -- or perhaps the task analysis changes or the HSI design. All of these things have the potential to circle back, if and when issues are found.

So how we have treated this in the past is not that you necessarily need to lock down those analyses and have them be complete and never touch them again, but they need to be relatively sophisticated and you should have at least done a first pass on the task analysis and these other analyses. If you need to go back and revisit them, by all means. I think that's the expectation that you will, but it's not -- you don't tie up all around it and never come back to it.

Now that being said, you know, you can especially with a compressed scheduled, that may make it tempting to start some of the design work very early and that may cause you problems, but there's nothing that says you can't do these in parallel. However, the MSV guidelines do say that those validation activities should happen in discrete stages. So you would want to propose how you were

going to do that, you know, and how you were going to control for that and there are multiple ways in which that could be done.

But I want to let Dave jump in here in case he sees that any differently than I do, but I think that's a great question.

MR. DESAULNIERS: No, Brian. I think you answered it well in that you commented on the analysis stages are not necessarily prerequisite to the design. And there's an iterative process here where there will be naturally feedback between the design and analysis. And the other part of the question was with respect to multi-stage validation. I think the question was does analysis need to precede multi-stage validation? Did I hear the question correctly?

MR. NOWAKOWSKI: That is correct.

MR. DESAULNIERS: And no, that would not be the case. The general guidance for multi-stage validation is to start your validation work as early as possible such that again, you know, you could consider doing validations of conceptual design in which case you're clearly still in the analysis process. And so we see these processes, the design development and multi-stage validation as processes that go hand in hand and should be complementary.

MR. NOWAKOWSKI: Okay.

MR. DESAULNIERS: I'd only note that I will agree with Brian that the strict definition of multi-stage validation is taking it from early in the process and doing it in discrete stages. The bottom line criteria that I think is important to our discussions today is keeping in mind the notion that these validation efforts could use some performance-based information that can support the final validation conclusions.

So there's quite a bit of flexibility there in terms of how it's constructed for a particular design modification or new design. So I wouldn't see that as necessarily being a strict constraint if that's a source of concern.

I did want to take -- I'll stop, pause there. I wanted to make sure I answered your question and then I wanted to go back and modify an answer I provided previously to whomever asked the question about the definitions of validation.

MR. NOWAKOWSKI: Yes, that was me.

MR. DESAULNIERS: That was you, okay. Did I answer your question here about MSV?

MR. NOWAKOWSKI: Yes. Thank you, appreciate it.

MR. DESAULNIERS: And going back to the question on validation, I did pull up the two documents to see where there might have been some point of confusion. And I just wanted to clarify that under 0711 we provide definitions for both validation and integrated system validation. And so right there, that should show that we consider those as two separate concepts.

I think where the alignment is is that IEEE defines validation. It does use different terminology for validation. It does specifically refer to performance-based testing and to various aspects of a design. I think, in fact, NUREG-0711 definition of validation is a little bit more open. So just be sure you're comparing the two different definitions of validation right now. For NRC purposes, we use the 0711 definition, although I don't think in a practical perspective that there's much difference between the two definitions.

MR. JAIN: Okay, we have a question from David Hooten.

David, you go ahead.

MR. HOOTEN: Yes, thank you. When the industry was working with the I&C Branch staff to develop ISG-6 Rev. 2, one of the ideas that was

discussed related to what level of detail needs to be achieved in the conceptual design to support the LAR submittal. Was this idea of the -- the conceptual design needed to be bounding relative to the future detail design. In other words, whatever was done in conceptual design, the detail design, as long as it stayed within the boundaries that were defined by conceptual design, that that would be okay.

Does the Human Factors Branch view that similarly relative to the HSI design that you would do the conceptual design of the HSI to be bounding relative to the detail design phase activities?

MR. GREEN: Let me think on that before I respond here. My initial thought is that with an MSV-type approach that, you know, if you were to have a conceptual design and work through the design process and find yourself in a place where that design has evolved to something different, you know, if you were following the data on that that would seem to be the reasonable and prudent path forward there, but I'd have to think a little bit more on that. I'm not sure how that's all necessarily used within the ARP. I'm not sure if that's creating an inconsistency there.

But I believe the MSV standard does say that if you find yourself in that place where you're

moving away from those concepts that you know, you would measure that and take -- you would try to -- I don't know if you necessarily go backwards, that's probably the wrong way to say it, but you would reevaluate where you are with the changes to the design.

MR. DESAULNIERS: Brian, I'll just add on to I think the notion that you were trying to capture there. I think it's an interesting question in terms of starting with a conceptual design. I think what's underlying that question is would a conceptual design be sufficient for the staff to be able to complete its HFE review is what I'm reading into the question. And so maybe I'll pause there and make sure that I'm answering the right question.

MR. HOOTEN: Well, the idea with the I & C Branch folks was that a LAR could be submitted based on the completion of conceptual design, but not the completion of detail design. So the idea was that if during detail design you change the design to the point that it was no longer bounded by the conceptual design, then you would need to either alter the LAR, pull it back and resubmit it, or possibly do a 50.59 on it, whatever the various regulatory options might be there. But I guess I just wanted to see if the

human factors folks would do things the same way as the I & C Branch folks along those lines and I guess so far I've heard we're not sure. We have to think about it, maybe.

MR. GREEN: I guess if I could -- it seems to me that the conceptual design is kind of a different place than where we are or at least as I've conceived on it thus far and maybe there's room for different opinions here.

But the conceptual design happens at a very early stage and our thoughts are that the MSV would have some sort of point later on into that, into the detail design portion. Perhaps the detail design is maybe not -- not 100 percent complete at that point which is the benefit of the MSV approach is that we'd be getting some preliminary validation prior to the ISV. But if you were to get to the ISV and find that you had significant changes from the final MSV stage, then I think that some -- the change process would be the right way to look at it to see if there's a significant difference.

One part of the human factors process that gives us some insight on this, although it might read a little funny in the MSV world is the design implementation program activity. It does have a

change control process built into it that is meant to capture any changes to the design that happened after ISV, but before the design is implemented. So there are a couple of criteria in there that help evaluate that. And I think maybe the way to conceive of that is to open up the scope between -- instead of marking ISV at the entry point into that, that the final MSV point would be the entry point.

MR. DESAULNIERS: And Brian, previously you started alluding to a process with an MSV. One of the criteria that's in the IEEE guidance essentially speaks to if your early testing of a design results in changes to the design, subsequent testing has to take a look at have you changed the design to the point where you've basically invalidated the earlier testing?

And so, I guess that's the closest I can think about how we've thought about whether you've somehow gone outside the bounds of the conceptual design. We've thought about it in terms of, not the conceptual design as the boundary, but the extent to which you can credit the testing, and whether you've changed the design in such a way that, as I said, the prior testing done would no longer be able to be credited as a valid test of that design.

MR. JAIN: Any more questions for the staff on HFE? If not, then I would once again wave to NEI to make the presentation on HFE.

MS. GOLUB: Yeah, thank you, I appreciate that. So, first, again, thank you to the staff for giving us the opportunity to participate in this workshop. As you can tell from the questions, and all of the interest, this is a big topic for industry, especially for some of the earlier adopters of the alternate review process trying to get protection systems, do digital upgrades for their systems.

So, very important, I appreciate the staff taking the time to really explain in that last presentation as much as they did. Next slide please. We're going to go through these slides, and actually a number of the topics we've already started discussing, so that's kind of perfect. We created these slides prior to seeing the NRC slides, so while this presentation follows the NRC's, they're not in response to the NRC's.

They were really done independently just based on industry's first attempt to try to get their arms around this issue. So, just a little bit of background, and I think we've covered some of this, but NEI members acknowledge that when doing the NRC's

integrated action plan, modernization plans, in particular MP4A, when that work was going on in 2017, there wasn't a lot of discussion on the part of NEI members regarding significant main control room modernizations.

Those discussions primarily focused on digital I&C, and we're with the digital I&C branch of the NRC, so we do recognize that that was the focus area of industry at the time, and the staff was very responsive to industry input, and industry concerns, and we appreciate that. However, as time has moved on, five years later, and these larger modifications are being scoped, and being undertaken, there's also recognition that to continue to improve plant safety, reliability, we do need to address the main control room, that modernization is needed there as well.

And so while we didn't think about it as much in 2017, or focus on it as much in 2017, we are where we are, and we do need to make sure that we're addressing equipment reliability, and other concerns in that area as well, again with a focus on continuing to improve safety. A key industry objective for the industry in providing input to the staff for MP4A was about earlier issuance of license amendments.

This was really to support overall

reduction of project risk for industry in terms of getting these larger modifications underway, and making sure that we keep that budget risk in a place that was acceptable. And the NRC was very responsive to that. And so we're hoping in that same light of, again, trying to improve safety, and trying to manage risk, that we can find a solution for this HFE, this ISV issue as well.

Next slide please. Okay, so again, this is just a little more background. So, under the alternate review process, the licensee is submitting design information earlier in the project life cycle. We recognize that the LAR includes an NRC approved software life cycle process, or information provided in the LAR that describes life cycle activities, there's allowances to that.

The pilot LAR relied on the vendor oversight program, and regulatory commitment for some of those later life cycle activities, so there was acknowledgment within ISG6, and this has to do with the question Dave Hooten asked as well. Dave was part of those discussions under MP4A about making, about providing staff information that was bounding, and then making sure as the detailed design was being undertaken, that the design was either staying within

those bounds, or if they were changes, those were evaluated, and communicated.

We're hoping that the same process can apply here in the world of HFE, and that if there are more significant design changes which impact the information that was submitted, or even information that was part of the NRC's SER, so the approval of the LAR, that the same process we would apply for the design information for digital I&C, would also apply for HFE.

So, we're really looking at it not as two discrete areas, but for industry, it's all one project, it's all one system. So, we would view them in a similar lens. And just when we were going through the MP4A work with the staff, providing input to the staff, this was a caution that the NRC did raise. That you're providing this information, this bounding, if it changes, you need to be aware that there could be an impact.

So, I think that's a risk that industry has already acknowledged is a possibility, whether it's in digital I&C, or in the HFE area. The next major bullet is on -- we recognize of course the NRC intends to use NUREG-0711 for the review of information, and this kind of ties into the question

that Rick Paese asked about what is the underlying regulatory requirement?

And so, in a previous public meeting, we thought we had heard the NRC say that the underlying regulation is 50.9 for completeness, and accuracy, and that's why that bullet is on there, because we thought we had heard that in a previous meeting. Brian, I see you have your hand up, do you want to ask a question right now, or?

MR. GREEN: I thought you were looking for a response on that, because I saw that in the slide. I can hold the question if you want.

MS. GOLUB: No, that's okay, if you have a response, go ahead.

MR. GREEN: Yeah, so we did discuss 50.9 at a recent meeting, and that was in response to there seemed to be some confusion about the implementation plans, and when they get submitted. So, that was how we have treated it before, is that in order to submit an LAR, an LAR needs to be complete when it's submitted. And one way that we have interpreted that is either with an IP, or an RSR at the time that it comes in.

So, that's the basis for why it would be a part of the application, because in that particular

case, there was thought that the IPs would not be submitted, and they would be audited in an ERR at some other point. And that begged the question on if we would be able to accept the application when it came in for the acceptance review. So, that was where the 50.9 discussion came in, and I see how that would be a confusion.

So, that's more of an administrative requirement than some stand up to the argument.

MS. GOLUB: Yes, okay, and that's helpful Brian, I appreciate that, because I guess we were -- and that's why Rick asked the question as well, just struggling a little bit with what is the underlying regulation, because as we try to find a path forward, it's always helpful to know what target you're shooting at. So, okay, that's helpful. The next item is, and this kind of ties back to what Dave Hooten was referring to, where we were trying to tie the content we provide in the area of HFE to a similar place for what we're providing in the area of digital I&C.

Again, from an industry perspective, these are not separate areas. HFE, digital I&C, these are really all the same projects, same system. And so we were trying to draw kind of a similar place, and similar line in the sand perhaps, that we provide this

type of information in the area of digital I&C, of guided information. We'd like to provide something similar for HFE.

And so these items here tie to the framework in the EPRI Digital Engineering Guide, which as you know, the bulk of the industry is using as the design framework. And under that framework, these activities already experience functional analysis, task analysis, staffing qualifications tied to this same area that the conceptual design information, requirements information, which forms the basis for the design information provided with the LAR edits.

And so that's why these activities were chosen here. And then similar, again to the way the I&C is handled, for later HFE life cycle activities, the LAR would describe that process for completion of those activities. So, there could be implementation plan type information, program plan type information, that's what we were looking for. And then the NRC could decide whether that was acceptable, how we were handling those later life cycle activities.

Okay, next slide. Okay, topic of the hour. So, for the integrated system validation, first NEI members are concern that the MSV approach provided by the staff doesn't really have a clear precedent,

and it's not clear to us exactly how it fits into the regulatory framework. Certainly appreciate, Brian, especially the presentation you made, it's clear that the NRC is also looking for a solution to try to preserve maybe some of the objectives that were achieved as part of the alternate review process.

And we appreciate that, really appreciate the fact that the NRC is also offering solutions to industry, not just kind of saying it's your problem, figure it out. So, appreciate that. Having said that, MSV is difficult, especially listening to all of the different criteria at the different stages, it's unclear how that would work. Now, you're going to hear in the presentation that follows my few slides, Idaho National Labs has kindly supported this call.

Supported providing some results from their research in this area in determining what leads to a successful integrated system validation. And I will say while the terminology is different, multi stage validation, from some of the terms that you're going to hear in the INL presentation, I can't help but feel there's a lot of similarities in the two approaches.

And one other thing that's kind of become clear to me through talking to both I&C people, and

HFE people is that the term validation may be used differently between these two sets of technical people. And so that could also be a source of maybe -- I don't want to say some confusion, but perhaps a perception that the two approaches are not as aligned as they are.

And so I ask the staff, when you hear the INL presentation, I don't know, maybe look at it from the lens that it may be closer to the approach that the staff has offered, than maybe the initial glance would tell. So, I'm looking forward to staff's feedback from that. And so one option for consideration, since the ISV is such a critical activity, and as has been acknowledged, the RSRs for all, or some of the earlier activities will likely not fit within that window of the license amendment review approval requested by industry in accordance with the alternate review process.

And I recognize that's a staff decision to determine what that schedule really looks like. But understanding that those RSRs may not fit within that category, and that ISV is so important, one option that industry is kind of offering is potentially including a licensed condition that the ISV will be completed in accordance with the process laid out in

the LAR.

So, trying to make it clear that it's not that industry does not intend to do the ISV, an ISV is part of these projects. But simply that the time lines may not align with what was discussed, or what was included for the alternate review process in ISG6. We do want to acknowledge that we do understand that the NRC's safety determination cannot depend on a license condition.

That unlike say ITAAC, or DAC, or some of the regulatory mechanisms in Part 52, a license condition is different. But the NRC does have to conclude in their SER that adequate safety has been achieved. And so, we want to be clear that we're not proposing that the safety determination depend on the license condition. But simply that it's one way to show that industry is going to complete this activity in accordance with the process described.

The strategy for addressing the VNB element will be included in the LAR, as I mentioned, and that's what the INL presentation is also going to cover, what does that strategy look like, and the INL presentation is one attempt to provide that strategy, but an attempt that has behind it, research showing that it would be successful. So, I think that's very

positive.

But we're going to keep the NRC apprised of any ongoing activity, so recognizing again that because there's not finality of all of these activities at the time of LAR submittal, if there are activities that the NRC wants to audit, or even review results of in some kind of an e-room, industry understands that we do need to continue to communicate when these activities are taking place.

And make sure we have that good communication so staff can participate, and do their audits, or inspections as the LAR review continues, and some of these other activities are continuing, or even ones outside of that LAR review scope. And then the last bullet here, that we request that the NRC consider making their safety determination for these alternate review process LARs based on the early HFE activity.

And then the plan based on INL research, which describes how completing these activities, performing these activities could lead to a successful integrated system validation. Okay, next slide please. Okay, so this is a little bit of kind of a summary. So, the LAR, and I put 50.9, because just from our earlier discussion we were trying to pick out

what the underlying regulation is.

So, we could show the staff that we thought we were meeting that underlying regulation, so that's why 50.9 is here. It would include these early HFE activity IPs, RSRs, or similar information. It would include the program plan based on INL research describing that the rate of HFE activities would assure a successful integrated system validation. It would include a license condition to perform this ISV in accordance with the LAR.

We note that the implementation plan for the ISV would be available for audit prior to the execution of ISV, industry of course would perform the ISV to close the license condition, and that the result summary report for ISV would be available for inspection. So, that's just a little bit of a summary for those activities. Next slide. Is that the end of mine?

Yeah, okay. And then, so we could pause here, or we could, maybe I would suggest we have Jeffrey, Joe, and Ron Boring go through their presentation first if it's okay, BP, and then take questions from the staff. How does that sound to you guys?

MR. JAIN: Sure, we can do that.

MS. GOLUB: Okay, all right, thank you. And I'm going to turn this over to INL.

MR. JOE: Okay, this is Jeffrey Joe, can you hear me?

MS. GOLUB: Yes.

MR. JOE: Okay, great. Yeah, so I am a senior human factors researcher at Idaho National Laboratory. I've been at INL for just about over 22 years now. I also want to thank NEI, and the NRC for the opportunity to talk about the human factors engineering, or HFE. R&D that my colleagues, and I have been doing at INL for the Department of Energy's light water reactor sustainability, or LWRS program. Next slide please.

Yeah, so the LWRS program conducts research to develop technologies, and other solutions to extend the operation of our nation's fleet of nuclear power plants primarily by improving their economic competitiveness. The part of this though, is that this is the programmatic context that undergirds both what Ron Boring, and I have to say in the next few slides. And so with that, I'm going to hand it over to Ron, and have him introduce himself.

MR. BORING: Thank you Jeffrey, can everybody hear me okay?

MR. GREEN: We can hear you.

MR. JOE: Yes.

MR. BORING: Excellent. If we could proceed to the next slide then? My name is Ron Boring, so I am the manager of the Human Factors and Reliability Department at INL, and I was heavily involved in the LWRS program in some of the earlier stages, primarily 2012 through 2018 where we were doing a lot of this foundational control, and modernization work.

Most of this work has to be understood in the context of different pathways of LWRS, and this work falls under the plant modernization pathway, which has a focus really to engage human factors researchers to support those types of I&C control room upgrades that we're talking about in this general meeting. So, really we're looking to do modernization that obviously is technically sound, that supports regulatory requirements, and is safety focused.

And really what we were doing in this process is trying to help utilities to have a roadmap for how to go about these activities. And you can see there on the right, we have this figure that depicts the four quadrants, where we're really taking it from initial engagement with utilities to find out their

needs, all the way through deploying it as a control room modernization activity.

And along the way, we were working on developing principles, many of those, which are found in the DHG that EPRI released to back end state of the art guidance specifically on control room modernization. Collaborating with industries, and that means many partners, owners, operators, and suppliers. And more importantly then, disseminating those lessons learned back to industry, and the regulators.

So, we would work with particular industry partners to develop the template for how we would go about control, and modernization, and then we would publish guidance on that to make sure that that would be a benefit to everyone. Next slide please. And so, really this was, if you go back to 2012 as we were kicking these activities up, this was a chance to address some of the technological obsolescence issues that we were experiencing in the industry specifically.

As we extended the life of reactors, and had a need to come up with upgrades for the then, mainly analog systems. Along the line of course, there was the opportunity to do more than for life.

So, there's the opportunity to figure out what, with the advent of digital technologies, what could be introduced that might actually be a benefit towards efficiency of the plants for example?

And so the industry in particular expressed a need for human factor support for modernization, and so we developed guidance on applying NUREG-0711. We captured the experience on how to incorporate human factors in design, and then kind of one of our capstone activities, you can see there in our photograph, was the development of the human systems simulation lab, which is really a test bed for design, and evaluation.

It's an engineering simulator that can be tied reconfigurably to the existing plant simulators, but gives plants an opportunity to stage those types of validation exercises, design validation exercises. And then next slide. And so, Jeffrey, and I are going to talk about a few of the examples, just very high level to captures -- apologies, it was very quiet on the street before I started speaking.

So, Jeffrey, and I are going to talk about some of the examples of these activities. And really what you can see here, you see our steadfast NUREG-0711 in the top right, and we developed some tools to

align design to ensure that it was meeting NUREG-0711 guidance. And so there was a lot of emphasis in here on how to go about doing those evaluations.

And in particular then, we found as we were doing those early stage evaluations on conceptual designs, a lot of the information was qualitative. This is not your traditional thing that makes its way into a LAR. It's qualitative information that helps to inform the design of the system, and then as you move along in the 0711 stages, which are on the upper right axis there, you can see that you get to that point of ISV, at which point you're looking at confirming the design.

And really what we found was this high level of confidence, as we did those early evaluation, and design activities, we would go into ISV with high confidence, because we had already tested all of the elements, and refined them. And with that, I believe that's my last slide Jeffrey, so I turn it over to you to continue the story.

MR. JOE: Yeah, thanks, we can go to the next slide please. So, Ron just described the iterative design evaluation processes that we created, these design processes align with the NUREG-0711 phases. This side is a continuation of what Ron was

describing before. This slide just shows some examples of R&D activities that we have done in that context.

So, the top picture shows ergonomic, and HFE analysis that we performed of I&C hardware, and its human system interface, or HSI to help identify the anthropometric, and other design issues. And so by improving the ergonomics, and human factors of the HSIs, we were helping improve the performance of the new digital control system, or DCS, digital control system.

So, we're improving the performance of the DCS, and the overall performance of the plant. The two pictures on the bottom half of this slide show how we conduct operator workshops to iteratively evaluate the HSI design, and other HFE elements of the DCS. So, the photo on the left shows a tabletop review of the HSIs by operators, other plant personnel, HFE experts, and the DCS vendor.

And so this is a static evaluation on the screen, something that we can do earlier in the upgrade process, rather than later of course. But the photo on the right shows how we developed a functional prototype of the upgraded control system, which we then iteratively evaluated with operators in the loop

as they dynamically interact with the system on the full scale simulator that Ron mentioned in our human systems simulation laboratory.

So, these dynamic operator in the loop workshops give the operators, and give the human factors engineers, the evaluators, an opportunity to evaluate, and also work with the new DCS currently in the upgrade process. And this, as Ron mentioned, provides the opportunity to modify the design, and further improve it. And in general, improve the plant performance prior to implementation.

And so these are the things that we can do that can be thought of as a lead in to the ISV aspects that was also a point that Ron had made. So, next slide please. So, this slide is perhaps a little bit redundant, but this slide shows where the HFE R&D activities that we have done under the LWRS program, how those activities fit within the existing HFE phases, and elements of 0711.

So, in this will be the items in black are the HFE elements of up to NUREG-0711, they should be of course very familiar. But of course the way these elements are listed in this table is a little different than how they're typically portrayed, but all of the elements of 0711 are shown in black. The

blue items are what we have done, and continue to do in our research to enhance human centered design.

These items are somewhat duplicative of the examples I showed on the previous slide, so I won't repeat them in detail. What I'm pointing out here though is INL researchers have adopted an 0711 framework, and our collaborations with our utility partners, we've done all these elements, but in addition to that we've done some other things that we've found to be very helpful.

So, for example, the 3D modeling, the development of prototype HSIs, these activities have proven to be beneficial from our view in the research to improve the overall HFE effort, and contributions. So, combined, these activities provide a staged, or iterative approach that helps provide confidence in the HFE aspects of the final design. Next slide please.

So, that really takes me -- that's really the take home message for me. The LWRS program, its goals, and objectives undergird the work that we've done to research, develop, demonstrate, and deploy HFE methods, and to make HFE design recommendations for all of the industry to use. And I just want to mention there are reports that we have, these

additional -- and additional details on what Ron, and I have presented can be found in these technical reports that are publicly available.

There's actually a website address cited on the next slide where you can find these reports. And these reports show how collectively the HFE methods, and recommendations address all elements of NUREG-0711, and increase the confidence in the final design of the upgrade control room. And that's really where I wanted to stop. There are some other slides where we provide some information. But I think the plan at this point was to open this up for questions.

MR. JAIN: So, there are questions for NEI's presentation?

MR. GREEN: Yeah, this is Brian, sorry, I was just finishing taking a note here. Yeah, if you wouldn't mind Jeffrey, do you mind going back to, I think it was one of the slides that Ron had spoke to, the formative, summative one. Next slide actually. Yeah, I like this slide a lot, and I find this to be very helpful, because I like the evaluation continuum that you have here between the formative, and summative.

And I think it shows, what we're trying to find with the MSV suggestion is some appropriate

checkpoint within the summative activities to get the confidence -- I think we agree that together, both the formative, and the summative process give us high confidence in the results, and that's why 0711 is structured the way that it is. We're just trying to find that right checkpoint to get some of the summative information for us to consider.

And keep it so that we don't just have formative information. And I was wondering if you could speak to -- maybe on the next slide, if there are places in the next table -- I'm sorry, one more slide, the one with the blue, and the black. Are there activities on this table that might provide us with opportunity for the NRC to observe, or see some of this?

My initial thought was maybe those initial prototypes, or the iterative evaluations of the I&C seem really reasonable to me. But I don't know if those are within the time frames, or if we have any thoughts on that. Is there a good checkpoint from your perspective?

MR. JOE: Yeah, Brian this is Jeffrey. I can certainly give an initial answer, I would also invite Ron Boring to also jump in as well. So, I understand that the question is where in these

additional R&D activities might there be good checkpoints for the NRC? Off the top of my head, it's a good question, and I'm not sure -- I'm not as familiar with what a licensee would need to do, just because I don't work for a licensee.

But I would say that as researchers, for every activity that we do, we always want to write a technical report, and that has always been the goal of the LWRS program, is to research these activities, and then write a report that not only describes what we did, but reports out on the findings of that particular activity. I would think offhand, that those technical reports could be a way for the NRC to accomplish this checkpoint thing that you're requesting.

But that's just what came to my head, Ron, do you have anything that you want to say in response to that?

MR. BORING: Well, it would be up to the individual utilities how they want to do that. Most of the blue here is still at some phase of the formative. So, you can see things like the ergonomic analysis is probably at the planning, and analysis stage, right? And that would obviously have documented artifacts coming from that, initial

prototypes, you can see how that moves from the conceptual getting it very close to that finalized design.

So, again, I would refer to Pareez, or NEI as to when might the appropriate checkpoints be. When we've done this more generally, of course we publish reports at each stage, and part of that dissemination was to get the ideas out there, and see are we capturing the right information? So, from my perspective, it would always be welcome, but utilities would have to figure out when the best intervals are. Pareez, any comments on that?

MS. GOLUB: Yeah Ron, and I think that makes sense. Certainly as we go through this process with the NRC, we can talk about what those checkpoints are, and determine the right ones. And that was part of what I was saying earlier about making sure we have good communication as we go through this, to make sure that we provide that confidence to the staff.

MR. GREEN: Yeah, I think, and I'm just kind of working through these for the first time here, but my initial thought is that if we were able to identify a checkpoint, or two, and that may be, for the way we had described it earlier, that may be the early MSV stage. I mean these may not be terribly

different in concept. So, there may be some room to align there, but I'd like to -- maybe that's a discussion for another time.

But if we could find a couple of those, I think Dave may have thoughts on it as well, but that's my initial impression.

MR. JAIN: There are three questions here. One, I'll have Bill, you go ahead with your question.

MR. HANNAMAN: If you can hear me, this is Bill Hannaman, and I'm with Paragon. I thought this was a very good presentation, and it brought to mind -- this may be a little bit redundant, but you said that you would produce research reports when you did an activity. Would that research report fall into the category of a validation?

That's where I think you can do a lot of early stuff that would fit into the MSV approach. But you would call, instead of a research report, can you put the term validation on it?

MR. JOE: This is Jeffrey, I'll jump in, if anyone thinks that question was directed to them as well, please speak up. I think of this as a researcher, and I think of these as potential artifacts for referenceable, technical documents that could be included in whatever additional documentation

that might need to be provided to the NRC. So, for example, little that I know about license amendment requests, there's a license application that a licensee would submit.

These technical reports, along with either results on reports, or implementation plans could be referenceable artifacts. But that would again, as Ron had mentioned, that would be up to the licensee to make that call as to what it would be. I actually can't really speak to whether, or not we would call these research reports validation reports, or not.

I don't think I am versed enough in the nuanced differences in terms of how one discipline of engineering might define validation, versus how it's defined in 2411, versus how it might be defined in 0711, or just at large in human factors. That's all I needed to say, anybody else on the human factors side want to jump in? Yeah, go ahead Pareez.

MS. GOLUB: So, I probably am not on the human factors side, but I guess I just wanted to go back to something I had mentioned in my presentation, which is that I think that there's a lot in this approach that's being put forward by INL, and industry of course, that isn't that far different than the MSV stuff. Even -- like letting go for a moment on the

exact terminology of validation.

But more on this idea that there are these earlier insights that show that this approach would be successful. And so I think if we can try to come to some alignment for these different licensees on what this approach would be, and describe it appropriately in the LAR, that's why I'm hoping there is a success path. The terminology is only one aspect, but I know it's more of a general approach.

MR. HANNAMAN: Thank you. I think that gives a broad picture of a kind of report that fits into the MSV framework. So, I like the ideas.

MR. JAIN: Okay, so the next question is from David. David, do you want to go ahead?

MR. DESAULNIERS: Thanks BP, actually it's not a question, and the time is perfect.

MR. JAIN: A comment?

MR. DESAULNIERS: Yes, it's a comment, and it follows directly on this conversation here, and the comments of Pareez, and Bill. With respect to where we see commonality between what INL is proposing as an HFE program, and what might fit into multi stage validation. So, there certainly is commonality in terms of types of activities. There are differences though, and Bill, you asked a good question.

Could you call these validation? What I'll try to summarize briefly here, but I'll point the audience to as a resource to consider that question, is that was an important aspect of what we considered when we were working on the NEA effort to further develop the MSV concept, and tried to distinguish multi stage validation from some similar, but competing concepts.

Because in developing multi stage validation, we often went back to this discussion of well, what in fact is the difference between what we are proposing to develop in terms of multi stage validation, and what you might call a design test in the general sense. And I believe that what you have here on the screen, and prior to getting into VNB is design testing.

And if you go to the NEA report, specifically section 2.4, there is a section specifically dedicated to describing the relationship between multi stage validation, and design testing. They are different concepts, but complementary. And the distinction gets into largely the controls that are put in place on the nature of the testing, and the objectives of the testing.

Design testing has some very broad -- can

have many different types of objectives. As for an example, you might be looking at comparing concept A against concept B, and trying to decide which is the more effective design to use for your particular application. Whereas invalidation, really your focus is -- your objective is more focused, and that's determining will this design successfully meet its intended use?

And the way you go about the testing may require, in order to have results -- and this is where I'll take a moment to just maybe correct my colleague Brian's -- he actually corrected himself, and I'd say he corrected in the wrong direction relative to how the terms are used say in the IEEE document with the difference between credible, and creditable. What is being produced perhaps in design testing, if done properly, is producing a credible result.

But for purposes of having something that we can use for a regulatory decision, what we want is something a little more that's a creditable result, and that means it has the pedigree associated with it in order to be able to support our decision. And that may mean for instance whereas a test under design testing is done by the individuals that are directly involved in the development of that design under a

validation test, it might be the same test.

But it's being done by an independent group of individuals developing that test, and evaluating the results, as just one particular difference. I think in the end though, when you appreciate those differences, there are ways to take what is being done by INL, and with appropriate adjustments, elevate design testing to something that would be considered a validation.

So, this is where we said -- and Brian alluded to earlier with respect to not trying to add a whole lot more work to it, but looking at what's being done. Does it actually -- what portions of your testing actually support the final conclusion, as will this design support its intended use? Not just improve it in some way. And provide the level of rigor, and documentation to that testing.

Such that it can then be part of the basis for the application. I'll pause there to see if I rambled on too much, and confused everybody, or made some clarification.

MR. HANNAMAN: Thank you for that response.

MR. JOE: That was helpful to me David, this is Jeffrey, and that's all I'll say, very

helpful, thank you.

MR. JAIN: Our next question from Warren. Warren, you want to go ahead with the question?

MR. ODESS-GILLETT: Thank you, and I'll lower my hand here. So, this is -- so Pareez, on slide three of the presentation, I just want to sort of simplify in my own head, the proposal. So, basically the idea on -- actually slide three of the NEI presentation, yeah. The idea is that for the operating experience, functional analysis, and allocation, task analysis, staffing qualifications, both an IP, and an RSR would be provided during LAR review?

MS. GOLUB: In this case, the RSR would be provided, yes. Yes, I shouldn't speak, so yeah, it's really either one, yeah. The licensee would have to decide, yes.

MR. ODESS-GILLETT: Okay, and then afterwards, those later life cycles, if you go to slide -- I'm on the wrong -- let's see.

MS. GOLUB: I think it's slide four of the NEI presentation, I think is where Warren is going. Here that bottom bullet Warren, is that where you're going?

MR. ODESS-GILLETT: Yes. That the --

actually, it was I think on the next slide. Yes, and the major bullet, and the second sub bullet says the HFE program planned based on INL research describing the later HFE activities assuring a successful ISV. My understand is that what would be submitted would be implementation plans based on the INL research that was presented that have demonstrated that the activities that INL had discovered contributed to a successful ISV.

These would be incorporated in implementation plans as part of the -- either as part of the LAR, or LAR review, is that true?

MS. GOLUB: Yeah. So, I guess I want to be clear, part of the implementation plan, or that content. Whether it's called an implementation plan, or it's just described in the LAR, but yes. Because the INL research of course has been -- I mean it's been, this is not sort of -- and please, Jeffrey, correct me if I'm wrong, but I mean that research has a basis, it's been proven.

There's been -- I think we have good confidence that that methodology leads to a successful ISV. And so that's -- what we're trying to say is that based on that research, not just something that industry is making up in an attempt to find some way

to resolve this issue with the staff, but based on that research, we believe that's the right approach. Did I answer your question?

MR. ODESS-GILLETT: It did, thank you.

MR. JOE: Pareez, did you want me to jump in on that as well, or?

MS. GOLUB: Please do, yeah, I would appreciate that.

MR. JOE: I would only speak in general terms. Our research has shown in certain cases steady improvement in the overall design from the conceptual, to detailed, to final implementation, and we have confidence that the research that we do in support of 0711 activities, as well as additional things that we have added to the HFE process contribute to that steady improvement.

I don't want to get into any specific results, or describe any detailed methodologies in detail. I would just only comment that I think it's a fairly common anecdote in the industry where some upgrades are implemented, and operations, and human factors are only brought in at the very end, when the plant is going into -- or the simulator is being modified.

And the common finding from that approach

is that that's too late to get operator input, and oftentimes when the operators, who are quite frankly the end users of these new systems, when they want to make design change recommendations, it's too late in the engineering process, it becomes very expensive, and then we find that we have to solve those problems in other ways.

And what I think our research generally points to is that we have a different way that gets around that, I think particularly common anecdotal finding.

MS. GOLUB: Yeah, and thank you Jeffrey, I appreciate you clarifying. Because I don't want to draw conclusions from the research that aren't there. But I also just want to point out this slide is kind of perfect. It's certainly not that industry is proposing to do the ISV. This is simply trying to provide the staff confidence that we're doing everything that needs to be done to make sure it's successful, so that the license amendment review can conclude without the ISV results being necessary.

And that's exactly why a license condition is being offered in addition, for that very reason, yeah.

MR. JAIN: Okay, Michael, you have

comments to make? Michael Marshall?

MR. MARSHALL: Yes, I had one question, and a comment. And I'll start with the comment first. I think this has been addressed, but I just want to make sure. With regards to 50.9 not being a technical requirement for a licensing decision, and that's just not limited to human factors, it's I&C, and others. 50.9 is a pretty broad requirement that governs a lot of correspondence between the NRC, and the licensee, and the documentation they maintain on site.

It's not a licensing requirement. But I think Brian addressed that by referring to it at the end as an administrative requirement. But someone else mentioned earlier before, especially for all the plants that were operating at the time of the TMI accident, your human factors requirements, your control room requirements, those are in TMI waters, and those aren't clean in a sense that it's in a single document.

Or single piece of paper, or single piece of correspondence. And it would be advisable for licensees to go back, recreate that if they have not done so already, to see what the requirements are for them when it comes to control rooms. I've only done it for a couple of plants, but again, I don't think

anything that we have been discussing with regards to 0711 is inconsistent with at least a couple orders.

Or the paperwork that comprise those requirements for the two plants I'm familiar with. The actual question I had was with regard to the license condition. I agree with the statement that an MSV approach is untested, but I would say the same would be true with a license condition approach, that would also be untested. Brian mentioned that there are challenges with license conditions.

And typically it comes down to how the license conditions are worded, and what exactly are governed by the license conditions. And right now, I don't know if you have specific language you were planning on sharing with us today, but I'm not sure we can give you a lot of meaningful feedback on the concept of a license condition versus the actual requirement as its written.

So, I don't know if you guys had thought as far as specifically what's the language that NEI is proposing to put in this license condition, because I'm not sure -- folks here on the NRC can argue both ways, because some of us have seen poorly written license conditions, which would be totally unacceptable. And then there are more better written

license conditions that tip toe that fine line of deferring actions that the staff are required to complete before it makes a regulatory finding.

Versus it being a confirmatory action just to ensure what was communicated, and what was reviewed by the staff is actually implemented by the licensee.

MS. GOLUB: Yes, and Michael, you're raising a very good point. And to be clear, this is not a small thing industry is offering, right? A license condition is a pretty significant regulatory mechanism. And so yes, the wording of that would definitely need to be something carefully thought through, and probably discussed in presubmittal meetings phase.

Similar to what we did for Waterford with the regulatory commitments. There was discussion between that licensee, and the NRC in presubmittal meeting space to make sure that the language was appropriate, that it was achieving that goal. And so, that should be the same case here. If a license condition is necessary, then -- necessary for industry to achieve the goal of getting the early approval in accordance with the alternate review process as we're trying to.

Then that language would need to be

carefully discussed in advance, and not just put into the LAR.

MR. JAIN: Next question is from Steve Kenney. Steve Kenney, can you unmute?

MR. KENNEY: Thank you JB. I'm a human factors consultant supporting the Dominion team currently. I have a question for Mr. Desaulniers, and Green. In the discussion of the iterative nature of the process, and the multi stage approach to validation, what are the margins of safety that would be considered relevant to the testing that needed to be demonstrated as part of acceptance criteria for the testing that would be part of such a multi stage process?

MR. GREEN: So, I'll start with that. It's hard to prescribe it, because the stages would be handled differently by different licensees. But I think some of the things that we would be concerned about -- or a good place to start of the discussion, I guess maybe that's the best way to put it. Is if there are any credited operator actions, or important human actions that are credited, some level of consideration on the feasibility of those within any sort of relevant time frames.

Could I tell you what kind of margin to

put on that? Not immediately, but you would put some thought into creating a validation that would test to see what those margins were, perhaps would be one way to do it. That's the first one that comes to mind, I'm sure we probably could think of some more. But again, it would all depend on what your stages were, and what your modifications were getting into, the sorts of modifications that were being made. Dave, if you wanted to expand on that?

MR. DESAULNIERS: Yeah. I don't know if we want to get down into too much detail here, if this is what you're really going for sir. But Brian commented on credited operator actions, and so a way to -- let me back it up. Under validations, we only have so many opportunities to test a certain operator action, and determine whether, or not it can be completed in the time required to -- before you have adverse consequences to the plant safety.

So, in conjunction with those, yeah, if we're taking that as a particular example, we're typically looking for margins associated with that. And as Brian said, it's difficult to prescribe a margin that might determine. Factors that go into determining that margin tend to be -- first off, how short of a period of time from onset of the event to

time that the operator needs to take action?

Are we talking about an action that needs to be taken in the realm of a couple minutes, or 30, or more minutes? And the further you go out, the nature of the margin consideration can change. One common guideline that we've used in looking at margins is to consider is time available to recover from credible errors associated with that event? In other cases, percentage time frames are used. But it does vary according to the case.

MR. JAIN: Thank you David.

MR. KENNEY: As a follow up then, is it reasonable to expect some clarification on this subject matter area as NRC proceeds with the formulation of these ideas around the multi stage validation?

MR. GREEN: I think that right now we're still evaluating options. So, I don't know that multi stage validation is the sole answer. So, if this license condition approach is the way that goes forward, then we may have to rethink that. There may be other options on the table as well. So, I don't know that we'd be putting forth guidance imminently on that.

However, there is, with regard to operator

actions, we do have existing guidance that has information on that. NUREG-1764 talks ad nauseam on the topic, and there is an appendix to NUREG-1852 that actually, it's fire human actions guidance, but it actually does a really nice time line analysis. That if we were to put forward some sort of guidance, I'm going to say we'd probably lean on one, or both of those documents.

MR. KENNEY: Thank you gentlemen.

MR. JAIN: David, do you have something to add?

MR. DESAULNIERS: Well, I have a question that goes back to thinking about the INL HFE program. And gaining clarity on what the NEI proposal is with regard to that program. But just as this last question raised, the devil is in the details on some of these things, on many of these things. And I think one concern that I see, and just thinking about the program as described at a general level, as we have in the slide, and I realize there's only so much you can do in the course of a brief presentation, and a PowerPoint.

But I guess the concern that I have is maybe a potential expectation that what we could come up with is a generic set of tests, or processes that

might apply that would say okay, this is the NEI endorsed INL program, and it will work for all applications coming in. And I think the -- what tests are necessary to show that a design is in fact going to be acceptable is going to depend from one design to the next.

And what level at which you need to do this testing at. So, I don't know if the expectation is that this would be modified from one application to the next, then this is just an example. I'm a little confused as to maybe what's exactly being proposed. But I am concerned that you might be missing the point of looking at the particular modification, and what's necessary for that modification in terms of testing.

These are good, all good HSI design, development activities. But frankly, pretty much what would have been expected under 0711, just drawn out as particular instances of the types of activities that could be done. So, I'm not sure it's adding new information, just maybe some specificity to a particular approach that may, or may not be applicable for a particular modification.

MS. GOLUB: I guess I'm not sure what to do with that feedback David. But you know, we're trying to put something forward, because there are

people who are in the middle of -- licensees in the middle right now of trying to get these mods done, and so we're trying to put something forward to get staff feedback. So, this is not information that NEI made up, we're trying to base our approach on research that's been done.

And so of course, all of this has to be adapted, the same way the MSV approach would have to be adapted to whatever the modification is. I mean everything has to be adapted to that modification. So, I guess I'm not sure what you are saying. Are you saying that you're not sure that this approach applies to the modifications, all of them, or -- could you please clarify a little bit?

MR. DESAULNIERS: My question was whether you're looking for NRC to endorse some general high level approach, or --

MS. GOLUB: Yeah, I don't think this is -- this is not endorsement, this is an approach we would like to describe in individual license amendment requests for particular designs. So, the scope is, this is not a generic scope, licensees will describe this in their LARs for their designs, and use that as the basis for the NRC to draw their safety conclusion if this process is followed.

But this is not a generic endorsement conversation, this is not like an NEI guideline that's being put forward. We're trying to find a way to help these early movers, early adopters find a success path. So, it would be LAR-specific, does that help?

MR. DESAULNIERS: Thank you, that does help. So, it would be LAR-specific, and yeah. Again, I think that it does -- we end up in the same place though in the end, when we're talking about MSV, or something, more guidance, and detail with respect to the focus of the testing, and the rigor with which it's applied would be needed in order to be able to determine if this is a viable pathway.

MS. GOLUB: Yeah, and I appreciate that. But I guess, I offered this to the agency in general, that we're here because we're trying to get feedback. We're trying to find a path forward, trying to offer things that are not always easy to offer, like license conditions, and try to enlist INL to help us find this path forward. So, yeah, I would say that --

MR. JAIN: Pareez, this is BP. We are running late, and perhaps do you want to schedule another public meeting on this topic? This very interesting topic. I get why --

(Simultaneous speaking.)

MS. GOLUB: I don't know if there's enough information here for licensees to move forward. So, I agree, I think we may need one. I don't want to speak on behalf of NEI, Alan can certainly speak to that, but just in my opinion as a member of industry, it doesn't seem needed.

MR. JOE: BP, this is Jeffrey, I'm sorry, if you could provide just a little more latitude, I noticed Bruce Hallbert had his hand up, I would very much like to hear what he wants to say here, recognizing that we are over time.

MR. JAIN: Okay, go ahead.

MR. HALLBERT: Thanks. Hi, my name is Bruce Hallbert, I'm the national technical director of the LWRS program, and I appreciate being invited to listen to this interesting discussion. I wanted to just respond to, first of all, say hello again to Dave Desaulniers, and I'll respond to the comment, or the question that he had. Our presentation wasn't so much to propose an approach, or even a path forward necessarily resolving whatever the perspectives are on this issue of 0711, or multi stage validation.

But really just to say we've been addressing human factors engineering issues as a part of sustainability efforts sponsored by the Department

of Energy that are needed to address the aging, and obsolescence of control room systems in place today. And we've been using 0711, I think that was one of the main points we wanted to just communicate. We've been using 0711, and 0711 does tell us the kinds of things that NRC is looking for.

It's good information, but it doesn't always tell us exactly how to do things for example. It says you need to do an operational experience review, but it doesn't say what you should do to do that. So, we've been working with a number of vendors, suppliers, and utilities owners, operators, and working out some of the details on a variety of different design projects fundamentally.

And what we've learned is that 0711 is very complete with regard to the guidance it provides. We know what NRC expects from a regulatory review. There are sufficient human factors methods out there for us to be able to conduct these activities, and overall, like Jeffrey was saying, it really does enhance the confidence you have in the final design once you get to integrated system validation.

So, I think that was the intent of the remarks that we were trying to provide today. I don't think there's a way for us to really resolve the

question of what is validation? We're using the definitions that are supplied in 0711 currently, but it sounds like there is a lot to be discussed as well.

MR. JAIN: Thank you Bruce, thank you. So, perhaps, like Pareez was saying, industry needs to offer if they want to discuss any further, a public meeting where we can discuss all this stuff. With that, I'll ask Entergy to make its presentation on the Waterfall experience.

MR. CHAMPAGNE: Hi, this is Jacob Champagne with Entergy, I'll share my screen here in a second. So, while this loads up I'll introduce a couple people we have in the room. So, my name is Jacob Champagne, I'm an Entergy project engineer. I'm the responsible engineer for the core protection calculator system here at Waterford. Also in the room we have Dave Moody, who is the manager of project engineering.

And we have William Truss, who is another I&C engineer on the project. My Teams system is loading, Entergy's system doesn't love Teams, so it's loading, it's thinking right now, so just give me a second.

MR. DARBALI: Hi Jacob, this is Samir, I have your slides up, do you --

MR. CHAMPAGNE: Samir, I was going to ask if you could share it, I think the system just completely locked up.

MR. DARBALI: All right, will do.

MR. CHAMPAGNE: Appreciate it. Okay, I can't even see it right now, but I'll continue on. So, like I said, this is for the Waterford core protection calculator project, and again, I'm Jacob Champagne, and you can go to slide two. It's a pretty brief presentation, but what I tried to do is break it up into a project background, and this is to give you an idea of the system, and a rough idea of the time line of events.

So, this is the replacement of the existing Interdata 7/16 digital computer system, and we're replacing it with the Westinghouse Common Q platform. If you have any familiarity with the Interdata 7/16 system, it is a 1960s, or 70s era system, so quite outdated, and obsolete. Our engineering change, if you're interested, it is documented in CMSBP, and it's 83843, and that was approved in April of 2021.

One big piece of this whole design is there's no impact to the existing safety related algorithms. The hardware, and those related changes

are the primary changes. The LAR was submitted in mid-2020, and there was some revisions, and follow up meetings. I also glossed over, we had plenty of presubmittal meetings since we filed a project in this process, where we met with the NRC prior to COVID, and after virtually to discuss how our submittal was going.

And the approval of the amendment, and our safety evaluation was received in August of 2021. We conducted our factory acceptance test at the Westinghouse testing facility, that went from late July to early August 2021. The NRC was involved, they observed us, and Westinghouse, and basically our vendor oversight of Westinghouse. We had our site acceptance testing at the Waterford location.

We had a testing location in one of our training buildings that we made a CBA extension of our warehouse. This was also observed over a number of days by the NRC. Our implementation is planned for refuel 24, which starts on April 22nd, so it's very soon. If you can go to the next slide for me Samir. So, this summarizes some lessons learned. We tried to keep it high level, and we can discuss further.

But basically I'll cover the Entergy lessons, and then I believe Warren Odess-Gillett will

talk with the Westinghouse. So, first of all is the vendor oversight plan, and the summary. So, our project had a formal vendor oversight plan for the process, and the summary was what we actually docketed. This was meant to be a shorter version of the vendor oversight plan covering high level details, but very specific details that were important to the oversight process.

One of the lessons learned was early on defining what would be in each, and identifying what was requested in each. Because it's a vendor oversight plan, I don't want to call it nebulous, but it's kind of a document that doesn't have a direct template, it can differ from project, to project. If you have a discussion early on, and identify what's needed in each document, I think that can save some revisions of those documents.

The next bullet is an involvement of regional inspectors early in the process. So, obviously early on in the design phase, you're dealing with the NRR as you work through the license submittal, and all those details. And then as you transition to the FAT, and the SAT, the reason we became involved, and we did finally have to redo some things, and fill in some gaps that we had provided in

previous submittals, and things.

And it wasn't a huge burden, or anything, it just I think some efficiency could be gained, and some consistency in the process if we did involve region inspectors earlier in the different audits, inspections, presubmittal meetings, just so they're aware of what's been discussed, and even some of the technical details behind the system.

The next one is a little more generic, but clarifying terminology. So, obviously each fleet is going to have its own terminology with regards to engineering changes. So, in the standard design process, you have a conceptual, and you have a detailed design, and a final design, but a lot of the terminology can be based on the actual product you're getting.

And the conceptual design for the product is different from the conceptual design in your engineering change package. So, sometimes when we would get questions for a particular life cycle phase, some of those documents may not have been available, some of the products weren't there yet that may have been expected. So, there was quite a few calls that I can remember that we had to clarify when things would happen, and how they fit in our process.

So, I think maybe early on in the process lining up the different life cycles with the fleet, the supplier, and the NRC, and making sure that everyone's on the same page with what's going to be available when, I think that would probably be efficient. And the last one is really from an Entergy side of things, the side river seat warehouse, and custody control, for Waterford this was really the first major digital upgrade of this kind of scale.

So, it just was learning to use our existing fleet processes to that scale of things. So, receipt inspection at the warehouse, storing it in our testing location, making sure that we have proper custody control per our procedures, and documenting that appropriately. And we took an action from, basically our factory acceptance test to our site acceptance test, and we created a cyber-receipt custody control document.

That's a project specific document that just lays out as we move it into the plant, how we're going to meet all those procedures that we have that are oftentimes spread out all over the place. And I think that'll help the NRC see exactly what we're doing, but it definitely was something that we had to learn to do on the fly, and apply those specific

procedures to this scale of a project. Warren, did you want to pick up from here for a Westinghouse lessons learned?

MR. ODESS-GILLETT: Thank you Jacob very much. So, contrary to the Entergy experience with the region inspectors, we were not expecting to engage with the vendor QA branch until somewhat toward the end of the detail design. But in fact though, we started engagement with the vendor QA branch nearly immediately after the LAR was accepted. It's not a bad thing. I mean early engagement's a good thing.

But we weren't prepared for the engagement, and so now we know that when a LAR is submitted, and accepted, that the vendor should start expecting engagement with the vendor QA branch. And we did have a struggle understanding the swim lanes between what the vendor QA branch was going to review, and what the LAR review was.

We were a little confused there, because we were the first out of the box. So, it was a little confusing. So, as described at the last February meeting in 2021, that was given to us early on to help us understand what's a vendor QA inspection role, and what is a law review role? Because they actually were starting to occur concurrently during the law review.

And then as I think Shiattin had mentioned, the FAT was really quite a logistical challenge.

We hosted the NRC vendor QA branch. We hosted the regional inspection branch, and we hosted the licensee. And the licensee was overseeing the vendor. The region branch was overseeing the licensee, and the vendor QA branch was inspecting the vendor. And so there was a lot of interplay between the organizations.

And it was a challenge because at a vendor site, unless you have unescorted access, you've got to be prepared to have a number of resources to escort, I would say -- I don't know how many people were there at that time, maybe 15, or something like that. Maybe even more, because now I'm thinking the Entergy party was quite significant.

So, we needed to really make sure we had the resources not only to answer all the questions from all of the different organizations, but also from a logistical perspective, making sure we had the escorts we needed to have all the various parties go from one location to another at the vendor site. So, that's all I have Jacob.

MR. CHAMPAGNE: Thanks Warren, appreciate that. Samir, you can go to the last slide, which is

really just questions, and comments. But I'll just follow it up by saying, obviously this being a pilot process, there was going to be lots of room for us to find things that could be better. But I give credit to both Westinghouse, and the NRC. It was always flexible, we were always willing to work with each other to make sure we got the documents, the information that needed to be given.

I will mention that we used Certrec to track all the questions, and provide those responses, and I think that works well. Especially if you're working virtually, which we were a lot of times. It can be harder to make sure that you have those questions documented. So, making sure that all those things are documented well, and you can provide your response, I think that was definitely something that benefitted us all. So, with that I'll leave it for any questions, or comment.

MR. JAIN: Are there any questions for Entergy?

MR. WATERS: Yes.

MR. JAIN: Yes Mike, go ahead.

MR. WATERS: This is Mike Waters, this is a great lessons learned presentation, thanks. And you actually mentioned Certrec, and I recollect we were

confused -- confused might not be the word, but at first because there were two separate rooms, or portals for an inspection versus the licensing, and I was running -- but any additional insights on the use of open item process?

And the way we communicated open items, and the frequency? We had bi-weekly meetings, and sometimes I think both parties felt those were too frequent sometimes, or not enough, anything to add weight on there?

MR. CHAMPAGNE: Yeah, so I know especially going into the FAT, and the SAT, we definitely had multiple inspections open in Certrec, which can be confusing. So, it does take some communication between the site, and the NRC just to make sure that we're in the same process. Because I know for the FAT specifically, we loaded in a bunch of details, and I don't think the right permissions were in Certrec, or something administrative like that.

So, it definitely can be confusing, it can become a burden, but I think with the proper communication, it can definitely be a valuable tool. For the meetings, I think the meetings were usually very valuable, because we got to see what information we provided, where the gaps were, or where the

information we provided, maybe we missed the interpretation of the original question.

And it broke down some of those barriers, that sometimes you have to wait awhile to get that, and you end up being kind of inefficient, because you could have answered that question earlier if you knew the question better, or understood it better. But it's one of those things where you setup a bi-weekly meeting, and there's going to be parts of the project where they're not going to require that bi-weekly meeting.

But it still was useful, because you can still, ahead of time kind of judge if you want to cancel those, or if people are unavailable, or something. I do think it was valuable, and I think Entergy gained a lot of insight from those meetings.

MR. WATERS: And I just wanted to follow up with one other comment here, and this is where I'm the broken record in all the application meetings, for future applicants, to inform us as much as you know, when you're in long cycle phases, when you're doing activities, it's more so a point in itself, and what was said is right on, it was very challenging to choreograph, and I know it was confusing to Entergy.

We see it in hindsight, but I think that

one of the issues is that the true RP -- I think there was assumption that NRC's design approval would happen, and then all of these, the implementation, testing would happen after that. And we're already a given fact of life those would happen in parallel with the licensing, it was an extra challenge to coordinate between the licensing review as one mode that we developed on, and develop swim lanes on what was licensee, and what was inspection. So, it was truly a lesson learned.

MR. JAIN: Thank you Mike. Are there any more questions, or comments? Yes, Richard?

MR. STATTEL: I think I heard you mentions that one of the challenges had to do with figuring out what information to provide at what point in the development life cycle, I think. And this kind of relates back to something that Pareez said during her presentation. I'm not sure I really understand that, because in ISG6, for the alternate review process, we expect all the information that's needed for a safety evaluation to be provided as part of the initial LAR.

And what Pareez had mentioned earlier was that somehow you're saying the alternate review process, the licensee is expected to submit design information earlier in the project life cycle. But

I've been looking at ISG6, and it really doesn't -- it's pretty silent on what part of the project life cycle the developers are at. Really what ISG6 identifies is what information is to be put into the LAR.

And the other point I would like to make is even with the tier one process, the exact same information for design information is required at exactly the same time, at the time of the LAR submittal. That's not phase two information. So, I'm trying to understand what the point was during Pareez's presentation, and I'm not quite sure I understand what your lesson learned was with regard to that.

MR. CHAMPAGNE: Yeah Rich, thanks, this is Jacob again. I'll speak to ours. So, ours was specifically -- there's a difference in life cycle when it comes to, for instance Westinghouse developing the TCP system, their conceptual design, and detailed design is a different part of the process than when we get into our engineering change, which documents the design basis, and the impacts of that.

Which as a conceptual design, we're really implementing, and reviewing their design, and incorporating it, making sure it meets our

requirements, making sure what design basis documents, and requirements, licensing basis documents, and there's a difference between those two.

MR. STATTEL: Okay, so you --

MR. CHAMPAGNE: Go ahead.

MR. STATTEL: I'm sorry, so you're referring to the interactions between your design processes, and Westinghouse's processes?

MR. CHAMPAGNE: Yes Rich. I think the reason we put it on here is because sometimes when we would get questions from you guys on a particular life cycle phase, it fit where Westinghouse was in their design more than it did in our engineering change process. We didn't have those documents in our system yet, we were still processing in Westinghouse, but it was just a gap in time frame between those two processes.

MR. STATTEL: Okay, thank you, that's helpful.

MS. GOLUB: Richard, it's Pareez. I think your point is well taken. I guess the only thing I meant, and I really shouldn't have said earlier, because it makes it sounds like it's earlier, as compared to other processes, which is not the case. What I really meant was just --

MR. STATTEL: I mean it's your choice, right? You can --

MS. GOLUB: Yes, that's exactly right. Because it's not -- matter of fact it's not that as soon as one phase ends, you just submit everything, right? You really have to pick the right time to submit when you feel confident that the material you're submitting won't change, that it is founding.

MR. STATTEL: Right, okay.

MS. GOLUB: And so that, I think was just -- that's what I intended to say, however it came out, it may not have been clear.

MR. STATTEL: Okay, thank you.

MR. JAIN: Thank you, any more questions for Entergy on this topic? If not then we will move on to, I'll request NextEra to make its presentation on (telephonic interference) experiences.

MR. FREWIN: Good afternoon, this is West Frewin, I'm just doing a microphone check first.

MR. JAIN: We can hear you.

MR. FREWIN: Okay, thank you. Samir, could you also put my slides up as well please?

MR. DARBALI: Yes, give me a minute.

MR. FREWIN: Thank you. And while he's putting those up, my name is Wes Frewin, I work for

NextEra Energy at the Jupiter West Corporate Office. We're presently working on a safety related digital upgrade for Turkey Point units three, and four. The scope involves reactor protection, system engineering, safety features, actuation systems, and nuclear instrumentation system replacement.

So, it is a sizeable budget, there are a lot of aspects to it, and just getting our arms around it has been a challenge. What I want to go through with my presentation is more of a focus on ISG6 from a process standpoint. I'm not going to get into any technical, or regulatory areas specific to a license amendment request, it's still in development. And we're still working with the NRC in the area of presubmittal meetings.

That is not an area that I will be going into at all. On the Teams call with me is Warren Busch, he is the lead project engineer at NextEra Energy, and we do have individuals from our independent third party review team, as well as our vendor. Our vendor is Framatome, and they're on the Teams call as well. Samir, I don't see the presentation up yet.

MR. DARBALI: I apologize, I thought I was sharing.

MR. FREWIN: No, that's okay. You can go to slide two please. So, the approach I'm taking is just to share some plus deltas challenges, improvement opportunities as we see specific to ISG6, and any comments, and questions at the end. Go to the next slide please. So, the first area I want to get into are the deltas. And so what we've been doing is working with the NRC, and presubmittal meetings without face to face engagement with the staff.

I do mention this as a delta because I know I've worked with the NRC face to face before, I was part of an NEI working group working on 50.59, and changes to 9601 Rev 1. And I know working face to face is far more efficient than via conference call. So, that by itself does create a challenge. We have obviously made it work because we've had to, but it is something that I think -- face to face is a far better way to engage, and get work done.

Scheduling has been a moving target, a lot of it is because of the scope. Scope, as I mentioned is sizeable, and unfortunately when it comes to a schedule that becomes a moving target, that in turn turns into challenges from an engineering standpoint, as well as regulatory uncertainty. And so we've been working very closely with the NRC, keeping them

informed of how things are going, and also seeking any clarification on any regulatory issues that we need to be aware of as we go along.

One of the other delta areas is a large time gap between presubmittal meetings. We did see this in one particular area between a presubmittal meeting that occurred in August of 2021, and then the next meeting was in March of 2022. The problem with that is we end up with different plays that come into the phone call on the second call that we're not familiar with, and we start to hear expectations that at least sound different than what we've understood previously.

And so, that creates a challenge I think, not only for us, but it creates a challenge as we try to understand those perceived changes, or expectations from the regulator side. So, there's kind of a lessons learned as well, is to make sure your presubmittal meetings, you keep them scheduled close together, obviously at reasonable times, but keep them close together, so that you do have continuity from one presubmittal meeting to the next.

Next topic is screening between the ultimate review process, and the tiered process. Although it is straight forward, we understand it, it

is narrow in the way that it's defined within ISG6. Some of the project specific considerations -- it doesn't seem to give us a whole lot of flexibility when it comes to perhaps moving to a hybrid approach. So, this has been challenging.

And again, we've decided to work very closely with the NRC, and in our presubmittal meetings, keeping them informed, of what our LAR submittal is going to look like, and how we will accomplish making sure that they get the documents they need as part of the LAR submittal, and any subsequent documents that they would need in order to ensure the approval of a license amendment request.

So, that's just one area that -- from an ISG6 standpoint, it just gives us a little bit of difficulty in working through that process. And the background of ISG6 being an infrequently performed process. It's not a procedure, or a regulatory document that you pick up every day, and exercise as you would other procedures that you have in house. The ARP process is -- the way it was, combined with the tiered process, it is very difficult to follow, there are sections within sections.

And it made it very difficult to determine okay, is this part of an ARP discussion, or is this

just part of a tiered approach discussion? And you combine that with enclosure bravo, and some of the topics that are discussed in the text are different than those discussed in enclosure bravo. Some of those are semantics, in other words, the words are different, or the titles are different. But it still required us to do some translation work with ISG6 in order to make sure we understood what documents were being referred to, and ensured that was going to be part of our LAR submittal.

Then last lastly, human factors, I know this has been brought up before, where it's brought up as an outside of scope. It just seems out of place, I guess is the best way to describe it. It seems out of place within ISG6, given that human factors is mentioned throughout ISG6 quite frequently actually. And Rich Stattel had just brought up about where it says in section C.2 that include necessary information at time of the LAR submittal.

So, obviously necessary information is going to include human factors documentation, so we know that that has to be part of it. So, it just seemed an odd example, I guess is the best way to say it. Next slide please. If you could back up one please. Or -- okay, something's out of order here.

I'm on the slide that talks about pluses. Either that, or I guess -- I'm sorry, my slide deck's out of order, sorry about that.

MR. DARBALI: Is this one it?

MR. FREWIN: Yeah, that's it, I'm sorry about that, I had slipped one side out of order. So the pluses, the presubmittal meetings are a plus, gave us an opportunity to work very closely with the NRC, and continues to be an area that we can meet the NRC teams, and get to know them, and understand what their expectations are for ISG6, and the LAR submittal.

The NRC has been very open in the discussion, which has been very helpful in understanding ISG6, and the expectations of the regulator. And it also gives us an opportunity to hear the NRC perspective firsthand, as opposed to either translating them through some guidance, or through email, or some other way. Obviously hearing it firsthand has been very helpful to us.

Although ISG6 does not talk about independent third party review teams, I do have to mention that is a plus. Not necessary for ISG6, but order to navigate through ISG6, we have an independent third party review team that is knowledgeable. There are members that have been part of the development of

ISG6 Rev 2.

Those have been very helpful in order to help us translate what he requirements are, what's behind the words, the discussion that occurred during the working teams with NEI, and the NRC on the development. So, that gave us really a firsthand perspective of understanding the direction we're going in, and make sure that we're getting it right the first time. Also their involvement in industry groups such as NEI, EPRI, and INL.

That in combination has just been a tremendous asset to the project team. And also the abundance of technical reports, there's a boatload of documents out there from various organizations such as EPRI, IEEE, and the regulator themselves. One thing ISG6 does is it helps us navigate through those documents, and points out documents that are important to putting together the LAR submittal, and the approaches that are recommended by the NRC for those.

If you go to the next side please. So, this one I just wanted to show the audience the various topics that we've discussed over the eight presubmittal meetings that we have had to date. The top two sub bullets are actually the most popular, which is vendor oversight plan, and the ISG6 Rev 2

process, and LAR content. So, that shouldn't be a surprised, based upon what we heard this morning from the NRC.

And a close second of course is human factors, and there are a couple others such as D3, and the life cycle phase process. So, that just gives you at least kind of a look at the topics that we've brought up during the presubmittal meetings. Next slide please. Can you go to page six? Thanks. So, the ISG6 challenges, just a couple things, these kind of echo what I've presented before, is the criteria between alternate review process, and the tiered process is trying to navigate our way through that.

And determine whether, or not a hybrid is more of where we are, and then defining what that is, making sure that that's crystal clear to the regulator, so that they understand that path that we're working through, and can support from a regulatory standpoint, the alternate review process from their standpoint. So, that is a challenge, it continues to be presently.

But we are working through that actively right now. NRC representatives, primarily during the presubmittal meetings have provided background on the various ISG06 statements, and often times what we

perceive is that there is a -- it's favored -- in other words the regulator tends to favor using the tiered process over the alternate review process. That just seems to be the impression that we get.

We still think we are in the alternate review process, we think it's appropriate, we think we screen into it. So, we are working with the regulator, obviously very closely, to make sure that we have all the right things in place for that, and to support it. And then what I brought up earlier with regard to the alternate review process, and the tier process, is the way editorial it's put into ISG6 that does offer some challenge there in understanding it.

So, improvement opportunities for ISG6, again, does not define necessarily the limitations of the alternate review process. We're kind of learning that as we go. We're learning that from the presubmittal meetings, our independent third party review team, and workshops like this, where we can hear firsthand from the NRC their position on certain things. But we understand that there are other attributes, such as complexity.

And what information is desired for docketing, and also as we've been discussing for the afternoon, human factors. And that concludes my

presentation, pending any comments, or questions.

MR. JAIN: Are there questions on NextEra's presentation?

MR. JAIN: I see a hand, Justin. Justin, do you have a question?

MR. VAZQUEZ: Hey yes, this is Justin Vasquez, I'm the lead technical reviewer for the Turkey Point application, the human factors team. I work with the Brian's group. I did want to speak to just one point really quick,, I think it was slide five with the deltas listed. Yeah, that's the one. So, just looking at the third bullet here. We did want to speak to just one really quick point, to that gap between that August meeting, and the March meeting.

We do recognize that that is a significant gap between I guess what we're technically classified as the presubmittal period, it was some engagement. In August of 2021, we learned some new information about the scheduling, and expected timing, and that's kind of what triggered us into having the internal discussions about how to consider the human factors engineering, and validation review, which we've been discussing quite a bit today.

And during that time period that we see

discussed in this bullet, we did have some engagement leading up to the end of the year period with the licensee, just kind of talking to them about some of our initial thoughts. We also had an additional meeting in early February to talk initially about the multi stage validation concept, and also hear some additional feedback from the licensee.

And we appreciate this discussion, so we just want to recommit that. We are committed to -- I mean engaging as efficiently, and as consistently as possible, and there also was mentioned the fact that we had some staff changes on the assignment. And I just wanted to clarify that a certain amount of that can be expected with these long term projects. Because with the NRC, I mean we do have our own staff movement currently, so sometimes we will have reassignments.

But we do maintain communication within our teams, and we try to keep things as consistent as possible throughout the process. So, we just wanted to say -- I mean we appreciate the point that's made here, and we also appreciate the frequent engagement with the licensee, and then keeping us up to speed on developments, but I just wanted to say that we have been making an effort to stay as engaged as we could,

even through those gaps between meetings.

Making sure that we have as common an understanding about expectations as possible. So, thank you.

MR. JAIN: Thank you Justin. Are there any more questions on NextEra presentation? If not, then I'll request Constellation to make its presentation on Limerick.

MR. DARBALI: We have a couple of questions.

MR. JAIN: Please, go ahead.

MR. WATERS: Hey, this is Mike. First, great presentation again, and to compliment NextEra, I think the pre-application meetings, although extensive, were beneficial, and again, I think NextEra was great about being open about what they were doing, were considering, and willing to engage us when we said we need the following information on this, or suggested topics for the next submittal of information, so thanks for that.

Yes, good comments on the ARP versus tiered process, that's something we need to chew on, and think how we could communicate better. I think one of the challenges here, and we can't solve the problem here, is alternate review process, and tiered

process, it's both what is the content, but also what is provided to us, right? So, there's differences, there's at least two axes here.

And sometimes we may be focused one, the timing versus the content, or vice versa. So, that's something that we may need to think about how to communicate it better down the road. Rich, did you have something to add?

MR. STATTEL: Yeah, I just wanted to respond to the process, the decision of which process to use. The object of the process, the goal of each process is the same. So, it's really just a matter of which is more applicable. The tiered process is oriented towards a product based evaluation. Whereas the alternate review process is more based on a process based evaluation.

So, the safety conclusions are the same, it's just what do we base our safety conclusion on? What information is provided to base your safety conclusion on? So, it's not our intent to express a preference for one, or the other, but we want to use the process that's most appropriate for the application, and the stage that you're at at the time of the submittal.

That's what we want to really get out

there. The alternate review process is not streamlined, it's not shorter, it's not less resources. It's the same, it's just a different process that uses different information as a basis for the safety conclusions. So, neither one is beneficial in terms of schedule, or commitments, or things like that. They're just different in that way. I just want to mention that.

MR. JAIN: any other comments from the staff? If not, then I will request Constellation to make its presentation on the Limerick.

MR. CONNELLY: Okay, Samir, can I ask you to present? Got it, thank you. Well, good afternoon everyone, I'm John Connelly, I'm the engineering manager for the Limerick Modernization Project. As has been stated multiple times during this meeting, we really do appreciate the NRC providing the opportunity to exchange information. This forum is particularly valuable as we're putting new processes into motion.

ISG6 alternate review, standardized digital engineering process, or NSBN04. Digital engineering guide, and then obviously inspection procedure 52003 as was discussed earlier. For those who are not familiar with the Limerick Modernization Project, we are digitizing the reactor protection

system, the nuclear steam supply shut off system, emergency core cooling system.

All of which will be replaced with the Westinghouse Common Q platform, and the redundant reactivity control system, or ATWS will be replaced with the Ovation platform. I'll be sharing some licensee learnings and observations. We've covered a lot of ground today, so I apologize in advance if there's any overlap with presentation materials. So, with that I'm going to touch very briefly on ISV versus MSV.

There's been a lot of good discussion today on that topic. I'll move forward into presubmittal meetings, learnings from that, and the NRC review process, and presubmittal discussion. So, if you could proceed to the next slide. Okay, again I'm going to cover this in very brief form. It's very clear that this is a work in progress, and that the industry, and the NRC are working to find a viable solution.

I did want to share a couple of thoughts that are pertinent to the subject. The multi stage validation introduces a degree of what we perceive to be some regulatory uncertainty in the form of neither any IEEE 2411, or the NEA 7466 having been endorsed by

the NRC. I know there is some degree of adaptation for that, but neither is an approved document. The second sub bullet here, the potential applicability of NuScale MSV is an interesting thing.

And may change the content for that second sub bullet, but it's going to take a bit of research to correlate two very different designs. And then to circle back on a point that Brian Green made earlier, from Chapter 18, that the ISV has to be complete before the implementation. We do recognize that this does put a timing constraint on both the licensee, and the NRC, so I thought it worth pointing out here.

One of the key takeaways from this is the development, and execution of a standalone MSV to be mated up with an ISV implementation plan, we're trying to figure out if that's more burden, or value. And one of the things that's kind of a chief concern for us, there's been a lot of discussion today around the need to do research, and negotiate a process, and create a path forward, and there's a lot of that kind of discussion going on.

But for purposes of the Limerick Modernization Project, our LAR submittal schedule has very limited margins. So, delays may emerge from the execution of a first of a kind activity does create

somewhat a degree of urgency to getting resolution behind this. With that I'll move on to the next slide. Okay, there's some pluses, and deltas. So, using the presubmittal meeting to determine the LAR content has been very helpful.

I think that was mentioned by the previous presentation. This is particularly important, because there's no single document from the NRC that lists exactly what content has to go in for complex visual modifications as the Limerick project does. Again, the interactions with the NRC staff during the presubmittal meetings is highly beneficial. But one of the things that's been a bit of a struggle for us is determining when the topic has been covered in sufficient depth as to take it off the to do list so to speak.

So, we want to make sure that we're covering topics to the staff's satisfaction without over performing on a given topic. The next observation is the NRC post-meeting summaries are sometimes at a level that's high enough that it's hard to determine whether, or not we've fully addressed NRC questions, comments, and concerns. So, deeper detail would be advantageous for both us, and the NRC, the licensees, and the NRC.

Three way communications is a good thing. Strictly following the alternate review process becomes a bit more complicated as we're introducing tangent processes to it. Human factors engineering is a really good example, and we've talked about that at length today. One thing I'll say that's been very advantageous for us is getting early staff comments on the presentation material in advance so that -- in advance the presubmittal meeting.

So that we have the capability to do whatever research is necessary, and formulate responses to the staff's questions in very timely fashion, so that's been very advantageous for us. And with that, I'll move on to the next slide. Okay, one of the other concerns we have, now we do understand that the license submittal review is a complex, and time consuming undertaking.

There's no way to minimalize that. But there may be some opportunities worth exploring that could reduce the total time require for LAR review, and this in turn would reduce, or could reduce project risk. As Warren Odess-Gillett, and Mike Waters mentioned earlier this morning, providing a licensed amendment, and draft form in advance of submittal does provide an opportunity to give early staff feedback.

This would be similar to the approach for I believe Waterford, and Vogtle 3, and 4 for their tech spec reductions. If there are areas that do require additional content, or detail, it's better to find them in advance, so that they can be addressed in the LAR, rather than being addressed through avoidable RAI. And we can leverage the presubmittal form as a good place for that kind of closed loop communications.

Second thing to consider, while every licensed amendment is going to be unique, there may be some opportunities to structure the presubmittal meetings in a way that provides more efficiency, or maximizes efficiency to ensure that specific topics are addressed to staff satisfaction. This would reduce the likelihood of avoidable RAIs. And the thinking would be, the structure could be framed around the scope of the project.

Not every project is similarly scoped, some of them require HFE considerations, others do not. So, there's going to be -- it's not intended to be a one size fits all, but there may be some value in coming up with somewhat of a framework that licensees, and the NRC can operate to. So, that's the first major bullet. The second major bullet I wanted to

talk about is something I just wanted to kind of put on everybody's radar.

As this audience knows, the industry has adopted the standardized digital engineering process, or NSB104, and the EPRI Digital Engineering Guide under the auspices of delivering the nuclear promise. It goes without saying the price of admission is that the design is at a level of maturity that is ready for staff review at the time the LAR is submitted. One thing to be aware of however, the complexity to be aware of.

It's that the DEG is an iterative systems engineering based process. This may create situations where design artifacts may have minor evolutions over time, and during the license amendment review. These would be refinements, they would not be functional changes. But this could create a degree of discontinuity between the design process, and the review process that the licensee, and the staff just need to be aware of, and communications are going to be essential as we progress here.

With that, that concludes my presentation. And I'll move forward to any questions, comments?

MR. JAIN: Yes, Mike? Mike, you have to unmute.

MR. WATERS: Thanks, did you get that John? I'm joking. Great presentation, interesting comment on approving the pre-application process, that's something we should explore further. It's a good point, I think -- I personally view it as the ramp up, or ramping up to a LAR, and of course we want a LAR, no surprise to anyone except in the pre-application process as the way we're doing it, it helps us ramp up to that, and gives us that stage.

I think you're suggesting something maybe more structured, or formatted, or can you maybe elaborate a little more on what you're thinking there?

MR. CONNELLY: Yeah, so to a degree, the presubmittal meetings are -- I won't call them ad-hoc, but they're flexible, and there's a lot of benefit to that to be honest. We can canvas the NRC for topics that they would be interested in hearing at the next meeting. There's -- it's a flexible way to exchange information. But if you -- and here's just one consideration, the human factors was basically off everybody's radar early on in the process.

And it would have been beneficial both for the NRC, and the licensees to bring that forward early on. So, if there was somewhat of a structure for things like that that may come into play, that could

be advantageous. That was my thinking.

MR. WATERS: Thanks.

MR. JAIN: Yes Richard, you can go ahead.

MR. STATTEL: Yeah, I was just going to mention the process that we use for pre-application meetings, we essentially create an account. So, we have something we charge our time to, but it's very limited resources. We don't have a lot of resources, so I think there's a little bit of difficulty involved with spending more time, and effort, and resources on pre-application activities.

And I think that's probably part of the reason why our meeting summaries are at the high level they are. And this also creates a problem when you talk about free draft submittals. We really don't have a process for that, and we don't have a real means of allocating resources for that kind of activity. So, we hear you, and we kind of went through a pseudo review of a draft version.

We did that for Waterford, but again, there's some opposition to doing this kind of out of process activity for which we don't have the real ability to allocate the necessary resources for it. So, I'm not saying it can't change, but it's somewhat problematic in our current environment.

MR. CONNELLY: Thanks Rich, that's exactly the kind of feedback that we're looking for.

MR. WATERS: Yeah, just to add on, resources will be getting tighter for NRC when we actually have these in house for future applications, but the ultimate challenge, you always hear the regular disclaimer, no decision will be made, and for pre-application meetings, we don't make final decisions that what you're going to submit is going to be okay until we actually see it.

So, there's a limit to the feedback we can give, and what we can document in the meeting summaries in terms of if there's an intent to look for, I guess closure to certain issues. And obviously, I think on most topics we leave the meetings with a greater understanding of what's going to be submitted, and I think there's an understanding based on NRC insights, and questions of whether you all will hit the mark on certain topics. But it's certainly something to think about, and improve upon going forward.

MR. CONNELLY: Yeah Mike, I agree. We're not looking for a regulatory commitment in the presubmittal meetings, that's not the right forum for that. Decidedly not asking for that, but the more

information that we can exchange, and getting closure to a particular item, it could be something as simple as okay, you've addressed this issue, we understand your position, and we move on from there. It could be something that simple.

MR. WATERS: Okay, absolutely.

MR. STATTEL: Yeah, part of the problem -- this is Richard again. Part of the problem is it's difficult for us to provide formal feedback because that can be used back against us, right? So, it's all pre-decisional, it's pre-application, it's pre-decisional. So, if we were to provide formal feedback to you, I think it's a legalistic problem, because that can be construed as being some kind of approval.

Or some preempting decision that is made during the license review itself. And so I think there's some legal ramifications that would have to be considered before we're able to do that.

MR. CONNELLY: Okay, thank you Rich.

MR. WATERS: This is Mike, and I want to leave on a positive. So, I think they've been very beneficial, and I think, I know Turkey Point, and Limerick, Maine. I have great views here, and the real test is when we get the LAR for acceptance review, right? That's the real test, and that's when

we'll know. And I would say, I believe Waterford was really successful.

I know looking backwards, after we issued the license, I think that the biggest surprise, and where we needed to align afterwards on the LAR was the DOP for example. That was brand new, but I felt for all the topics for example, Waterford the D3 that required more specifications, and software development, we had a great understanding of what was going to be submitted through pre-application, and got generally what we expected.

There were some open items, and RAIs, a little more work for VOP, but in that regard I thought it was pretty successful. I'm hoping that it'll be true for these NextEra, and Constellation, to the extent that we can on all these topics. But it's something that we can continually focus on right up to the LAR.

MR. CONNELLY: We share that hope.

MR. JAIN: We are pretty close to our workshop schedule, so now the floor is open for any question on any topic anybody might have. Would like to discuss. If not, then I'd like to ask if any of the participants would like to provide closing remarks.

MR. WATERS: Well BP, are you asking me,

or someone else?

MR. JAIN: Well, first we give a chance to the stakeholders, if anyone of them want to make --

MR. WATERS: Yes, please, if there are any members of the stakeholders, or the public that want to make comments.

MR. JAIN: So, I see a hand raised. Yes Alan, please go ahead.

MR. CAMPBELL: BP, I just wanted to again thank the NRC for the opportunity to have this forum. I think very helpful for many as prospective, and our members. Just note that we had representatives from I&C, cyber, HFE, vendor QA, safety analysis, the regions, this is a very integrated process, and I think that the ability to get us all together, and share information is just invaluable, and so appreciate that.

We do look forward to further discussion, specifically on human factors, there's definitely some interest there. Regarding furthering the discussion at the industry level to ensure that we can continue to provide the regulatory confidence using this alternate review process. So, again, thank you all very much for the engagement, and we appreciate the time.

MR. JAIN: Thank you Alan. Mike, can you provide the closing remarks for the NRC?

MR. WATERS: Well, in a similar manner, a few things, these are my perspectives. Yes, we do need to engage more. And my view on human factors, I'm not a supervisor of human factors, so I'll have to defer to them, but I think a couple things in that area, we recognize human factors is a topic, and I think there's two tracks, and our PM can communicate, well if the licensee is in the hopper on these questions, you know who you are, and we can engage on that in the pre-application submittal conversations that we have ongoing, so we should do that.

And yes, if we need to engage further on a joint, more generic basis on human factors, or anything else related to I&C, let's do that. Second, I thought it was a great meeting today. Awesome participation from industry, and as you noted Alan, all the NRC staff, so thanks to them. I did appreciate the presentations, personally from NextEra, and Constellation, Entergy on their perspectives.

I honestly wish we had more time to talk about it in a more expanded discussion, so we could really hone down on some improvements here, and perhaps we can do that. Third, please in the next few

days, weeks, provide BP any feedback on how the next workshop can be better. What can we talk about, can the format be different? And what can we do to improve a future workshop?

The what, where, when, why, and how is something we look for feedback as well. So, please feel free to email BP, or even me, or Jeanne Johnston on those topics. But that's great, I would offer Brian, or Lauren, because HFE was a significant topic, do you have any other closing remarks?

MR. JAIN: Brian?

MS. NIST: Hi, this is Lauren Nist, sorry. I am the Operator Licensing and Human Factors Branch Chief, and unfortunately Brian had to leave the meeting. But I think I'll just echo your comments Mike, and thank you everybody for your discussion today.

MR. JAIN: Okay, I'd like to thank everyone for their time, and if you have any comments, or feedback on any aspect of this workshop, please contact me, or Michael Marshall. We will provide you the necessary forms. With that, the meeting is adjourned, thank you everyone.

(Whereupon, the above-entitled matter went off the record at 4:37 p.m.)