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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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PUBLIC MEETING WITH NORTHWEST MEDICAL ISOTOPES, LLC

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THURSDAY,

FEBRUARY 18, 2016

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ROCKVILLE, MARYLAND

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The Public Meeting commenced in Room O-16B4, One White Flint North, 11555 Rockville Pike, at 8:30 a.m., Mike Balazik, Project Manager, presiding.

NRC STAFF PRESENT:

LAWRENCE KOKAJKO, Director, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation

WILLIAM DEAN, Regional Administrator, Region I

CRAIG ERLANGER, Acting Director, Division of Fuel Cycle Safety, Safeguards, & Environmental Review, Office of Nuclear Material Safety and Safeguards

MICHELE EVANS, Deputy Director, Office of Nuclear Reactor Regulation

JANE MARSHALL, Deputy Director, Division of License Renewal, Office of Nuclear Reactor Regulation

MICHAEL BALAZIK, Project Manager, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation

ALEXANDER ADAMS, Chief, Research and Test Reactors Licensing, Office of Nuclear Reactor Regulation

MIRELA GAVRILAS, Deputy Director, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation

SHANA HELTON, Acting Deputy Division Director, Division of Fuel Cycle Safety, Safeguards & Environmental Review, Office of Nuclear Material Safety and Safeguards

ROBERT JOHNSON, Chief, Fuel Manufacturing Branch, Office of Nuclear Material Safety and Safeguards

STEVE LYNCH, Project Manager, Research and Test Reactors Licensing Branch, Office of Nuclear Reactor Regulation

NANCY MARTINEZ, Environmental Project Manager, Office of Nuclear Reactor Regulation

DAVE TIKTINSKY, Project Manager, Fuel Manufacturing Branch, Office of Nuclear Material Safety and Safeguards

ALSO PRESENT:

NICHOLAS FOWLER, Chief Executive Officer, NWMI

CAROLYN HAASS, Chief Operating Officer, NWMI

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(8:33 a.m.)

MR. BALAZIK: All right, good morning. I'd like welcome everyone in attendance today. My name is Mike Balazik. I'm a project manager in the Division of Policy and Rulemaking at the NRC.

Northwest Medical Isotopes has agreed to meet with the NRC staff today to discuss licensing for their radio isotope facility.

This is a Category 1 public meeting conducted in accordance with the Commission's Police Statement on enhancing public participation in NRC meetings. As such is intended to be a dialogue between the NRC and Northwest Medical Isotopes concerning topics related to licensing in Northwest Medical Isotope facility project.

The public in invited to observe the meeting and will have the opportunity to communicate with the NRC staff after the business portion of the meeting, but before the meeting is adjourned. Northwest may respond to comments or questions from the public but is not obligated to do so.

When we go through the introductions I ask everybody identify yourself and your affiliation. There's a sign-in sheet that may be moving around the

room right now. I ask everyone sign in. Yes, thank you.

If you wish to provide any comments on the meeting, I can provide you a meeting feedback form. Or you can also go to the public meeting cite and do it electronically.

This meeting is scheduled to last till approximately 3:00 p.m. I'd like to emphasize that this meeting is primary for the NRC to discuss general licensing processes and reviews, the NRC regulations and guidance with the Northwest. There are no regulatory decisions will be made at this meeting.

Also, as a reminder, this meeting is being transcribed today. And for everybody on the phone, the slide presentation is available. It's publically available. And I'm going to provide the NO number right now for everyone. The number is ML16048A, as in Alpha, 554.

Does anybody on the phone need that repeated? All right, I'm not hearing any.

(Off record comment)

MR. BALAZIK: All right, I'll continue on. A meeting summary will be made publically available within 30 days of this meeting.

Before we begin, a couple of items I'd

like to mention. First of all, please limit interruptions. Silence your cell phone and please keep side conversations to a minimum.

I ask you speak one at a time. And individuals on the phone, please mute your phone unless you're going to provide any comment.

Also, please identify yourself when you speak so people on the phone knows who's speaking. And again, submit any questions or comments to me at mfb@nrc.gov.

Next I'd like to remind you that you're within a NRC controlled space. Should there be an emergency all occupants should begin to calmly evacuate using the nearest stairwell to exit the building.

All visitors will be escorted by the NRC staff. Disables persons, who due to health reasons feel they cannot safety walk down the stairs to evacuate, may use the elevators. Exit through the nearest door and then go to the pause area in front of One White Flint and report their presence with the guard.

So you experience, observe anyone with a life threatening medical complaint while evacuating, call 911 and report your location and nature of the

emergency.

Also, if you need to use the restroom, you'll need to be escorted.

All right. So let's now run though introductions. I'd ask everyone to speak loudly so people on the phone can here you. And let's start around the table.

As I said earlier, my name is Mike Balazik. I'm a Project Manager in Division of Policy and Rulemaking.

MS. MARTINEZ: Good morning. I'm Nancy Martinez, NRC Environmental Project Manager.

MS. GAVRILAS: Mirela Gavrilas, Deputy Director, Division of Policy and Rulemaking in NRR at the NRC.

MR. LYNCH: This is Steve Lynch. I'm a Project Manager with Research and Test Reactors.

And real quick, before we go on with the introductions, if you are participating on the phone, could you please put your phone on mute? We're getting a lot of feedback in the room here. Thank you.

MR. ADAMS: Al Adams, Chief of Research and Test Reactor Licensing, NRC.

MR. TIKTINSKY: Dave Tiktinsky, Project

Manager of the Field Manufacturing Branch in Office of Nuclear Material Safety and Safeguards.

MR. JOHNSON: Good morning. Robert Johnson, Fuel Manufacturing Branch Chief, NMSS.

MS. HELTON: Shana Helton, Acting Deputy Division Director at Fuel Cycle NMSS.

MR. FOWLER: Nick Fowler, the Chief Executive Officer of Northwest Medical Isotopes.

MS. HAASS: Carolyn Haass, Chief Operating Office, Northwest Medical Isotopes.

MS. KEIM: Andrea Keim, Vendor Inspection and Quality Assurance, NRR.

MR. MATULA: Tom Matula, NMSS, Project Manager.

MR. MORRISSEY: Kevin Morrissey, Fuel Cycle Review.

MS. ADAMS: Mary Adams, Fuel Cycle Safety and Environmental Review.

MS. LONDON: Lisa London, Office of General Counsel.

MS. BIELECKI: Jessica Bielecki, Office of General Counsel.

MR. LINDELL: Joseph Lindell, Office of General Counsel.

MS. KANATAS: Catherine Kanatas, Office of

General Counsel.

MS. YOUNG: Mitzi Young, Office of the General Counsel.

MS. TRAN: Linh Tran, Research and Test Reactor Licensing Branch, NRC.

MR. ALLEN: Eben Allen, Research and Test Reactor, Project Manager.

MR. BALAZIK: This is Mike Balazik, please mute your phones. Somebody's got an open line and they're speaking and we're hearing you in the room.

MR. LYNCH: Star 6.

MR. DANNA: Jim Danna, NRR, Division of License Renewal.

MR. MILLER: Chris Miller, Office of Nuclear Reactor Regulation. And I'm the Director of the Division of License Group.

MR. ISAAC: Patrick Isaac, Research Reactor Oversight Branch.

MR. BALAZIK: All right, this is Mike Balazik again. Let's go to the phone line. I ask individuals to identify themselves.

MR. RODRIGUEZ: Michael Rodriguez, NRC, NSIR EP.

MR. FLAGG: Michael Flagg, University of Missouri Research Reactor.

MS. MCCULLOUGH: Kara McCullough, NSIR, NRLB.

MR. BERICK: Dave Berick with Senator Ron Wyden.

MS. RIVERA: Alison Rivera, NSIR EP.

MS. BANERJEE: Good morning. Maitri Banerjee, ACRS Staff.

MS. WEIL: Jenny Weil, Congressional Affairs.

MS. FRAZIER: Andy Frazier, Region III Office.

MS. MOSER: Michelle Moser, Environmental Energy Staff.

MR. BARTELME: Jeff Bartelme, SHINE Medical Technologies.

MR. NAQUIN: Ty Naquin, NMSS, Fuel Manufacturing Branch.

MR. TEAL: Charles Teal, NSIR Fuel Cycle Transportation Security Branch.

MR. FOLK: Kevin Folk, NRC Environmental Staff.

MR. WEBER: Carl Weber, NRC, Office of New Reactors.

MR. BALAZIK: Is there anybody else on the phone that wishes to identify themselves? Okay, I'm

hearing none.

So now I'd like to turn it over to Mirela, who would like to provide some opening remarks.

MS. GAVRILAS: Thank you, Mike. Welcome everyone. I want to start out with a very high level statement which is, that we, the Agency, recognize the importance of establishing a reliable domestic supply of molybdenum-99.

And as such, we recognize our role to support that national effort. So you will see, you will hear today about what we do and how we do it and why we do it.

And you'll also hear, you see already that the room is filled with technical experts and with regulatory experts who are here to answer all your questions. Because the main objective of this meeting is to obtain clarity in our communications.

It is very important to us that we hear each other correctly. Because we realize that every time we take time out to clear out misunderstanding, we spent resources and time that would be better spent moving the review and the effort forward.

So our main objective today is basically to discuss the topics that we agreed with Northwest Medical, should be discussed today. And we want to

have open dialogue. So please ask questions at any time.

Again, we have the technical and the regulatory experts in the room to address your questions. So we want to make sure that at the end of the meeting, we're aligned in terms of our understanding of where we are in terms of the review of the construction permit that's in front of us now, as well we the preview of the operating license that is still to come.

So with that, I'm going to pass it to Shana who is going to give a couple of additional opening remarks.

MS. HELTON: Thanks, Mirela. I agree with Mirela's points. I can't emphasize enough the need to obtain clarity on both sides, so that we can have an efficient, effective licensing path forward.

And to that end, I just want to say, that while multiple offices are involved with this review, we do act as one NRC. You will hear from us with one voice.

Mike Balazik will be your primary point of contact. So you don't have to worry about trying to correlate between different offices.

And just as we go through this, one point

that I wanted to emphasize is that for each application that we receive as an Agency, not just in this area of medical isotopes, we review each application based on its merits.

So really we need to look at what's before us today. And as we go through the construction permit, that will be one aspect of the review.

One goal, on our end, is to really gain clarity on the nature of any of your future submittals, since you've indicated that some of your activities would be regulated under Part 70 and under Part 30. So I look forward to learning more about that path forward as well.

So with that, you know, I just look forward to having a good meeting. Thank you for coming here today. And for everybody on the phone.

MR. BALAZIK: This is Mike Balazik. Thank you, Shana. Now I'll turn it over to Northwest Medical Isotopes for some opening remarks.

MR. FOWLER: Well, and I would add my thanks to everyone that's assembled here. In that we all understand the importance of serving a reliable and secure supply within the United States for moly-99.

And we met with the executive director and

his direct staff and a number of folks who are in this room a month ago. And we believe, Northwest Medical Isotopes believe, it was an excellent conversation. Part of a long-term relationship building exercise to make these conversations as productive as possible.

We invited with us, a couple of people to provide perspective. One of whom was the chief executive officer of a leading healthcare services provider in the United States.

And we all recognize the need for this reliable supply of moly in the United States. But sometimes hearing it from a healthcare services provider that's responsible for millions of people, who can provide that direct testimony of what it means when there are shortages, is important. And we thought that important to provide that direct perspective into the executive meeting a month ago.

We also invited Mallinckrodt to speak on the state of the supply chain. And what is coming forward in the near future and the potential fragility of that supply chain that really puts a point on why these activities that are before the NRC are so important.

We then had a fruitful discussion on two questions that Northwest Medical Isotopes had

specifically. And we hope that this meeting today directly addresses those two questions as follow up to that meeting.

The first had to do with the licensing approach as our activities do incorporate both Part 50 and Part 70 activity in our intended operations.

And the other was recognizing the need for this domestic supply, exploring mechanisms by which the review schedule can be accelerated, expedited, done in the most productive fashion possible.

And we are committed to not only understanding the process of the NRC and being extremely responsive to that process, but also doing everything we can possibly do to make that review as expeditious as possible. And we hope to have that kind of conversation today to understand how we might work better together to get the review done and as quickly as possible, without compromising our combined committee to public safety, as well as public health.

And so I did have the opportunity on the nine hour trip yesterday, in the care of one of our major airlines, to review the materials that Mike had provided to Carolyn in advance.

And in the interest of everybody's time assembled, I think the package is great from an

educational standpoint. I think we understand largely the background.

And so perhaps going through the general information as quickly as possible, and getting specifically more to those two follow up items, could save us all some time. Because we have reviewed all the guidance from the NRC. We've reviewed the general information.

And so getting quickly to the areas of combined interest is certainly our objective here. So, Michael, thank you very much for providing the materials early.

And with that, I'd like to turn it back to the NRC to begin this, what we all hope, to be a very productive meeting.

MR. BALAZIK: Thank you, Nicholas, I appreciate that.

MS. GAVRILAS: So just one comment. The slides that you have, we really appreciated the fact that you reviewed them before we're going to talk about them.

They're intended to engage you in dialogue with us. They're intended to basically, we're talking in general, and you may want to take the opportunity to ask, how does this impact us.

What we're trying to understand is, not just what your questions are, but why you asked those questions. Because we want to make sure that we're answering, not just the words, but the intent of what you're trying to find out.

So again, thank you for going through them, this is great. It seldomly happens. And we'll just use them as context for the rest of the discussion. So please, at any time, just stop us and talk to us about everything. Thanks.

MR. BALAZIK: All right, this is Mike Balazik again. First of all, for transcription purposes, please identify yourself prior to speaking. And let's start the presentation.

One item that I'd like to add is that no proprietary materials planned to be discussed by this staff during this meeting. However, if Northwest Medical Isotopes believes that we are starting to move in that direction, please let us know so that we can cut off the discussion right there. So thank you.

All right, these -- here's the staff that's presenting today. Earlier we've all identified ourselves so we'll go through these slides real quick.

Basically this is the meeting purpose. Here's some of the main topics we want to cover today.

Just provide a general overview of the NRC, oops, I'm sorry. It skipped one on me.

Provide an overview of NRC licensing processes, provide an overview of NRC regulations and guidance for construction permit operating license and a Part 70 license, as well as a 30 license. Discuss review timeline. Provide status of the construction permit application review and discuss communications. Okay?

And next we'll go into the licensing.

MR. LYNCH: Sure. This is Steve Lynch. And just to give myself a little bit more of an introduction.

For those who don't know, I was involved with the SHINE review and was the lead projector manager for that. So I'm helping out with the Northwest review to provide insights and input to help gain efficiencies and lessons learned from previous reviews that we've done. And apply them.

And that's what we try doing at the NRC. Is we've done something before, hopefully the next time we do it we can apply the lessons learned from before.

So to get started with this introduction here, these considerations are for both the applicant

and the NRC. We want to emphasis that where we pick the licensing process from the regulations is driven by the technology that's put in front of us.

And especially with the medical isotope facilities. Some of the considerations that we look at are, how much material are you going to have, what types of material will be onsite.

That will help determine where you fall in the regulations, the activities that you're actually going to be performing with this material.

Are you going to be making targets, are you going to be irradiating targets, will you be processing targets. How will you be irradiating your targets. Will you be using a nuclear reactor. Will an accelerator be involved.

Then we also look at the, how you're going to be processing the targets afterwards. And the bigger driver for licensing regimes there is, looking at the batch size.

As I'm sure you're very well aware, if you're processing batches of greater than 100 grams of special nuclear material, that will put that activity into the Part 50 licensing process.

And then one of the other considerations we look at is, will you be using new or existing

facilities. And as I understand with Northwest, it will be a mixture of both. Using existing research reactors as well as constructing a new facility for processing.

Next slide. So once we've looked at all the technology and how you're going to be using the material, the next step is to try putting it into the different boxes we have in our regulations.

These are not all of the regulations that you need to follow in order to get a license. But these, in terms of the application that you provided, are some of the main technological boxes that we'll be looking at in terms of licensing the production facility in Part 50.

The special nuclear material will be looked at under Part 70. The moly that's produced we'll be looking at under Part 30.

And then with all of this, we'll be looking at the environmental impacts of these actions and how the material will be used.

Next slide. So we're going to spend today highlighting some of the different processes that we use from that previous slide. Especially focusing on Part 50, for the production facility, Part 70, for material. And then also Part 51 for the environmental

review process.

And we just kind of want to step through these processes to see if you have any questions about how we are conducting the review of the application that you've provided us.

So we'll get started with an introduction to how we're looking to have a Part 50. In order to go through the Part 50 and licensing process, there are two licenses that you will need to apply for and get from the NRC in order to operate your facility.

And that's a construction permit, which you have applied for, and an operating license that we will look forward to reviewing, if you choose to submit one.

The main components of the construction permit are the environmental report and the preliminary safety analysis report. You've submitted both of those, so you're familiar with their content.

And then for the operating license application, we'll be looking at your final safety analysis report, which includes more information, and was in your PSAR. Including your plans for operation, handling emergencies and your technical specifications.

Another main component of the operating

license application will be the Physical Security Plan.

Our commitment to doing these reviews, for both the construction permit and the operating license, is to finish these reviews within a year and a half to two years from docketing the application.

Based on the experience that we have recently with applications like this, we believe that we can meet that review schedule.

Yes, we're going to go into more detail about ways that we can, that factors that may accelerate or hinder our ability to meet this.

Next slide. So today we'll focus mostly on the regulations and licensing surrounding construction permits. Since that's the application that we have in-house.

If you would like to gain better understanding of the operating license review process, we can certainly discuss that in a future meeting.

For here, I wanted to highlight some of the more important regulations concerning the construction permit. This is highlighting the main, you know, 50.22 puts you into the realm of the commercial facility under the Atomic Energy Act. That's Section 103.

And as I'm sure you're aware, this is slightly different than most of the other non-power facilities that we license under Part 50. Those are generally research reactors that are non-commercial facilities.

And the main difference that we see there is that there will be a mandatory hearing on your application. And there will be a review by the ACRS as well.

The other, some of the other things that you're aware of under 50.30, you're to submit an environmental report, which you have done. And submit a preliminary safety analysis report under 50.34, also what you have done.

And then some of the other important regulations that you address in your accident analysis are meeting both occupational and public dose requirements under Part 20.

All right, then after we finished our review of your application, what the NRC is fighting to come to a conclusion is, can you construct your facility as described in your PSAR?

And what we're looking at there are these regulations that I have listed at the end there. 50.35, which I'll go into more detail on on the next

slide, as far as the findings that the commission needs to make in order to issue a construction permit. And those are supported also by the findings that are in 50.40, 50.42 and 50.50.

Next slide. So as the NRC evaluates your application, these are the primary four findings that we are looking to make, based on the information that you have provided.

We'll look at, to see, have you provided the proposed facility design. And the emphasis here is, what we're looking at for is, have you given us your principle design criteria in this first bullet.

As you're aware, 50.34(a) does require that you describe your principle design criteria. Unlike nuclear power reactors, the principle design criteria are not enumerated in Appendix A of Part 50. And that you are left to propose your own design criteria per your facility in this case.

We also recognize that we are being provided a preliminary design. And as such, there may be information that you have not provided at this time.

We're looking to make the conclusion that the information you have chosen to provide at a later date is acceptable, but we don't need it at this time

in order to establish a preliminary design.

Something else, 50.34(a)(8) allows ongoing research and development through construction. For those areas that you've identified that you have ongoing research and development, we'll be looking to see that you have a research and development program developed and setup in order to resolve any safety questions associated with those items.

And then all this comes down to, that we need reasonable assurance, that prior to the completion of construction, any safety questions that are opened, will be resolved in the interest of public health and safety.

Next slide. So this slide, what I wanted to emphasize is the difference between the determinations that we're making at the construction stage and at the operating license stage.

At the construction stage, we're essentially only -- we're allowing you to go forward and construct. You've given us enough information for us to say, go ahead and get started.

In contrast, when we issue an operating license, this is when we say that, based on the final design of the facility, that we believe it can be operated safety. So I just wanted to emphasize the

difference in the emphasis that we place in those two determinations.

Next slide. So I'm hoping this slide helps partially answer one of your questions that you had about the licensing process and how we look at your applications and how you can submit them. And we'll go into some more detail on this when we get specific with your application.

But both the Atomic Energy Act and the regulations allow for an applicant to combine applications. And this is common.

There's, and mostly we'll see this with the operating license application. In order for reactors to operate, they will also require a Part 70 license in order to possess and use material on their site.

And then following that up, the commission does combine those licenses. So you see, and Al will show you an example of that later today.

When reactors are issued licenses, there is typically a Part 70 license. And the Part 30 license, and sometimes the Part 40 license that are combined together in that, is on a single piece of paper and a single license.

So we are --

MR. FOWLER: Can I ask a question at this point?

MR. LYNCH: Yes.

MR. FOWLER: At the executive director meeting, Mirela, I believe you did a, at least you helped me, and I'll use the, I could use inappropriate terms in the regulatory environment because it's not an environment that I deal with every day, but I understood from your presentation, in that meeting, that we had the choice. That we could submit a separate Part 70 license or we could submit, under the Part 50 umbrella, the Part 70 requirements with the important caveat that the Part 70 information, at that point of submission, needed to be final because it was a one-step process.

And so I understood our follow up to be within one week of that meeting, to confirm that understanding to us that we had that option, between those two choices. And, so I think in the interest of time, if we could simply confirm that, that our understanding is compatible with your understanding, I think we're all set.

MS. GAVRILAS: What I said at the meeting is still what our position is. And we'll walk you through the slides.

This just helps explain the details. The bottom line is, we look at your activities from a safety perspective. And the security perspective.

So as long as we -- and our rules and our guidance help us know what we need to evaluate in those activities.

So whether the description of how you make your safety case comes on one piece of paper or on two pieces of paper, is not that important. In the end we're going give you one license that captures all of those activities.

But the review is going to be, we're going to look at every safety component that we need to and every security component of all the activities that you are proposing.

So in other words, it doesn't matter how the information comes in, the regulation is designed to allow us to combine that information into one license. And the regulation does allow us to basically eliminate repetition.

So if you provided something in one context, you don't need to resubmit that information, because you do get credit for it under the activity. If the activity was described on one piece of paper, you get credit for it. You don't need to describe it

again.

MS. HELTON: Mirela, I agree. I just want to make sure that it's clear that the packaging is up to you. How you package it all together, multi submissions, a single submission.

What needs to be clear, in your submission or submittals, however you decide to do it is, what regulations you're seeking to comply with. And then you also have to fully demonstrate your compliance with those regulations.

So it just has, however you do your packaging, it has to be very clear that if you intend for this information to satisfy Part 70, subpart (h), or whatever you're going to do, that you have to very explicitly.

That will help our review greatly if you very explicitly say, this is the information that complies part umptysquat. But, you know, we can't identify that for you, you have to identify what parts of the regulation you need to comply with, and then you have to demonstrate how you comply.

MS. GAVRILAS: And to add to what Shana is saying, you can cross reference in all of your document that you submitted.

MS. HELTON: Right.

MS. GAVRILAS: And right away, that adds to the case that I'm trying to make in this piece of paper.

MR. FOWLER: So very simplistically, from my standpoint, again, because I'm not schooled in the art of regulatory review, is the final Part 70 information, we can include, either in our operating license under Part 50 application or as a separate Part 70 document, but we need to be clear about what we're submitting under which format.

MS. HELTON: Right.

MR. FOWLER: So if I have that very high level kind of understanding, that will put it in my brain, Carolyn will take care of the details. But at least now I have it in my brain that the Part 70 is either under an operating license or under a separate Part 70 submission.

MR. LYNCH: Yes. And I think what's most important there is, we're looking to make our safety determination based on technical information that you provide.

Whether it's Part 50 or Part 70, we still have to say, we have technical requirements that we're trying to make to justify safety. So we're looking for technical information.

And when we have all that technical information, we can figure out which box, you know, will it be a full, will it be Part 50 with Part 70 as part of that or separately. But we will evaluate that based on the request that you ask of us.

MS. HAAS: We understand the safety aspect. I mean Nick is just trying to bring it up --

MR. FOWLER: Yes.

MS. HAAS: -- because it's based on conversations we've had over the last two or three years and it got modified within your organization. So we just wanted to make sure that we understood it, and we do. So thank you for the input and we'll move on.

MS. GAVRILAS: You know, we start every public meeting with a disclaimer, which is, we're not going to reach regulatory decisions here and there's a reason for that.

Everything that the staff reviews needs to be on the docket. I mean that's the tentative of how we operate.

So we have dialogue here. So right now, what we have for review in front of us and what we can be very specific on, at least the portions that we've reviewed, is the construction permit. The Part 50

construction permit.

Anything else is in pre-application space. If that makes sense?

So if there is -- if we're sometimes tentative or give you our best opinion, we will clarify. That opinion will become definitive, once we have an application in front of us.

It's worth repeating because, again, in the absence of information, all we can do is say what the most likely path is.

MR. LYNCH: Okay. Next slide. So what we're going to transition to now is talking a little bit more about the actual review process for the construction permit. And we'll get into timelines and what our expectations are for the review that we have ahead of us.

So to introduce this, this is just kind of a high level flow chart to highlight the main pieces of the construction permit review. We have two parallel reviews that we'll be going on.

And this is our safety review of your preliminary safety analysis report and the environmental review of your environmental report.

The results of each of these reviews will feed into a number of things that will lead ultimately

to the commission's decision to either grant or deny your request for a permit.

The review, the output of that will be the safety evaluation report prepared by the staff. That will be reviewed by the ACRS.

And as part of their independent review, it will also be considered by the commission and the mandatory hearing.

There's also a possibility that there could be contentions filed as a result of this. And we'll talk a little bit more about that in a few slides, but that's another step that could be in this process.

The environmental review will also be, the environmental impact statement that's being prepared, will also be considered by the commission and its decision to grant or deny the construction permit.

So right now I'm going to turn the presentation over the Nancy Martinez, the project manager leading the review of your environmental report. And she's going to talk through some of the specifics of the environmental review process and the status of their review.

MS. MARTINEZ: Thank you, Steve. As Steve mentioned, I'm the environmental project manager for

the application. And I'm going to discuss the environmental review process.

The environmental review is going to be performed in accordance with the National Environmental Policy Act of 1969. Commonly known as NEPA.

NEPA requires fellow agencies to follow a systematic approach in evaluating the potential environmental impacts of the proposed action and to assess the alternatives to those actions. The NEPA process involves public participation and disclosure.

NRC's environmental regulations implementing NEPA are contained in 10 CFR Part 51.

Slide 17 please. This slide presents an overview on the steps that lead to the environmental review process.

When an application is submitted to the NRC, the NRC conducts an acceptance review. And an acceptance review determines if the application has sufficient information for the staff to conduct its technical review.

If the application is accepted, the NRC staff conducts a NEPA document determination. And that is to whether develop and prepare an environmental assessment or an environmental impact

statement.

I will discuss in later slides, for the Northwest application, the staff determined to prepare an environmental impact statement. Once the NEPA determination is made, the environmental review process is conducted in accordance with 10 CFR Part 51.

Slide 18 please. This slide presents an overview for NRC's environmental process. Specifically for the environmental impact statement.

The environment review for an EIS begins with the scoping process. Which includes a public meeting.

Scoping is a process by which the NRC staff identifies a specific impact and significant issues to be considered in preparation of the environmental impact statement.

Following the scoping process, the NRC staff will perform its environmental analysis, which will consist in part, of issuing request for additional information to the applicant and preparing the draft EIS.

The draft EIS is issued for public comment. Once comments are received on the draft, the NRC staff will consider those comments and issue its

final environmental impact statement.

Slide 19 please. The environmental review for the environmental impact statement will take 18 to 22 months. This slide provides a detailed breakdown of the process and timeframes.

As I previously mentioned, the environmental review will begin with the scoping process. Which for Northwest consisted of a 45 day scoping period and a public meeting.

After the scoping period ends, the staff develops a scoping summary report that addresses public comments that were received during the scoping period. This takes a minimum of 90 days and depends on the number of comments that were received during the scoping period.

The environmental analysis, in part, will consist of developing and issuing a request for additional information. Each round of RAIs will take approximately 90 days.

And this will consist of developing and issuing the RAIs, a 30 day response period and then the staff reviewing the responses for clarity and adequacy. The number of RAI rounds will depend on the quality of RAI responses and the application.

Information from the applicant's report,

RAI responses, the scoping process, coordination with other federal, state, tribal and local agencies, as well as the staff's independent research, will be used to draft the EIS.

When the draft EIS is published, it will be made publically available for review and comment for a 45 day period, in accordance with our regulations. The comment period will include a public meeting.

After the draft EIS comment period, the staff will respond to comments provided on the draft EIS and update the EIS as necessary. And this can take approximately 120 to 150 days. And depends on the number of comments and also the necessary EIS updates. The final EIS is then issued.

Slide 20 please. The staff will perform its environmental review in accordance with 10 CFR Part 51. And will also use Interim Staff Guidance augmenting NUREG-1537.

Slide 21 please. On February 5th, 2015, Northwest resubmitted Part 1 of its construction permit application. The public notice of receipt and availability was issued on April 21st, 2015.

The NRC staff conducted an acceptance review of the Northwest environment report, Chapter 19

of the application, in accordance with 10 CFR Part 51, which identifies the information that shall be contained in the applicant's environmental report.

An acceptance review is a completance review that determines if the application has sufficient information for the NRC staff to begin its technical review.

Part 1 of the Northwest application was accepted and the notice of acceptance was issued on June 8th, 2015.

Slide 22. In accordance with 10 CFR 51.25, the staff determined whether to prepare an environmental assessment or an environmental impact statement.

Pursuant to 10 CFR 51.20(a)(2), the staff determined that an EIS should be developed for the proposed action. This determination was based on operation of the proposed Northwest facility.

Connected action to the issuance of a construction permit, consisting of target fabrication and scrap recovery. A process similar to the process used by field fabrication facilities, for which an EIS is required under 10 CFR 51.20(b)(7).

Slide 23 please. The environmental review will consider the impacts of construction, operation

and decommissioning of the Northwest facility. We will also consider the impacts of alternatives to the proposed action, including alternative sites, alternative technologies and the impacts of not issuing a construction permit.

The environmental impact statement will also consider the impacts from irradiation services provided by the research and test reactors. Which is a connected action to the proposed action.

Ultimately, the purpose of the environmental review is to take a detailed hard look at the environmental impacts of the proposed Northwest facility. And after balancing the benefits versus the cost or impacts of the proposed project, make a recommendation to the commission on whether or not to issue a construction permit.

Slide 24. The Northwest environmental scoping period ended January 4th, 2016. The staff is currently developing the scoping summary report and responding to comments.

Two rounds of RAIs have been issued. The first on November 2nd. Northwest responded to those RAIs on December 3rd. The staff reviewed the responses and had some follow ups. And those RAIs were issued on January 19.

NRC anticipates that the draft EIS will be issued on October 2016 and that the final EIS will be issued on May 2017. And this is based on the timeframes in the slide that I have provided earlier. And is keep within the 18 to 22 month schedule.

And that concludes my presentation on environmental review.

MR. LYNCH: All right, next slide please. For those on the phone, this is Steve Lynch again. And I'm going to talk a little bit about the construction permit safety review process.

Briefly touching on the content of the PSAR in a little bit more detail, as well as going through some of the assumptions that we made and coming up with this 18 to 24 month timeline for our review schedule.

So as I mentioned, I've mentioned most of this before. The main components of the preliminary safety analysis safety report are the preliminary design of the facility. A preliminary analysis of structure systems and components with an eye towards how those will be used to prevent and mitigate accidents.

While you're not required to submit technical specifications at this time, we are looking

for the application to identify probable subjects of technical specifications.

And again, while emergency plan also is not required, there are some requirements in Appendix E of Part 50, to address a preliminary emergency plan.

We'll also be looking at your quality assurance program and any planned research and development that you have.

Next slide please. So for the review that we do, so the last slide talked about the regulatory requirements that need to be met. We had developed guidance in order to evaluate whether those requirements have been met.

And for your application, the guidance that we are primarily using is NUREG-1537, as augmented by Interim Staff Guidance.

And the most applicable part of that, as you used in the development of your application, was the guidance for radio isotope production facilities. And that was largely based on guidance in NUREG-1520 that Dave will talk about in a little bit.

Other guidance that we used. There are ANSI standards that are referenced in these documents we used for our reviews as well.

Next slide please. So getting more into

the process and timeline. After you submit your application, first thing the NRC staff does is review the application to see if we have enough information to accept it for docketing.

What goes into this acceptance review is, we look at the request you made for the type of application you are seeking. We see if we have the technical information, the application to support that request to conduct our review.

And if we're aligned on the request you're making and we think we can review it under that licensing process, then we make sure that we have all of the information required by the regulations for that process.

We're not doing a detailed review at this time, we're looking for completeness of the application. And if we believe that the application is complete and has addressed all of the regulatory requirements necessary for that type of application, we will accept the application and docket it.

And once docketed, that indicates the beginning of our formal technical review of your application.

And following that, our technical review ultimately will result in the publication of a safety

evaluation report. Which documents the NRC's findings on the application and our recommendation to the commission on whether we believe the construction should be, permit should be granted or not.

In support of development of this safety evaluation report, the staff may find it necessary to request additional information to help us understand the information that's in the application or to provide any additional details we need to make our conclusions.

After we complete our safety evaluation report, we will present this report and you will present your PSAR to the ACRS. There will be subcommittee and full committee meetings on this.

And the ACRS will provide an independent review of your application and the NRC staffs evaluation and provide a recommendation to the commission on whether they believe the construction permit should be issued.

Following this, we do have the potential for a contested hearing. And there will be a mandatory hearing. Where, again, the adequacy of the safety and environmental reviews will be considered. And that will ultimately lead to the decision to grant or deny the construction permit.

Next slide please. So I put together a sample 22 month safety review timeline that's based on our previous reviews. And also just kind of a middle ground between that 18 to 24 month time period.

And I wanted to highlight just some of what went into that so it doesn't, it isn't a complete mystery of what we're doing while we're reviewing your application.

So after docketing your application, within about two months we are, our goal is to begin issuing requests for additional information, if necessary.

Our goal is to complete issuing our first round of request for additional information within about a six month time period. So that will take us to, as you see on the screen there, in eight months after the docketing of the application, our goal is to issue all of the requests for additional information that we may have on your application.

Typically, when we issue a request for additional information, we will ask for a 30 day response timeframe. If this is not something you believe you can meet, you can talk to your project manager and workout a time period that will work for both of you.

So after about nine months, our goal would be to have received responses from you on all of the requests that we have issued. Following that, reviewing the information and providing request for additional information, it may be necessary to ask additional RAIs.

So in this timeline we've incorporated the need for a potential second round of requests for additional information. That would require another six months' time period.

After all of our requests for additional information have been answered, and the staff is able to complete a safety evaluation report, then we go the ACRS. And right now, in this timeline, we have about 19 months after accepting the application for docketing, we would hold our first ACRS subcommittee meeting.

Based on our past experiences, with licensing similar applications, we have seen that it will be likely necessary to have multiple ACRS subcommittee meetings.

In this timeline we have anticipated there could be two ACRS subcommittee meetings. And these can be held, essentially you would have an opportunity, at most, once a month, while the ACRS is

in session, to meet with them to discuss that.

Once the ACRS is satisfied, at the subcommittee level, that you have addressed all of their technical concerns with the application, a full committee meeting can be scheduled. And after the full committee meeting, the ACRS would prepare its recommendation to the commission on your application.

Following the completion of the ACRS full committee, the staff has been able to finalize its safety evaluation report based on feedback provided by the ACRS. And after that is when we would schedule the hearing.

Next slide please.

MR. ADAMS: Can I, this is Al Adams, can I -- I just want to emphasize one point on this slide. Although this slide shows 22 months, that you can see the licensing activities are completed on this slide in the first 18 months.

So there is time that is devoted to activities, which are beyond the development of the safety analysis. The visits to the ACRS and the mandatary hearing.

So although it may seem like a 22 month schedule, the actual licensing work is condensed into the first 18 months of that. Thanks.

MR. FOWLER: And what I -- pardon the interject here, but I see, you know, the objective that I have in this meeting are to explore, how do we accelerate schedules.

MR. LYNCH: Yes.

MR. FOWLER: And I appreciate this outline. There is implicit assumptions about cycles in here.

And that's an obvious opportunity to reduce the overall time, if we reduce the number of cycles.

MR. LYNCH: Yes.

MR. FOWLER: What is less clear to me is, what drives subsequent cycles? Is there a threshold?

What's the bar that we, as a company, need to meet to avoid a subsequent cycle and therefore accelerate the schedule? That's what's not so clear to me.

MR. LYNCH: So I think that there's a number of things that we can do. And when we ask, what we can do is, when we ask, request for additional information, it's important that you understand the questions that we're asking.

You can go to the next slide. Let me answer your question and then we'll go through the

slides as well. You can click to the next slide. But it's all related. That's the next topic I was getting to.

But when we issued the request for additional information, it's important that after they're sent to you, you have them, read through them, have a phone call with us. If we need to meet, we can do that as well.

But we want to make sure that for every question we ask, you clearly understand what we're asking. And if you don't understand, you ask us to clarify.

Because it cannot be the best use of either of our times if you don't understand the question we're asking. You answer what you think we're asking, but that's not what we're looking for, then we have to ask the question again.

So making sure that we have a clear, mutual understanding of what the information gap is that needs to be filled, that can help.

And then as you're preparing your responses, check in with us again and make sure that you still understand and you're going down the right path. And providing complete answers the first time they're asked can also help.

So I think one of the keys two reducing the iterations that we have to go through in that RAI process, is making sure that you understand the question that's being asked and providing complete responses to that.

MR. FOWLER: So we're learning how to work with each other?

MR. LYNCH: Yes.

MR. FOWLER: And we've had some experience. And, Nancy, maybe I can put you on the spot here because we've now had two cycles of requests for additional information with the environmental portion of the technical review.

How would you characterize the ability for the two organizations to communicate?

Is the second cycle driven by a communications challenge or is it driven by, you peel the layers of the onion back and you find something that you didn't see the first time that initiated a second round of questions?

So in order to be productive, help us to understand, from the limited experience we have already, how we could do it even better on the next cycle.

MS. MARTINEZ: So for the environmental

review RAIs, the second round of those RAIs were driven by follow ups to the first round where the question was not addressed adequately. So we had some follow ups on that.

But we also had some follow ups on the responses because information was provided, and then we needed additional information just based on the response. It was really a combination of some of the questions were not answered completely, and then there was responses provided, and then we had follow up to that.

We also did, you know, when we issued the RAIs, as Steve mentioned, we did say, let us know if these are clear and if you would like to have a call to discuss them. We did that for both rounds.

So we're hoping that that will open that communication channel, as you just said.

MS. GAVRILAS: I want to take it a step higher, because this is general. So you mentioned the two cases. Indeed, those are the two instances for which we ask additional RAIs.

There's an expectation that the technical reviewers have started to write their safety evaluations and are well along their safety evaluations.

So when they ask, when they request additional information, it's designed specifically to augment the piece that they're writing right now. So that means it truly -- they know exactly what they want. Or they have a very clear picture of what they want.

I'm not saying that the peel the orange, you know, or onion, whatever you're peeling, doesn't happen, but that's rare. Because of how we do, how the expectation is that when you ask an RAI, you basically know what kind of information you're seeking to document your safety conclusion.

So along the lines of dialogue, there's two times that there's opportunity for dialogue when it comes to a request for additional information.

One is, when we are drafting the question itself. Right? Because then we want to make sure that we engage with you and make sure that the words that we put on paper, do convey our needs.

And then there's a second opportunity to engage in dialogue. Which is, when you've drafted your answer, we have an opportunity to check that indeed your answer answers the mail.

That is, in our experience, the most efficient and effective way to deal with responses for

additional information.

MR. LYNCH: Nicholas?

MR. TIKTINSKY: And I'd like to add a little more on that too. A lot of it's nature of the rounds of questions. And this is Dave Tiktinsky.

A lot of it is nature of the rounds of questions. So if the questions are, you provided 90 percent of the information we want and we need some clarifications of something, then usually it only requires one round.

If the questions are more like, you need to develop or give us your methodology that you, how you develop something or you're programing, we need to understand what that is. Once we get that answer, about what your program is or what your methodology is, that may lead us to other questions.

So really it's the nature of how the information was in the application, how specific it was. And really the level of what that question is.

The specific questions, usually can handle them in one round. The more programmatic, methodology kind of questions frequently require follow ups.

MR. ADAMS: And, this is Al Adams, I just want to build on something Mirela said. That that discussion that we have, once you start to develop

your answers, that's not a sort of a verbal review of your answer.

I mean, you know, the reviewers have to sit down and carefully consider the answers. What that is looking for, if we're expecting an answer to go in this direction, and when you talk to us, we find out that you're going in a completely different direction.

So it's basically to find significant issues before you submit the answers to us. So if you submit the answers to us without having that discussion with us then, you know, then there's just possibility for a misunderstanding or miscommunications in the RAI process. And that can contribute to additional questions.

MS. GAVRILAS: And we cannot, this is Mirela again, we cannot emphasize enough how important that dialogue is. Those are the, probably the biggest contributors to our expediting the review.

MR. LYNCH: Okay. Actually, so I think we've talked mostly through Slide 30. Let's go to Slide 31, which will continue this conversation we have on impacts to schedule.

And this, in addition to RAIs, there is other things that we can do to help ensure that our

review is moving along efficiently. And can impact schedule.

One is the quality of the application where all the regulatory requirements met. And this is, I'm speaking hypothetically and not in your application.

But if we do a review of the application and the regulatory requirement is not met, it could result in the application being rejected and needing to be resubmitted. Or it could result in significant new information that does need to be presented and for review.

Technical and completeness. Again, the more information you give us without having to ask for it, the more efficiently we can review the application.

And then also just attention to detail. And this has to do with the organization of the application, formatting, looking at proprietary markings. Just those little details that maybe aren't necessarily technical, but can help us in our review. If we don't have to worry about the little things.

Then building on our conversation on request for additional information, in addition to the number of rounds we ask, the quicker that you provide

responses to us, the quicker we can continue on with our review.

So timeliness, responsiveness, completeness of our requests and how you provide answers to them, that can all help facilitate our review.

And I think a good point that Dave mentioned was, what can take more time is if in these requests for additional information, significant new information is provided that we have not reviewed before. That can take additional time. And could result in additional requests.

MR. ADAMS: Can I -- Al Adams. Can I jump in here?

And completeness is probably the most important of those things. If you, you know, we asked for a 30 day response and you come in in 20 days and look, you know, you've come in ten days sooner. But those answers aren't complete and result in another round of RAIs, that round is going to consume a lot more than the ten days that you saved by coming in early.

So completeness is the most important, I think, aspect of this. And I think what you're seeing is, you know, the thing that draws out schedules is

having to go additional rounds of RAIs.

That's the most, you know, our experience has shown us that's the most significant contributor to schedules being drawn out.

MR. TIKTINSKY: Another thing I might want to add too is, we're not going to wait till the end to give you all the RAIs at one time. You saw that, the schedule that Steve had shown there.

The idea is, when major portions of the review are done, we will ask RAIs that are appropriate. We don't want to be asking you the same technical area a bunch of different times.

So when we're done with an area and we feel like we're done with that part of the review and comfortable with that, we'll ask those rounds of questions. But we want to spread it out over that time period, the six month time period that Steve had outlined.

It's more efficient that way and it allows your staff to work on it. Also, we don't want to hold somebody up, you know, waiting for another disciplines review to be done.

MR. ADAMS: So you may get a second letter from us, but it's actually the first round of RAIs in that area. And there's nothing to be gained by

sitting on the RAIs and giving you a hundred questions at once and overwhelming your ability to answer.

So when we have an area ready to go, we will send it to you to allow you to spread out your, you know, your limited resources also. And ours too.

MS. HELTON: This is Shana Helton. I'd just like to reemphasize that when, especially when you're crossing different portions of the regulations, that the clearer you are in your initial submittal about, this is how we're meeting 70.32, this is how we're meeting 50.20.

I mean just the clearer you are in your application, will help us avoid those types of request for additional information where we say, hey, tell us how you're meeting the requirements in here.

And then if we're at that sort of basic level of, how are you meeting the regulations when you give us that answer, that's almost guaranteed a second round because now we're going to ask you questions about that.

I mean every applicant wants to avoid going multiple rounds of request for additional information. But it's just been our experience that when we have to do those basic sort of questions about, how are you meeting our regulations, that tends

to, once we see the detailed technical information, we tend to then have questions about that.

So I can't emphasize enough that initial clarity in your submittal.

MS. GAVRILAS: So if I -- I'm sorry.

MR. MORRISSEY: No, that's okay.

MS. GAVRILAS: More comments on RAIs. Because I want to --

MR. MORRISSEY: No, I had just a discussion about the technical reviews. My name, Kevin Morrissey.

As having been a technical reviewer for a long time, and actually I was a licensee, is my advice would be, don't be shy about asking the staff what they want.

You know, we're talking about all the things we expect from you, you should expect to think the same things and clarity from the staff. You know, lots of time we go, I shouldn't ask this, I shouldn't ask that. Is you really have to dig down sometimes and let your staff talk to our staff and really get down to exactly where you're going.

Then you're less likely to end up in the wrong place and wasting your time. So don't be shy. That would be my advice.

MS. HELTON: Absolutely. Getting the technical experts to communicate directly so there's an understanding, is a good practice. To have a public meeting on those RAIs.

MS. GAVRILAS: So again, it's important to sum up. It's important to distinguish between various increments at the same round, the RAIs and follow up RAIs.

The increments are designed to help us all. To move the process along.

The follow up required are basically because we needed additional information. And while we can't, those are the ones that we target for, for minimizing. We can't eliminate them completely, but we target for minimal follow up RAIs.

I want to go back on Slide 30, Steve, if you can, for just one moment. Because there's -- we've talked a lot about RAIs and how you can do, what you can do to basically help us out, speed the process along.

But what's important in our timeline is also to recognize that there's a safety reason for how the timeline is developed. There's nothing that's carved in stone, because it's arbitrary.

And I'll give you, as an example, the

writing of the SER. It doesn't help to distribute a chapter in a technical area amongst reviewer. That won't speed up the process. The review has to be comprehensive. The reviewer needs to see everything.

If there are chapters that cross over technical expertise, that needs to be seen by everybody. So the timelines that you see that it takes the staff to draft the SER and to come up with RAIs, is also informed by basically what we need to do to come up with a safety finding.

And with that, I'll turn it back to where it was.

MR. LYNCH: Sure. Back to Slide 31. Again, this is Steve Lynch. Other impacts that, to schedule, could be if there are policy questions that need to be resolved. I can give an example from a past, a past review.

In the case with SHINE, we had to go to the commission to resolve how, you know, whether SHINE should be under Part 50 versus Part 70, and we ended up needing to do a rulemaking in order to classify them under Part 50. That can be a potential impact to schedule if that's something that's necessary in our review.

Also, the one thing that can drive

schedule, is the number of times we have to go to the ACRS. Limiting the number of subcommittee meetings that we have to have, by addressing the technical concerns with the ACRS, can significantly improve or delay the schedule.

MR. ADAMS: Al Adams. I just want to, the ACRS tells us when they've received enough information before they can write the letter they need to write to the commission.

So it's something that quality has control over, but we don't run the ACRS and the committee. And they have to do the review and reach the conclusions they need to reach given what they're responsibilities are.

MR. LYNCH: Yes. And what we can do to help them is, when they do identify areas that they need additional information, that both the applicant and the NRC staff provide that as quickly as possible.

All right, next slide please. So on the previous slide I was mostly addressing the things that both the applicant and the staff can do to impact schedule.

This slide is focused on the things that are outside of the staff and the applicants control, to a certain extent. And this gets into the hearing

process.

And this comes after the ACRS meeting has been held, the staff has completed its environmental impact statement and the staff has completed its safety evaluation report.

There will be a mandatory hearing on this application since it is a commercial facility. And as I just mentioned, but there's a lot of things that have to happen before this mandatory hearing can be held.

In addition, there is a potential, and we put this out in our notice of opportunity for hearing, members of the public could file a contention on a portion of the application or the activities that are being conducted. Or proposed.

And if that happens, those separate hearings would need to be held and those issues resolved before the mandatary hearing could be held.

After any hearings that need to be held are held, including the mandatary hearing, then we get the Commission's decision to deny or issue the construction permit. Based on what we've seen for the combined operating license applications, that have followed a similar process to this, we have seen the commission decision come anywhere between two and five

months following the mandatory hearing.

So after the hearing happens, there is additional time. And that's not time that the staff can control, that's on the commission's schedule when they make that decision.

Next slide please.

MR. BALAZIK: Hey, this Mike Balazik. I'd like to provide a quick status update on the NRC's review of Northwest construction printout application.

This slide shows the proposed schedule for the review. Steve and others mentioned some items that can drive the schedule, either delay or expedite.

As you can see, that NRC is actually reviewing the application. And I just want to assure you that we've allocated the necessary resources and have the technical expertise to review all aspects of the application.

As you can see on this schedule, the staff has targeted September of 2017 for completing the safety evaluation report. And then there's a couple of milestones that we can't really put a date next to yet.

There's a couple of related activities, not on this schedule, I'd like to mention. One is the license amendment application by Oregon State

University to irradiate three prototype targets. This amendment was issued in January of 2016.

And other item I'd like to mention is, for the research reactors that you've proposed to do the irradiations for Northwest, each research reactor would have to submit a license amendment to irradiate the targets commercially.

And we've received notice from the University of Missouri that we can expect the license amendment in calendar year 2016. And Oregon State University has also notified the NRC that they plan to submit their license amendment in first quarter calendar year 2017.

MR. LYNCH: Okay. While we're on this slide, do you have any questions about our review schedule?

I think, and this is mostly based on previous reviews and the sample timeline that we developed. Do you have any questions on where we're going?

MR. FOWLER: Well, I have an observation. And I appreciate this information. And I was somewhat familiar with reading it.

And again, I'm looking to explore how we can work together, while maintaining arms' length.

Obviously you have an ombudsman role and a review role that is independent and so forth.

But I view this as a very critical public health need. And I know everyone recognizes that, but our sponsors and investors are major healthcare institutions servicing tens of millions of Americans. They see this as a real issue that we do work together.

They are not for profit organizations. They have a service mission to the American public. And they extend that service mission through us. To provide this.

And they're expectation is that we work collaboratively and creatively to not compromise health or safety, but figure out ways where we can reduce the number of RAIs.

How can the NRC better set our expectations of what will minimize those rounds of RAIs?

How can we work together to ensure that the ACRS review is done in a single pass, rather than two or three passes?

What do we need to do together?

And if we drop the ball, it's on us. Absolutely it's on us, if we drop the ball.

But if we know what the threshold is that we're trying to reach, we will work our darndest to get there. And that's what we're looking for. Is, how do reduce the number of RAIs?

How do we, as much as we can, ensure that there aren't multiple rounds through the ACRS?

Because if we reduce those number of rounds and if we reduce the assumed number of RAIs, we get a critical isotope to public much more quickly than is even on this schedule. Or we, by insurers, that this schedule is met and doesn't slip.

And that's the exploration that I'm very keen on hosting. Because I think we have an understanding of the process. Now how do we work within that process, to have the most expedited schedule possible?

MR. LYNCH: Okay. So I think, just at a high level -- so where we're at right now, we're in this February 2016 timeframe. We're anticipating getting out our first request for additional information on the safety review side. And I believe we're on target for that.

So this is all heading towards completing our draft safety evaluation report. So I guessing you're looking at drive, making that June 2017 time

come up sooner.

I think the best chance we have of working towards that goal together, would be once those requests for additional information are issued, just like we discussed earlier, let's get a call setup as quickly as possible so that we can discuss and make sure you understand what we're asking. And --

MR. FOWLER: So to that point, Steve.

MR. LYNCH: Yes.

MR. FOWLER: You have insight by the technical reviewers when an RAI is going to be issued. So rather than wait until it's issued, for us to request a public meeting to follow up and then have the mandatary noticing period and so forth, why don't we automatically schedule a public meeting within certain number of days of the RAI insight issuance, so they don't have to wait longer?

MR. LYNCH: There are different ways that we can do this. Yes.

And there have -- and the NRC can, you could set up a standing public meeting once a month or once every two months. You know, something like that. That could definitely happen so it's noticed and it's already setup. That can be done.

Now it also depends on the nature of the

discussion you would like to have on the RAIs. The public meetings are more necessary if we need to have detailed technical discussions about the RAIs.

If you would like to have a call, just strictly on, do you understand this, yes or no, could you explain to me at a high level if I'm not understanding what it is, that does not necessarily need to be a public meeting. That could be a phone call between you and your project manager.

Or you and with appropriate technical staff. Those could be very quick calls. If it's just for understanding.

So it kind of depends on what we need. So that can buy some time too. If it doesn't need to be a public meeting, that can be done much more quickly.

MS. HAASS: Well, and that's why there was the request, when we were at the EDO, was to go get that standing meeting done every week, very short and sweet, to say, okay, do we understand this. And then we move on.

And so I'm glad that that got instituted or executed that we're now doing that. And that has helped.

MS. HELTON: I think when you talk about the frequency, the right frequency for the standing

public meetings, and they haven't been established yet, but we certainly can do that. And we've got other examples working applicants where we've met on a biweekly basis.

So in terms, I wanted to chat and, I'm sorry, this Shana Helton, about this question on threshold. And what's the regulatory threshold that you have to meet, as the applicant, to operate this facility.

So the regulations, we went over the NUREGs as they've been supplemented by the Interim Staff Guidance. That is what we have set as the threshold, if you will.

And each applicant is going to meet those regulations in unique ways. With that said, you know, we operated in a public manner. Everything is on the docket.

We've alluded to similar reviews in terms of looking at reducing the number of RAIs. I think it would be helpful for you to do some research in ADAMS for what similar designs, the types of requests for additional information that we have had, and the types of responses that have satisfied those additional requests for information. And that should really help to identify the threshold.

I mean that said, each application is different, we review it on its merits. We're going to have to take into consideration the unique factors. But that can at least give you a sense of the way we think when we're going through these regulatory reviews.

MR. LYNCH: Absolutely. I think that's a very good point. And even more detailed in that, if you really want to see, if you open up the safety evaluation reports we write, especially those -- you can look, for a good example, we just finished our safety evaluation report for the SHINE review. And using the same guidance that you used.

The guidance sets the threshold of the, at the end of that, the NRC is explicit and the conclusions that we are trying to make in each section and each chapter that's provided. And there are bullet points there.

And once our reviewers are doing the reviews, they're looking at the bullet point, you know, for the acceptance criteria. Was this information provided. And then there's another bullet point, can we draw this following conclusion from that information.

So when we're looking at your application,

we're trying to answer those questions. If we can't answer a question affirmatively, that's one of the times we'll go to you for a request for additional information.

Also, as you'll realize for a construction permit, you may not have all of the information that you would submit at the operating license stage. What can also help the reviews is an explanation of the information that you don't have right now, because your design isn't compete, explaining why it's not ready right now, but also acknowledging that you recognize it is something necessary for the final design.

The more, again, it comes back to the completeness. The more information that you can provide us, addressing the information that we're looking for in the guidance, the quicker we can get through the review.

And also we are kind of, since we're using our guidance, NUREG-1537 and the ISG, that's kind of the format that we're looking for. You can submit your application in whatever form that suits you.

However, if you can expedite the review, it does make it easier if it's generally aligned with the guidance that we're using to go through with. So

that's some other insight.

MR. TIKTINSKY: If I could add some more on the RAI meetings? You're right. We don't just wait until they're all done and then make a phone call to you. We know when they're coming, we know when the reviews are done because we, as project managers, we work internally with our reviewers to try and make sure we're asking questions that are clear, that have appropriate regulatory basis.

So we're working internally. So we know pretty, some time in advance, before we're getting ready to formally issue the rounds of RAIs. And we've had a lot of experience doing that. And having setting up meetings.

And just for your information, you know, parts of the information, like within the ISA, there's other categories, besides proprietary information. There's security related information.

So the public meetings that we have, we try and talk as much as we can in publically available information. But there may be some portions of the meetings that are closed. Not only for proprietary, but for security related information and other discussions.

So what we try and, you know, we develop

in RAI, we try as best as we can to make the RAIs themselves publically available. So that information is out there.

Your answers may or may not be publically available, but like I said, we've had a lot of experience in other reviews of making sure we have those conversations.

I'd also like to emphasize the point too is, depending upon the nature of the answers, we do the same thing. Have the same kind of meetings when you submit answers.

So before you formally submit something to us, it may be a call or you may have a meeting too. If you have substantial discussions about something to make sure that you're really are hitting the mark.

Again, we don't do reviews on the fly, but you can get a pretty good sense that, yes, if you're on the right track or not. And that would minimize any problems.

But yes, we do plan things out. We try and coordinate that carefully with the reviewers. And we know where the status of things are.

And again, that's why I mentioned before, we're not going to just consolidate a bunch of different disciplines and do it at one time, we're

going to try to phase this through, review it and try to make it as efficient as we can.

MR. ADAMS: And this is Al. I'll just add two things. One is, NUREG-1537 is a guidance document, but it is an important document in that it's a format content guide and the staff standard review plan.

What we expect for RAIs is that the RAI will start by saying, either here's a regulatory requirement or here's something that the standard review plan is looking for, here's where your application, the information in your application seems to say something different or doesn't seem to have this information. And then the question will come.

So, you know, NUREG-1537 is your friend for understanding what we're looking for.

The other thing, you talked about the ACRS for similar application to yours. There are transcripts of the ACRS meetings. You can go read those transcripts and see what areas interest the ACRS, what areas they focused on, where they asked both us and the applicant questions and issues that became, you know, issues that were sort of follow-on issues.

So there is an advantage for you being

second in the queue that there is information that's available to you. And that's an important source of understanding how the ACRS works, what they think, what they look at, what they consider important.

MS. HELTON: Also publically, this is Shana Helton again, also publically available on the advisory committee is their charter. You know, I encourage you to look at that. They're mandated by statute. They're an advisory buddy to the commission.

The staff does not have much influence over how they operate with their schedule. The members need whatever information they need before they'll go to a committee and write a letter.

So while we can attempt to work with the ACRS and, you know, it's very difficult to try to manage that schedule. They've got competing demands and they only get together once a month. There are certain months of the year that they typically do not meet. So it tends to be fair.

You know, you see an August meeting up there, I don't think they usually meet in August. Sometimes they make --

MR. LYNCH: Subcommittee does, full committee does not.

MS. HELTON: Full committee does not. So

I'm just saying, there is some limitations in working with the ACRS. They have a statutory role to fulfill and they take it very seriously.

So looking at those old transcripts can help try to predict what, as they're membership changes, you know, it's just, it's a variable that's well out of the staff's hands. That's all I can say.

MS. GAVRILAS: This is Mirela Gavrilas. And we have, the staff has experienced working with the ACRS. The staff knows the ACRS' schedule.

The ACRS itself, from our previous experience, the ACRS too recognizes the importance of this activity. Of establishing a reliable, domestic supply of molybdenum-99.

So while there are challenges, they will work with us. We know how to work with them. And past experience says we've been successful to make that as effective of interaction as possible.

MS. HELTON: Absolutely.

MR. BALAZIK: This is Mike Balazik. I guess I just have one question. We've been, for the environmental review, we've been through two rounds of RAIs.

We have been sharing those in draft form. We've offered calls. I mean, is there more that we

can do on these?

I mean, I guess I'm just kind of asking, what can we do differently? We've been through two rounds to help Northwest with the understanding of the RAIs. I guess it's just a question that --

MS. HAASS: Yes, I don't think there's a disagreement of we don't understand the RAIs. There were actually, you know, we had a public meeting, you know, when we did the site visit, there was some agreement that the RAIs were complete. You did come back and then say you wanted some additional information.

Then there were quite a few additional ones in the second round as well. And it was based upon some additional information you asked for.

And so I do think it's complete. And it's sitting here for you.

MR. BALAZIK: But it, this is Mike Balazik --

MS. HAASS: Now, there really isn't anything else we can do accept keep communicating. But remember, it wasn't until the EDO meeting, until we requested that we have these weekly meetings here, I'm sure that there was an understanding.

MR. BALAZIK: This is Mike Balazik again.

There's a difference between the weekly status call, which is just overall --

MS. HAASS: I know the staff, knowing what we had and where there is a question and how we would go about resolving that. And it could be a public meeting or it could be just, you know, there was a misunderstanding and it was just a quick, you know, we understood it.

MR. FOWLER: So I see three areas that offer opportunities to explore expediting. The first I'll call administrative in nature. And those are the mandatory noticing periods, the number of meetings and so forth.

The better we can be in advance of understanding when those need to happen, we can eliminate more time that's simply waiting for one of these periods. Or waiting to have a meeting.

That's probably the most frustrating to me is having to wait for things. I never want either team to be in a position of waiting for things. Because that, by definition, is lost time in the schedule. So I call that administrative.

Then there's this area of technical. And what I'm -- I've heard the term, completeness used sufficiently that it will be lodged in my memory.

And so -- and that comes through dialogue. In order to meet this threshold of completeness, the technical teams need to be in communication so there's no misunderstanding of what completeness is required.

And I want to test to see we have the appropriate communications mechanisms in place, to be sure we're meeting the completeness guidance.

Then there's the regulatory or precedent guidance. Which comes to what I've termed threshold. What threshold do we need to meet.

And that's really on us. We've got to do, and have been doing and will continue to do, research into threshold regulatory.

So those are the three areas. Obviously the last one is something that we have to work on independently.

The other two I believe are areas to explore whether we've done everything together that we possibly can do to meet and better the schedule.

And I'm sorry, Mirela, you were going to make a comment.

MS. GAVRILAS: Wow, that was, I'm taking notes furiously because I want to answer to, to answer a couple of things.

So let me go with, as far as the status

meetings are concerned, that's our practice. So I'm not sure when we implemented it, but I know that we had the same --

MR. LYNCH: We talked about it in November. Or no, actually August, at the National Academy of Science --

MS. HAASS: It just didn't get implemented until about a month ago.

MS. GAVRILAS: Okay. But that is part of our practice. To have those status meetings. But their status meetings do not touch on anything that Nick just mentioned.

Okay. So as far as communication, that's what I was writing. The regulatory guidance is the first place to look to see what the yardstick is for completeness.

Our discussions, discussions with the staff are intended to augment that. Not replace that. So they come in addition.

And sometimes there's no additional needs for communication. Sometimes there are needs for communication.

So we need to work together. As soon as you identify a need for further discussion, you need to let us know. And we'll do our part in anticipating

when it's likely that you will have additional requests.

Because, for example, if we know that we're asking a broad reaching RAI, like Dave just mentioned. If we're asking you something, what was your methodology, then we can see how that would require an interaction in the public to discuss further.

So it's both sides. We both need to be aware. And I think we can both, at least we can committee to our part, to have that awareness and try to be proactive.

MR. BALAZIK: Yes. And this Mike Balazik. And the whole idea of the status call, the weekly status call, that was to be implemented as when we accepted the application.

I didn't see it, weekly calls, before that, until we got to that point of acceptance of the application. So that was --

MS. HAASS: And that was a little different understanding. But no, I'm just glad it's done.

MR. BALAZIK: Okay.

MR. LYNCH: So, just to finish up with this slide, did we help with understanding ways that

we might be able to help accelerate the schedule in terms of strategy? Any other questions do you have on that right now?

MR. FOWLER: I think I have a good understanding of the areas that I tried to summarize.

MR. LYNCH: Okay.

MR. FOWLER: And what I would like to see and what I would ask of our team is, okay, now translate those areas into a plan. What are the processes and procedures that we've put in place, what are the accountabilities, what are the milestones, what in fact are the definitions of success or lack thereof so we know we're on plan or off plan.

It's all about project management, once we understand what the plan it.

MR. LYNCH: Okay.

MR. BALAZIK: All right, this is Mike Balazik, I'll continue on. We want to go through docketing. Steve mentioned earlier what docketing was. And I just wanted to go through the timeframe for docketing of the Northwest application.

First I'll start with the Part 1. Northwest submitted Part 1 of its application three times. Once in October 15th, another time, 29th, and November 7th of 2014. This was before providing the

NRC with a version that was acceptable for processing and conducting an acceptance review on February 5th.

The NRC issued a letter to Northwest on January 23rd notifying Northwest its application was incomplete and unacceptable for docketing. Northwest was allowed 30 days to supplement that application. And Northwest chose to withdraw the application and resubmit. And that was the February 5th, 2015 date.

The reason for some of the delays was inappropriate markings of proprietary information. Also, ADAMS had rejected the document due to numbering of pages.

When they see a document has so many pages and it doesn't match up, they'll reject the document and try and get it resolved.

So Part 1 of Northwest's applications accepted for docketing in June of 2015. And that was approximately two months after successfully processing it into ADAMS.

And just real quick on Part 2. They submitted the application, Northwest submitted the application, on July 20th, 2015. However, due to formatting and improper proprietary markings, the application was not fully put into ADAMS until September 18th.

The staff completed its acceptance review in the mid to late November 2015. And before notifying Northwest on its acceptance decision, the staff held a public meeting in late November. And provided Northwest an opportunity to clarify its requested licensing action.

Following the public meeting, the letter of acceptance was issued in December of 2015.

One thing I would like to add is that Northwest submitted large portions of its applications in hard copy form, which lead to delays in processing. In ADAMS, when you submit 1,600 pages, it takes awhile for them to process that.

Going forward, submission using the electronic information exchange may reduce those delays. I know that, Carolyn, you've expressed some difficulties using that system, but I can provide you a contact that can help you provide documents in that form. So just --

MS. HAASS: So is, I'll put it this way. If you begin to do that, you have restrictions and limitations. Because it is a very archaic system.

And because of that, the granularity of graphics and pictures would not be coming out appropriately. And it just absolutely made no sense.

And we had a lot of difficulty with your system that we would have two different files, exactly the same thing, one would be accepted and one wouldn't. And we couldn't figure out why.

And it was taking too much of our time. That's why you saw the first part tried to be submitted twice. Because we couldn't get it through the electronic system.

You have a graphic capability of 300dpi. Our logo is more than 300dpi. And it's on every page. It just isn't worth our time.

MR. LYNCH: I believe the 300dpi is a minimum, not a maximum.

MS. HAASS: No, it's maximum. I mean there's some real difficulties. And we have a premier person who does our documents, and I'm going to tell you, it is one of the more difficult systems that we've ever had to use.

MS. GAVRILAS: So --

MS. HAASS: You know, I don't want to take this meeting over with that, and we can discuss it later, but --

MR. FOWLER: This is an area, so fully understand the dates. We're well aware of the dates. The report that I get from my team would characterize

the difficulties differently from the way the NRC characterizes the difficulties of receipt.

I think we can summarize this, that this is an area that is, we should better understand whether this can be improved. Because we sit here today with another stack of paper, to respond to RAIs, because of my teams perceived inability to work with the electronic submission system. That's a problem.

Now it could be us, it could be the system. But let's take it off and figure out how to fix that.

MS. GAVRILAS: Just a point of information. Quick one. The system is designed the way it is because the intent of the system was to enhance transparency. So that the documents can be viewed on the processors that were prevalent at the time at which it was deployed.

MS. HAASS: Right. And that was the issue.

MS. GAVRILAS: So it was an optimized --

MS. HAASS: Right.

MS. GAVRILAS: -- optimized two aspects of our mission. One is, openness, reached the broadest set of stakeholders. And the other one is, making it easier for our stakeholders, for another set of

stakeholders, the applicants and licensees to use.

MS. HAASS: Right. I mean it is a catch-22, but we also had to get to a point where we did it the easiest for us because it would, you know, if you have to take every graphic out and do everything individually and save it individually, it becomes so cumbersome that you will make more mistakes.

So we can look into it, you've heard my comments on your system, and there's lots of room for improvement on that side as well.

MS. GAVRILAS: Noted.

MS. YOUNG: Well perhaps we can get them in touch with or possibly with somebody can stop in today and just give a general explanation of the electronic filing.

MS. HAASS: We --

MS. YOUNG: Because my understanding is, not only do people submit by transmitting electronically, but they also put information on the CDs. But if the CD files meet the format, it can be easily put in.

And applications like --

MS. HAASS: We do put a --

(Simultaneously speaking)

MS. YOUNG: -- requirement.

MS. HAASS: We've tried the CD submission. But, you know, we have talked with them. We can do that more in the future.

MS. YOUNG: Because I know you're interested in saving time. And any unnecessary --

MS. HAASS: Yes, but we're not going to solve either problem today.

MR. BALAZIK: I think this is a good spot to take a quick break. Next we'll go into Part 70.

So ten, 15. Let's take a 15 minute break and start at 10:30. All right, we're going to go mute on the phone and we'll be back at 10:30. All right, thank you.

(Whereupon, the above-entitled matter went off the record at 10:14 a.m. and resumed at 10:33 a.m.)

MR. BALAZIK: Good morning. This is Mike Balazik again and we are going to resume the public meeting.

Right now we are on Slide 36, the NRC Licensing Process. This is, we're going to be discussing Part 70 and I'll turn it over to Dave Tiktinsky.

MR. TIKTINSKY: Okay. Thanks, Mike. I'll kind of make a point, my presentation is generally

more, you know, general Part 70, but I have a couple of things that came up from this morning's discussion that maybe will help sort of set the frame.

Some of it is some of the keys to effectively, at least on the Part 70-type things, is making sure there is a good understanding of applicable regulatory requirements.

So we talked a lot about RAIs, that's sort of the finer thing after you submit something, but in the case of Part 70 is making sure you understand the requirements and if you, you know, if you understand them then obviously when you submit an application related to those things you'll be able to, you know, hit the mark better.

And, of course, if there are any specific questions related to applicability of specific sections of Part 70, how it gets implemented, then, you know, the form of pre-application, public meetings that we've had on other things for the Part 50 part, you know, may be appropriate.

So that's some other ways of making sure, you know -- You know, a lot of the discussion was, you know, you give us a quality application, well in the CP you have already given us an application, so whether, you know, maybe you would have done something

different in the future, it doesn't really matter now if that's already there.

For other future applications you can take a lot more of that into account of the experiences that you'll have with the CP as well as the other experiences that we talked about for other facilities to try and make sure, you know -- You know, the best way to minimize, you know, RAIs is to hit the mark as much as you can.

So just sort of to get started on Slide 37, just a little bit about Part 70 requirements. You know, Part 70 is relatively brought up if you have broad regulation to cover a whole bunch of different things and it talks about, you know, establishing procedures for issuance of licenses, you know, to title to own, acquire, deliver, receive, possess, use, and transfer.

So that's a quite a lot of different that it covers. There is a lot of activities that are in there related to, you know, possession and use. There is the scrap recovery and licensing a fuel cycle facility.

So that's, it's a -- Again, it's a fairly broad regulation to cover a lot of types of facilities and activities for special nuclear material.

The next slide, Slide 38. It's a good example here of, you know, kind of in parallel to what Steve talked about in Part 50, and these, again, not to, tend to be comprehensive, you know.

The regulations in 70.21 what the application should be, how to file it, that, again, emphasize the fact that you can incorporate information by reference.

So if there is information that you already provided for your other parts of the facility you don't need to repeat them, you can just reference them.

Again, the clarity of those references helps the reviewers a lot, you know, the use of crosswalks, tools, you know, whatever is efficient.

We want to make sure that the reviewers know where the information is, know how to find it, find it quickly, you know, and shows how it meets those particular regulatory requirements.

It also has allowance to, if in Part 70 in 70.21(b) that you can have other licensed activities specified in regulation, as long as the specified regulations are met.

So, again, it's the combining of applications and licenses. It's not just in 50, it's

in 70, it's in other parts, so you are allowed to do that.

Again, the biggest emphasis that I will have on that is regardless of the form that it turns out you need to be able to demonstrate that the regulatory requirements are met and the clearer that is demonstrated the easier it is to get through the review process and then timeliness for that.

70.22, the content of applications, there is various requirements in there. 70.23 talks about approval, so, you know, 70 is a little different than 50, the requirements are somewhat different, the findings are different, but they are sort of still in parallel to the, you know, public health and safety.

So it's the same theme even if some of the details are different. I think related to criticality accidents, for example, you know, criticality monitoring systems and the applicability of, you know, subpart (h) which has additional requirements for certain types of licenses authorized to possess critical mass and material.

The next slide, Slide 39. So NUREG-1520, which is the standard review plan that we use for a fuel cycle facility license application, the first thing to think about is the information that's in 1520

shouldn't be, you know, that much different than what you've seen in 1537, the augmented ISG, because a lot of that was taken from 1520 and some of it just copied for the applicable portion so a lot of it is the same types of methodologies that you would use for the Part 70 application under 1520 or already in 1537.

So it's not like you would have to demonstrate using different approaches for Part 70, it's the same approaches and then -- or 1520. Again, the regulatory findings that are discussed in 1520 talk about Part 70 regulatory findings.

The regulatory findings in 1537 talk about the regulatory findings for Part 50. So that's sort of where the difference the staff in its review of Part 70 applications has to make Part 70 findings for, so it's sort of, you know, tailored to the specific regulation.

The document, you know, provides guidance to the reviewers, perform safety environmental reviews. Again, you are not required to follow what's in there, you can propose alternatives with justifications, certainly perfectly acceptable.

Things that are usually smooth, if you're trying to go, you know, veer a lot from what's in there and you have to prove it, and your case may be

difficult, it may take more time.

Again, it's not a definite on that. It is, again, depending upon what it is and what is your approach and what's appropriate for your particular facility.

Following formats that match something that we recognize are easier. Again, the easier we have to track the information that we need, the easier the review goes.

It also provides guidance for various things, you know, new facilities, amendment renewals, a lot of different activities, but the activities are similar to the things that you are doing under, in Northwest.

So it's not a foreign -- 1520 relates very directly to the kinds of things that you are doing that would be in your application, so a lot of it is applicable.

It also makes references to other NRC guidance documents, some of them like 1513, which relates to the ISA, Integrated Safety Analysis Guidance, which, again, what's in 1537 refers to the same to documents, so, again, it's not a foreign concept of what it is referring to.

The next slide, Slide 40. So sort of the

purpose of, you know, why we even have an SRP it's, you know, if you have a, it's across the board for quality uniformity of review.

We want -- It's guidance for the staff of what they should be looking for and how it should be looked across various facilities so we treat everybody the same regardless of what type of facility it is.

At least in uniformity the review would be the same even if the information may be different based on specific requirements in the regulations for a specific type of facility.

Again, it's the guidance related, it's meeting the underlying objectives and the regulatory requirements, so there is more information in there. Again, if you look at the regulation it talks about the kinds of things you have to do.

The idea of having the SRP is to give more guidance and details of some of the kinds of methodologies and approaches that the staff would find acceptable.

As I mention this flexibility, you don't have to follow it, but you have to, you can provide alternatives and also address it as, you know, Part 20, Standards of Radiation Protection, and Part 70.

You know, Part 70, what's somewhat

different than Part 50 is, you know, the chemical-related hazards that are considered in Part 70 based on the nature of the activities that are done under Part 70 facilities.

Next slide, Slide 41. So the guidance that we have in the regulations of 70.31 for issuing a license, so once we determine that all the applicable regulatory requirements are met we can issue a license in the form and then you will have conditions as appropriate.

You know, conditions, for example, may relate to, you know, you have to A, B, and C before you can have material. There may be other things. Again, as we do the review and we see where you are there may be specific requirements of things that we would put in in the license conditions.

We have done this for other facilities. Again, it's not different than any other fuel cycle facility. If you look at other fuel cycle facility licenses you will a series of some standard conditions and then other ones that are specific to that facility.

So we would expect something to be here for this, this particular activity also. Even in a combined license you still have license conditions

that you find in there.

So then we would -- Again, if it was one piece of paper you would still find the same technical conditions, license conditions in that piece of paper.

Next slide, Slide 42. So, you know, how does the applicant demonstrate, and let's say that the regulatory requirements are met, we talked a little bit earlier about, you know, how you do that. So you can, you have a choice.

You can combine it with the Part 50, Production Facility Applications, in the case it could be the OL. Again, where it's not specific of exactly when you would submit that document you could do it as a standalone document. Again, you choice.

The key thing, again, I'd like to emphasis is you have to demonstrate the regulatory requirements are met and if you are going to use multiple applications in different places then, you know, the easier you make it for the staff to know where those requirements are found the easier the review will go.

MS. HAASS: Will you be doing a separate safety evaluation report from 70 to 50 even if it was combined, if it's separate you would do them separately, if it was combined would there be one? How would that work within the NRC?

MR. TIKTINSKY: Well part of it is, and exactly where and how many documents sort of depends upon how you submitted it to us, but we --

MS. HAASS: But it was combined?

MR. TIKTINSKY: We would have to make, our SER would have to make combined regulatory findings if we were making the regulatory findings on the Part 50 side.

MS. HAASS: Okay.

MR. TIKTINSKY: We would have conclusions for the Part 50 part. We would have to make regulatory conclusions in the same document for the Part 70 part.

So we would have to make sure we had them all in there, that they were comprehensive. So just like you would need to demonstrate that you met all the applicable regulatory requirements, our SER would talk about the staff's acceptance, the reasonable assurance, for all those regulatory requirements.

MR. FOWLER: More pertinent to the previous conversation is does one pathway offer an easier, faster schedule than the other pathway?

MR. TIKTINSKY: It's hard to say in terms of the speed. Clearly, the easier you can make it on us to understand what you are doing and, you know, not

-- Again, I should say, if there is a long time period between submittals of one and the other then, you know, tech reviewers that reviewed one part have to go back and look at it to make sure they have covered it.

So there is some efficiencies in having the same people looking at both aspects at the same time. So I know about that --

MS. HELTON: If we go ahead a couple of slides I think we're going to get to that, too, but Dave is also going to talk about the differences between the 2-step Part 50 license and the 1-step Part 70 license.

So Part 70 is a 1-step licensing process, so there are some differences and the key I think is ensuring that whenever you seek to fulfill the requirements of Part 70 that you provide all the information.

MS. HAASS: Right.

MS. HELTON: There is different -- You know, you have seen that the bar for the construction permit, it's a different bar, you don't have a design set and --

(Simultaneous speaking)

MR. FOWLER: And this is why from -- I have narrowed it, the choices in my mind are narrowed

to two because we have to have all of our finalized design complete for the operating license under Part 50, which is then a 1-step process because the first step has been complete, or we submit it under Part 70.

So if I make my question more precise, is there a difference between providing the same information, meeting all the regulatory hurdles under the operating license for Part 50 in contrast to a separate application on your Part 70?

MS. HELTON: It might be helpful to step forward in the slides and see if we don't address that.

MR. TIKTINSKY: Okay. Yes, see if we go through and see if I answered the question or not.

MS. HELTON: Yes.

MR. TIKTINSKY: How about that?

MR. FOWLER: Okay.

MS. HELTON: Sure.

MR. TIKTINSKY: So, and, again, just the thinker that if they are combined then we need to make sure how they are met so it's clear to reviewers.

Forty-three. So to sort go with what we have looked at, so from what we have received in the docket so far the staff doesn't believe we have sufficient information to do the conduct review of the

target fabrication scrap recovery activities right now. So I think --

MS. HAASS: But it was never expected to be at that level.

MR. TIKTINSKY: Yes. So it's just that, that's my understanding that there was not.

(Simultaneous speaking)

MS. HAASS: Yes.

MR. TIKTINSKY: We just want agreement then, we all agree that there is not, we don't believe there is sufficient information.

And from our review of those activities, you had mentioned in your application that you believed they were under Part 70, so how we look at them they, I guess the first part is they don't appear to be covered by Part 50, so that's sort of, it's not, it doesn't meet the definitions of production facility under Part 50 and they appear to be subject to Part 70.

So that's sort of our looking at what -- Even, again, you have not submitted the application, so it's hard for us to make a definitive, you know, determination of what is there without that, but that's what we believe at this time.

And for us to actually conduct, you know,

the safety review and issue a license, because obviously you would need to submit an application meeting all the regulatory requirements.

And the burden is always on the licensee to demonstrate that they, or the applicant and the licensee to demonstrate that they meet regulatory requirements.

The staff does findings of reasonable assurance that you do meet them to protect the public health and safety, but the burden is on the applicant.

Sort of in addition to or in lieu of for some specific licensing questions related to, you know, specific aspects of what's applicable, you know, we talked we talked about pre-application meetings.

We would like to know, you know, if you believe certain parts of Part 70 are applicable or not applicable and have why they are not applicable we can have pre-application discussions of them.

Again, going back to my first point of making sure there is a good understanding of things because for any facility pretty much in, or activity in Part 70, there are some parts that apply and some parts that don't apply just on the nature because Part 70 is a broad regulation.

You can, you know, control things like MOX

facilities, which is different than, you know, uranium enrichment facilities, so there -- But the regulation is written broadly, so, you know, your understanding of what you think you need to meet, having discussions on that would probably be useful to make sure we were, you know, had some alignment, you know.

We don't want to play the bring me rock where you just, you know, send something in and we say no, you missed the mark, so we want to have those discussions because there where you add to timeliness, or had the time to doing a review if you do that.

So, you know, as we have mentioned, you know, many times those communications and understandings are really important to make sure we hit the mark.

But, again, it is, you know, Northwest's responsibility to demonstrate what they think they meet, what you think activities apply, what regulations do you think you meet, and how are you going to demonstrate that they are met.

The Slide 44 talked a little bit about schedule and, you know, Steve had presented a schedule to you, and that was a very good outline of the types of activities that get done in a review, so what I present here is sort of, you know, if you were just

submitting a Part 70 application this is what we would tell you that, you know, it's typically about 18 months to do a review.

We do a technical review of the application. Again, whatever it was, if it was submitted with the Part 50 or not we will do a technical review of the applicable regulatory requirements, issue additional requests for additional information, draft a safety evaluation report, you know.

There is slight differences in terms of, you know, the process and terms of, you know, there is not a mandatory hearing for this type of facility in Part 70 compared to 50, so there's some, you know, subtle differences.

But I guess the major point here is the review can be done in parallel or a series, so it sort of depends when you submit it.

So the 18 months I show here, you know, if you wait until after you submit it and we reviewed an operating license application under Part 50 then you sent us one then that clock would start when you submitted it.

If it's with it then we could do that review in parallel, so it wouldn't be adding to the

time.

So, again, a lot of it depends upon where you want to submit it, what is strategic, you know, for your company, when you think you are ready to have all the requirements.

And, again, in Part 70 the 1-step license requires, you know, a further development of things than a construction permit and it is also slightly different than what's in an operating license.

Again, the regulatory requirements are different so it doesn't necessarily line up 100 percent but it is your choice to, when your information is available, that you think you can meet to demonstrate the Part 70 then you can submit it.

If that happens to be with the operating license that's perfectly acceptable to us. If it happens to be before or after, I mean, again, that's acceptable, you know.

Again, the key is to make sure that, you know, you have an application that's complete, that has all the applicable regulatory requirements addressed.

MR. LYNCH: And just to add on, and I think Dave is absolutely right. I guess what it comes down to, I'm glad we're in agreement on the

information itself that needs to provided and I think that the main comment in terms of what's more timely, the sooner we have the information the sooner we can begin reviewing it, if that helps you in planning when you submit.

But I think from a Part 50 standpoint it's important to think about, also, that is there still related activities that are happening under the same roof.

So in order for us to make our safety findings under Part 50 for a production facility we will be interested in how other activities happening within that building could impact, and I'm sure it's the same going both ways.

So while you can submit the information whenever you would like to, it's all related and we need to know the impacts that those activities will have on the different, within the building on the different other activities that are happening as well, and whether it's the manufacturing of the targets or the processing of those targets.

MS. HAASS: Well and that was the concept of our Part 1, Part 2 submission was we showed an overall facility, because you are trying to show all the safety-related activities, you know, and how they

interact with one another.

MR. LYNCH: Yes.

MR. TIKTINSKY: Yes, it sort of emphasizes --

(Simultaneous speaking)

MS. HAASS: But I can't do one without the other?

MR. TIKTINSKY: Yes, to emphasize Steve's point, I mean we, you know, individually look at the Part 50 portion of the facility we need to consider, you know, an external, which isn't really external in this case because it's maybe the room next door.

But you still have to consider those activities in the Part 70 one and on the 50, and just, and the same way we would, if you were just looking at just the 70 piece in isolation we would be interested in the impacts of what the Part 50 facility around it was impacting on that in terms of, you know, accidents and analysis and things like that.

So we would look at it both ways because, again, we have to make a regulatory finding for those specific parts of the facility for those parts.

MR. JOHNSON: So, Nick, did that answer the question that you asked a couple slides back about are there efficiency -- What a thought your question

was, are there efficiencies with going one route versus the other, submitting a separate standalone Part 70 versus incorporating all of the, how you are satisfying all of the requirements into the CP, is that what you were asking?

MR. FOWLER: Yes. And, further, is there a material difference between the strategy of application submission?

And what I concluded from the conversation there is not a material difference between submitting under a construction, or an operating license out of Part 50 in contrast to a separate and distinct Part 70, the same steps, that it's not going to be easier for the NRC.

In many companies it would be easier to have a separate Part 70 application because some of the conversations could be more easily compartmentalized even though they do relate to other things.

What I concluded, rightly or wrongly, there is not a material difference. And to be clear from what's in my head there is a 2-month difference right now between the critical path of us entering the supply chain with quantities of moly under Part 50, a 2-month slip on the Part 70 puts Part 70 on the

critical path. That's how tight these two things are together.

Plugging in all of the assumptions from, well the guidance that we receive from the NRC, there are only two months difference right now and so if there were a material difference in review process cycle time it could very easily affect the entrance of this critical isotope into the supply chain.

That's how granular -- I manage the schedule. We're down to a month.

MS. HELTON: So I think, you know, we've emphasized the importance of communication on both sides. You know, you want the frequent public meetings, we can do that.

And I think what would be really helpful is to have a public meeting or a series of pre-application meetings where as you solidify your plans for your operating license and meeting the Part 70 that, you know, you keep us in the loop about how your project plan is starting to -- and we don't need those, necessarily all the details, but just in terms of what you are thinking about how to meet the requirements and going forward.

I've seen another complex application, I was in operating reactor licensing before this job,

where, you know, we've had as many or seven or eight pre-application meetings to talk about each of the different technical chapters and what they're going to be doing to meet the requirements, and you might want to consider doing something like that just so there is no surprises.

MS. HAASS: And we have done that in the past.

MS. HELTON: Yes.

MS. HAASS: Yes, so --

MS. HELTON: Yes.

MS. GAVRILAS: So just one reminder. This is Mirela again. Just one reminder that these are estimates, the timelines, and we try to walk you through the parameters, that impact held with that estimate that --

So it's almost like you are talking project management, what we visualize in our mind is sort of Gantt chart with the end in mind, you know, how the review of these various activities basically lead towards the point that which you get an operating license.

MR. BALAZIK: This is Mike Balazik. Is there any other questions on the Part 70 piece, because now we're going to shift to something else?

MR. ADAMS: And now for something different.

MR. BALAZIK: All right, Al.

MR. ADAMS: So what I'd like to do is, you know, we have discussed the, you know, general requirements for licensing, your proposed activities, you know, we discussed where the current status review.

Using your cover letter for Part 2 of the application and the NRC reply I'd like to try to pull everything together and hopefully the goal here is to reach a common understanding of how to move forward.

I am, you know, because of the excellent presentations that came before me, you know, some of this, you know, some of what I am going to say will be redundant, but, again, repeating it in the light of your application requests.

So, next slide. So, you know, here is I think probably the most important statement from, well one of the important statements from your cover letter, that you are applying to the NRC to obtain a license for a production facility under 10 CFR Part 50.

So, next slide. So I think, you know, we understand that statement that you are looking for a

construction permit for a production facility, you know, to dig a little bit deeper that you are looking for a license to construct a facility where you plan to conduct activities to separate moly-99 from irradiated uranium and other byproduct material.

That's consistent with the third definition of production facility in 10 CFR 50.2. There is three basic definitions of production facility.

One is facilities that are involved in the formation of plutonium, basically plutonium production reactors. The other one are facilities that are primarily separating plutonium, and there is the third definition which is on the slide, any facility design or used for the processing of irradiated materials containing special nuclear material.

(Off the record comments)

MR. BALAZIK: This is Mike Balazik, please Star 6 your phone to mute it. We can hear some background conversation.

(Off the record comments)

MR. BALAZIK: This is Mike Balazik. We are picking up some background conversation. I ask you please mute your phone, Star 6.

MR. ADAMS: And there is, you know, there

is a safety reason behind the definition and that's when you are processing irradiated materials containing special nuclear material basically you are separating out fission products from irradiated special nuclear material.

That involves additional hazards from what you would see in what I would call traditional fuel cycle facilities, the fact that you are dealing with irradiated material.

You are dealing with fission products, radioactive material, gaseous fission products, which, you know, which creates different accident scenarios and potential for dose.

So that's sort of the theory and the idea is once you introduce these irradiated materials that your intensity of our Part 50 where we are interested not only in the materials, the licensing of the materials, but also the licensing of the facility that contains the materials.

The third definition does contain some exceptions and you have indicated that you are not looking to license under any of those exceptions and those exceptions are that basically your separation is being done on a laboratory scale, so that's the first exception.

The other one is if you are, that if your batches are less than 100 grams of uranium then it's not a production facility. You indicated that your batches will be greater than 100 grams of uranium.

And the third is that if the irradiated material that the fission product concentrations and the plutonium concentrations are less than the cutoffs in the definition then you are not a production facility.

So you indicated that you are not looking to fall under any of those exceptions, which means you are a production facility under Part 50.

Next. So here is another statement in your letter to us.

(Off microphone comment)

MR. ADAMS: Oh, I'm sorry. Yes, that's what it says here. So, I'm sorry, this is our letter back to you where we completed the review and we agree that you have an application for a construction permit for a production facility as defined in 50.2 and you've met the requirements of 2.101(a)(5) and the information required by 50.34 and we found your application acceptable for docketing.

So based on that we are going ahead and reviewing the application for the production facility.

Okay, now Slide 49.

So in your cover letter you discussed your intent to apply for a single part, a 10 CFR Part 50 license. You indicated following NUREG-1537 and you also referenced the regulations in 50.31 and 50.32.

Slide 50. So just to repeat what 50.31 and 50.32 say, so the regulations in Part 50 allows combining of applications under Chapter 1 of 10 CFR and Chapter 1 is all of the NRC regulations, so we, you know, so applications can be combined.

And there is a regulation 50.32 and there is a parallel regulation in Part 70, 70.21, and they allow an incorporation by reference information contained in, you know, previous applications, other information. The requirement is that the references are clear and specific.

Slide 51. So your cover letter referred to NUREG-1537. I assume that when you say NUREG-1537 you are referring to the ISG, that augmented 1537 --

MS. HAASS: Correct.

MR. ADAMS: -- which provides applicable guidance for licensing radioisotope production facilities and aqueous homogenous reactors, you know, the guidance on aqueous homogenous reactors isn't applicable to your proposed facility.

NUREG-1537 has a couple of statements that are applicable to what you are proposing on doing here. Section 9-5 of NUREG-1537 contains guidance that materials used in the production facility license need to meet the regulatory requirements for that material. In other words, special nuclear material needs to meet the regulations in Part 70.

NUREG-1537 also says that materials required to operate the utilization of a production facility can be included in the license and this permits the combining of licenses.

Fifty-two. So your cover talked about embedded in the 10 CFR 50 license facility activities under Part 70 and Part 30.

Slide 53. As I mentioned, as discussed in Section 9-5 of NUREG-1537 the Part 50 license can include other activities, however, the issuance of a Part 50 license doesn't automatically include other activities, other licenses.

For example, you know, Part 70, Part 40, Part 30 licenses. These licenses are combined only in the Part 50 license if the applicant has submitted the needed information and the applicable requirements.

So I think as we said several times, at this time we don't believe that your construction

permit application has the information required to grant the additional licenses and I think we're looking for a better understanding of what you mean by when you say "embedded activities."

Next slide. So this is an example of a Part 50 utilization of an operating license. We call them included activities. What I am looking for is to understand if our included activities are the same as your embedded activities.

As you can see in this license the different licensing clauses. Number 1 on this slide that is the license for the facility, so that's where the license is granted for the Part 50 facility. This is an example of a Class 103 license, which is similar to the Class license you are looking for.

Where you see the three dots, where you see the dots there and that phraseology, that just listed who the licensees were and for this particular facility there was a very long list of applicants.

And so Number 2 is you see an included activity, so you can see this is the Part 70 clause so the included activities to receive, possess, and use at any time special nuclear material, in this case it's reactor fuel in accordance with the limitations for storage and the amounts required for reactor

operation as described in the application.

And you can see in Number 3 there is Part 30, 40, and 70 license to receive byproduct, source, and special nuclear material falls under other uses, neutron sources for startup, sealed sources for instrumentation, calibration, radiation monitoring, fission detectors.

Number 4 is a clause, it's a reactor clause. It's Part 30, 40, and 70, you can see, to receive, possess, and use in any amounts is required in any byproduct source of special nuclear material, so you can see the included activities.

C is just a reiteration that even though it's a Part 50 license that the activities under the other parts, 40, 30, 70, need to follow those regulations. So that's how these concepts are put in place in the license.

So, 55. You mention that the RPF will include the fabrication of LEU targets which will be licensed under 10 CFR Part 70.

Fifty-six. So, you know, we understand that, you know, you understand that the fabrication of targets is under 10 CFR Part 70 as we discussed several times and this was reflected in our docketing acceptance letter which stated that staff expects that

and Northwest will submit an application for fabricating low-enriched uranium targets under 10 CFR Part 70.

And next is 57 --

MR. FOWLER: So I want to --

MR. ADAMS: Yes?

MR. FOWLER: Al, I I'd just to clarify that.

MR. ADAMS: Sure.

MR. FOWLER: Part of what triggered a serious of conversations was the meeting immediately preceding Thanksgiving in which our internalization of the communication was a requirement to bifurcate our application between Part 50 and Part 70.

I was on the phone and I explicitly heard that there would be a separate requirement for a Part 70 application, where previously we had socialized, and I'll use the term socialized because it was only discussed, socialized and put embedded activities, our assumption that everything would be under Part 50.

So now 2-1/2, three months later I'm understanding the language differently, which so long as the information is there it can be either under the 50 umbrella or separate.

MR. ADAMS: It's still that type of

license, but, you know, there is choices on how you put in your application, there choices on how the license looks.

However, to get from Point A to Point B we need to follow the regulatory lane for that activity. In other words, because I give you a Part 50 license it doesn't automatically spawn these other licenses.

The Part 50 license by itself is a, you know, is a license for a very expensive building without, you know, without the other, you know, without possession of material that building doesn't do very much.

So I think that's the nuance that I think we kind of missed in the conversations back and forth, and I hope we have clarified.

MS. HELTON: Yes. Just to add to that, I agree. This is Shana Helton for the phone. The point I think back at the Thanksgiving meeting that is being reinforced today is that we need to see something from you that demonstrates compliance with the requirements in Part 70.

MS. HAASS: There was --

MS. HELTON: Right. So I think that's --

(Simultaneous speaking)

MS. HAASS: Right, but there was never any

disagreement with that when we were socializing it when we had originally sent our letter over a year ago.

MS. HELTON: Right.

MS. HAASS: There was no disagreement on that, but there was a 1-step process versus a two, you know, and, you know, there is a nuance and, you know, we agree with that.

I mean what we need to do today is move forward and we understand completeness, we understand compliance, and we will get back with you on how we plan on dealing with the Part 70, if it's going to be combined with 50 or not.

MS. GAVRILAS: This is the main objective of this meeting. We need to make sure that all the areas where there is uncertainty, where we are not aligned, today is our opportunity to address them.

You know that's why we exchanged the topics that we covered today with Carolyn before the meeting to make sure that everything that we are presenting here does address your concerns and does actually get us to the point to which we can align on the things that have some uncertainty associated with them.

MR. FOWLER: And so to that point I see

everyone's head nodding that we are now in alignment with respect to the previous kind of crosswise communications on 70 and 50 and for that we can successfully tick off that as we have met that objective of the meeting.

The second and broader objective of the meeting was to explore how we ensure that we most efficiently accelerate the schedule to meet the needs that we all recognize in the United States.

So I appreciate that we can tick off that first objective of the meeting successfully.

MR. ADAMS: And I think I have one more slide. Number, I think Slide 57. So that the current application that you are not, at this point you are not seeking an operating license for the proposed facility.

This is a discussion we would like to have with you today to the extent, you know, that we can have it as to what your plans are for submitting your operating license application because that does influence timing, that does influence, you know, what we do on, you know, what we need to do and what you need to do, too.

So, you know, that's an area that we need to, that we'd like to understand better for, we're

prepared.

The second point, current application does not request a license to produce SNM for the fabrication of LEU targets, I think we beat that one into submission.

MS. HAASS: Well it doesn't, it's not a current operating license application.

MR. ADAMS: That's right, it's not.

MS. HAASS: It's Part 70.

MS. HELTON: Right.

MR. ADAMS: Yes. That's right, and that's a separate point from my first one.

MS. HAASS: Right.

MR. ADAMS: And a facility can have multiple licenses, that a single building can be a place of use under multiple licenses.

When I was a licensee my containment building was a place of use under my reactor license, it was a place of use under our NRC SNM license, it was a place of use under a state byproduct license.

The important thing, which I think Dave and Steve alluded to, is we need to look to make sure that those multiple activities don't impact the safety of each other.

MS. HAASS: Yes.

MR. ADAMS: So that's the important thing, but there is no rule that says that, you know, a certain piece of turf can only, you know, can only be occupied by one license, and I think that is consistent with what we have discussed today.

So like I said I think the, you know, before the day is out we would like to discuss, you know, what are, you know, your plans for moving forward with your operating license application for, you know, for we understand them and we can be, you know, prepared.

That's it for me.

MR. BALAZIK: All right. Real quick, this is Mike Balazik again, and I know we have touched on some of these topics but I just want to reemphasize them.

On communications, that internal and external communications is important to support a quality and timely application review. I just wanted to go through some of those channels that we have already set in place.

One that Shana mentioned early in the meeting about essentially one-stop shopping, that I am your contact even though you've got, down the road there is potential licenses, I am your main contact,

and, you know, on a lot of our calls, on our weekly status calls I'll have Dave and Nancy on those calls.

The next item, clarifying, calls for REIs. We've done a couple of those for the environmental and we plan to continue those for the safety, sharing those RAIs with you draft form, make sure there is an understanding, and if there is not, you know, we can discuss it and even modify the RAIs so that it is clear.

Since we are discussing RAIs I'd just like to share one item for thought going forward. Even though there is no regulatory requirement to update your PSAR, we've seen a good practice, or identified a good practice that if you update your PSAR with the RAIs that that can also lead to a timely review, but even future steps it will help us, to keep your updated PSAR.

But realize there is no, you know --

MS. GAVRILAS: I'll just mention one thing, ACRS. It's easier for the ACRS, we accept your responses, right, as a supplement to your submission, they become part, they are docketed and they become part of the docket.

It makes it much easier when the ACRS looks at the package to have the package as complete

as possible.

We were talking about places where efficiencies can be realized, that's a place where an efficiency can be realized.

MS. HAASS: So a good example is the RAIs we have received on Chapter 19. We've already updated Chapter 19. You have not received it, but we have already updated it.

We actually when we get them we do it right then and there. I am more than happy to provide you an updated 19 if you want it right now. I don't know why we'd need it right at the moment, but we will be providing a revised PSAR with all the RAIs. It's already in the plan.

MS. GAVRILAS: That's terrific.

MR. TIKTINSKY: The practice that we find that works a lot is sometimes, you know, answers to RAIs are long but changes to the applications don't necessarily, aren't -- Well you might change one thing in an application and have a 3-page thing backing it up.

MS. HAASS: Right.

MR. TIKTINSKY: So at the end of the day, at the end of the review it's good to have one application that we know everything that's in the

application that we can write an SER against rather than writing SERs against all these little sort of sidebar discussions.

So, again, as Mike said it's not a regulatory requirement but it's certainly an efficiency that we found in not only 50 reviews but certainly in 70 reviews also.

MS. HAASS: But remember it's difficult for us to manage if we don't do that. That makes us inefficient, so it's only good practice on our part and to move forward to the operating license.

MR. TIKTINSKY: That could be changed pages, you know. It doesn't have be, you know, every time you make something it doesn't need a whole chapter, it's just whatever related to, you know, the change from an RAI and is, you know, and you manage it however you find most efficient.

MR. BALAZIK: All right. Another item, responsiveness, we've also talked about that, especially timely response to RAIs and when we share the draft RAIs if there is something that you see in there that you can't get in 30 days or a certain timeframe just let us know.

Let us know that this, hey, we can answer RAIs 1 through 5 but, you know what, six is going to

take us a little bit longer. You know, we just need that communication back and forth that there may be something up there that may take a little bit longer.

Quality of submissions, we also talked about this, identifying proprietary information, removing that, and just that answers are complete.

Also, just clarify previous communications or socializing. We mentioned this earlier that no regulatory decisions are made in public meetings and that public meetings are not a substitute for submittal of information on the docket and also that, you know, we don't make decisions on our weekly calls.

And, finally, just that the NRC has an opening policy and if we chose to close a meeting, you know, it's reserved for information that must be withheld in accordance with our regulation.

So that's pretty much it for communications. I don't know if anybody else wants to add -- Yes?

MR. LYNCH: I just wanted -- I was really glad to hear that we were able to meet one of your objectives in terms of licensing, that we have a shared understanding that additional technical information is needed for, to meet Part 70 requirements and how you choose to submit that is up

to you and regardless of how it is submitted it's still the same technical information that we are looking for. I'm glad we've got that objective met.

I want to make sure that we can also hopefully meet that second objective that you stated at the beginning, which was exploring mechanisms to expedite the review.

I tried making a summary. I think Mike highlighted them and I just kind of want to read through those again and make sure that we understand everything you are looking for and to reiterate our points that can help facilitate that expedition.

One of those areas we've talked a lot about, RAIs, trying to reduce the number of rounds of RAIs and even the total number of RAIs, things that can go that, the quality of your responses, completeness and the timeliness, we explore different ways of communicating that to help facilitate that.

Mike has his weekly status calls. We have talked about -- and on the status calls we can make, talk further about if we want to set up standing public meetings. If that can help we can certainly get those set up as well.

And broader with communication, you know, those weekly status calls are good opportunities to

identify problems you see coming down the road that we, both parties can be thinking about and, you know, maybe it's not something we address immediately, but at least we can put them on the list of things NRC needs to think about and things that Northwest needs to think about, and they can topics of future public meetings.

We can also talk about, you know, email communication works, too, send emails. You can update and propose topics that we can have on those weekly calls, topics for public meetings, if we can get those, and it helps, too, we can discuss ahead of time before we have those calls.

Al touched on this, also that's important to us is updates to your schedule. This can be updates as Mike was talking about with responses to RAIs.

If it's going to take you a little bit longer to get certain responses to us work that out with Mike, let us know what's going on with your schedule so that we can plan and make sure that we have people available and ready to review your responses when they come in.

Also, when you plan on submitting additional applications, primarily your operating

license application, helping us have a good idea of when that's coming in to make sure that we have people ready to review it when it comes in.

So letting us know delays that might come up or if your schedule is getting pushed up, it helps us align our budget and our resources to make sure that we are ready for your application.

We also talked about pre-application meetings. So when you are getting ready to submit your next application for your operating license we can have meetings ahead of that submission to make sure that we have a shared understanding of the information that's coming in that and have discussions about that so it helps encourage that a quality submission comes in for your operating license and could help potentially reduce that review time as well.

In talking about the operating license application I wanted emphasize again, because ultimately we complete this construction permit review in our 18 to 24-month timeframe, we're still anticipating an additional 18 to 24-month review for the operating license application, and I understand it's critical that we can get that review done efficiently as well.

So I think for those exploring, those pre-application meetings can be a good way of getting us started on that review and knowing when it's coming in can help us be prepared.

We highlighted following the guidance. You can gain insight from NUREG-1537, the ISG, our standard review plan, so you know exactly what the NRC is looking for when we review the application that you sent in, also looking at past applications that have come in to get ideas of questions we have asked in the past and the level of detail of information that we found acceptable in the past.

We also talked about reducing administrative time so that we don't have time that's spent with people not doing anything, and I think that's good and I think those weekly calls, again, are going to be crucial to reducing that administrative time for processing.

And Mike highlighted again at the end updating the application as you are responding to RAIs. That was my list. Were there other things that I missed that we can --

MR. ADAMS: There's probably one I want to touch on. I think I touched on it briefly and that's the operating license application.

The last research reactor that we licensed submitted a complete application at the construction permit stage so our review was for both the construction permit and the operating license at the same time.

Obviously, that has the potential to, you know, reduce the review time significantly so that's why we are interested in knowing what's your timing on your operating license that, you know, that has an effect because, you know, the theory is that the construction permit you've given us so much of, say, you know, your complete design that you've given us so much of that design and, you know, there is enough there to make a decision to allow the facility to be constructed and then the rest of the details on the design come in with the operating license that, you know -- so there is a lot of variability what that, you know, what those parts, you know, what those two parts look like.

The first part is here, you know, what needs to come in to fill and, you know, to fill in the rest of the information and when that information is coming in I think is important, you know, in the discussion of, you know, how to change the, you know, the timing of this and, you know, not only, you know,

talking talk the timing from, you know, the beginning to you have an operating license.

MR. TIKTINSKY: If I add a little emphasis from Steve's point on the Part 70 side, you know, there is many examples of the kinds of the RAIs that we have asked for Part 70 applications as well as SERS, so you can sort of see when we write up things related to 1520 what the kind of things we're looking for, the kind of questions we had.

And, also, you know, emphasizing of the use -- You've got multiple things here, the use of crosswalks, you know, again, the clearer that you can make it that we understand where the information is the easier it will be for the reviewers to get the job done and minimize questions of because we just can't find information.

MR. FOWLER: So to the list that Steve summarized very nicely I would add a program/project management process, just as I manage a program inside of a private company I have far less insight into the detailed activities in what's happening at the NRC and whether we're on track, off track, what are the constraints, what are the barriers, those kinds of things.

So a consolidated program project

management structure I think is very, very important to keep things on track.

MS. HAASS: Yes.

MR. LYNCH: And I think to that, yes, I think it's very important from both sides to keep each other updated on where we are at in our reviews and I think with the calls we can do that.

Also, what we're going to try doing is, you know, keep you updated on our overall review schedule. We have this initial review schedule that we shared here today on our slides, but as things come up that may necessitate that changing, either expedited or delays, we need to communicate that to you as soon as possible, and that's a commitment that we can make as well.

We are also going to, you'll be seeing shortly, we're working on developing a public website that should be going live in the next couple weeks that you can be able to also have all of your application data displayed as well, that can be easily accessed and see our review schedule.

MR. ADAMS: The public --

MS. HAASS: The public would -- Sorry. For Northwest Isotopes or for other things as well?

MR. LYNCH: Both. So Northwest specific

and general moly-99.

MS. HAASS: Okay, got it.

MR. ADAMS: And your public information, not your --

MS. HAASS: I understand.

MR. LYNCH: But, yes, and, you know, as we continue with the review I'm sure both sides will have new ideas.

MS. HAASS: Yes.

MR. LYNCH: So chair them and we can continue to improve.

MR. BALAZIK: All right. At this point we're a little ahead of schedule. Our senior managers want to come down for our closing remarks and summary.

The timeframe for that is 2:30, but I wanted to ask Northwest if they had additional discussion they want to do in the afternoon on any of the topics we presented, any topics that we didn't present today that they would like to discuss in a public meeting. I've got that scheduled for 1:30 and lasting about an hour.

MS. GAVRILAS: Yes, I have a suggestion, that we mull over everything we have heard and perhaps after lunch we reconvene and that will be the time, unless you want us to research something over lunch.

It's going to be after lunch we reconvene and we sort of discuss any outstanding items, how's that?

MS. HAASS: That's fine.

MR. FOWLER: Sounds good.

MR. ADAMS: And another question, is, you know, giving us information on where you see your schedule moving forward, you know, especially giving us the operating license application, is that something that you are prepared to talk to us today in this swarm or --

MR. FOWLER: We would certainly be prepared to respond and provide some answers in a non-public format, as it's dependent upon a lot of the questions that were asked of us that are of a proprietary nature to come up with the anticipated scheduled.

MR. ADAMS: Okay.

MR. BALAZIK: Okay.

MS. GAVRILAS: Enjoy lunch.

MR. BALAZIK: Yes.

MR. ADAMS: What time --

MS. GAVRILAS: We'll reconvene at --

MR. BALAZIK: Well let's reconvene at 1:30 for discussion of additional topics and then at 2:30

we'll do the closing remarks.

MS. GAVRILAS: Yes. And we have an opportunity before the public to --

MR. BALAZIK: Yes, we're going to do that, too, yes.

MS. GAVRILAS: So we need to stick to the agenda because --

MS. HAASS: Is there any opportunity for a non-public portion of this?

MR. BALAZIK: No, there is not.

MS. HAASS: Okay.

MS. GAVRILAS: So we need to stick to the agenda because the agenda is made available so that everybody can listen, so we'll just meet back at 1:30 and we'll talk more then.

MS. HAASS: Right.

MR. FOWLER: Very good.

MALE PARTICIPANT: Thank you.

MR. BALAZIK: This is Mike Balazik. We'll be coming back at 1:30 and we're going on mute until then.

(Whereupon, the above-entitled matter went off the record at 11:32 a.m. and resumed at 1:35 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:35 p.m.)

MR. BALAZIK: Hi, this is Mike Balazik, and we want to resume the public meeting with Northwest Medical Isotopes. Right now in the agenda we have Northwest Medical Isotope topics. If there's anything that Northwest wants to discuss with the staff?

MR. FOWLER: We did not have topics in public form. We'll arrange a separate non-public meeting to discuss some topics.

MS. GAVRILAS: Mike, you want to talk about the setting up closed meetings please, because apparently there was some miscommunication on what requirements we must need before we can do that.

MR. BALAZIK: Yes, the requirements for a closed meeting is to submit an affidavit with the letter, but with the specific topics that are going to be discussed in the closed forum.

So then what we would do is we would look at those topics and agree that yes, these are proper to be discussed in a closed setting vice an open public meeting.

So in the affidavit that was provided, I felt that it was very general, and I received some

advice that it did not contain sufficient detail to close the meeting.

MS. HAASS: And as discussed with you, we were, we didn't quite know what would be in the non-public forum because this discussion had to occur and that's why it was general. So it's not that we didn't understand, it was because of how the meeting was set up.

MS. GAVRILAS: I understand. So the other thing that we tried to see is if it's okay for us to close a portion of this meeting. So that was the homework we did during lunch. And we were advised that that's not okay because the topics need to be submitted by affidavit. So we tried.

MS. HAASS: It's a catch 22.

MS. GAVRILAS: Yes.

MS. HAASS: But no, we do understand, you know, the requirements for a non-public meeting. But we just didn't have enough data to be able to give you any more specifics.

MR. LYNCH: That's understood. Well maybe, if we have some time maybe we could use for time our over here is to maybe make a list of some action items that we can take for going forward, and this could include topics for future meetings that you

might like to have, things you would like to see, and other things you would like to go forward on both sides that we can take back and then we can get back to each other on. Does that sound like something you would like to go over?

MS. HAASS: I would say we can take some action items. But just as long as we know it's subject to change because, you know, I still have some discussions I need to do.

MR. LYNCH: Understood, understood. Yes, this is not meant to commit you to anything. This is intended to help us get an idea of when we leave here today what should we be most focused on, aside from reviewing your application.

Mike, did you want to lead with any topics there?

MR. BALAZIK: One thing we've discussed before, and again stop me if we're going into proprietary information. But one thing we've discussed in the past is facility design, final design.

And what we've talked about earlier are our resources for future applications, future submittals. Is it possible we could get some sort of idea of how far down that path Northwest is?

MS. HAASS: I think we can state that we are in the process of finishing our final design. But from a schedule perspective, that would have to be discussed in a closed session.

MR. LYNCH: Yes, I think the topic from that is what, something the NRC is interested in understanding better from you is when will your final design be complete, and also how do you think you might consider submitting that because there are different ways that the final design can be provided to the NRC.

The final design can be provided as part of your operating license application, or you can amend your current construction permit with additional design information as you finish it.

And however you choose to do that is fine. But it does help us to anticipate when that information might be coming in. So that's just, that is a topic that would be useful for us to discuss in the future.

MS. HAASS: Well, and I would be interested, because this is the closed question, what have you preferred in the past? Would you like to see it, like, you know, before the operating license submission with the, maybe the finalization of the

construction permit.

I mean, I don't know. I mean, I don't know what's the best timing for you guys I guess I would ask. And then, you know, we'll try and work that into a schedule.

MR. LYNCH: I think for us, you know, we're willing to work with you with whichever way you would prefer. You know, we haven't done something like this in a very, very long time. So I don't know if there's a lot of precedent we can necessarily point to.

But I think we want to work with your proposal. And by notifying us when it's coming, we can make sure we have the appropriate resources available for that.

MR. ADAMS: This is Al. I think, you know, the understanding of the timing is important because we're going to, you know, spend time and effort reviewing what you've given us.

And if we're 85 percent complete with that review and all of a sudden we have a whole new bunch of information, it might be advantageous to finish that 15 percent, take that licensing action and then try to reset, try to, you know, blend those two together and start reviewing sort of an expanded

scope.

So you know, part of it depends on the timing versus if we're only, like, ten percent into looking at something and the new information comes in, then the effort or cost of changing your direction, changing your scope is minimal. So I think that's an important solution.

MR. LYNCH: Maybe that's a better way to capture what we can provide that too. We won't advise you on which way is better than the other. But we can discuss, as Al was going to, what potential impacts of your decisions could be.

MR. BALAZIK: This is Mike Balazik. I guess another potential item is exemptions. I don't know if Northwest has looked at any potential exemptions that could come down the road that we could be aware of or could prepare for, just kind of another item that would benefit us in future reviews on exemptions.

MS. HAASS: Okay.

MR. LYNCH: And even more broadly, just other licensing actions in addition to your primary construction permit or operating license, or material license and application that we might need to consider and the timing. And for example, that could include

the other research reactors that might be seeking amendments to support that, knowing the timings that those licensing actions can help us as well.

MR. ADAMS: Another example would be if there's any need for shipping packages that would be unique to what you're doing that, you know, don't exist. That's another part of NRC and that's, you know, a discussion that they have their own timelines for doing that type of work.

MS. HAASS: And we've had brief conversations with the other organizations, too.

MS. YOUNG: And that's under Part 71.

MR. LYNCH: Another topic that, you know, that I think we could discuss going forward to our, we've touched on the topic of potentially setting up standing public meetings.

Put that on the list of establishing if that's something that you want to pursue, what you think appropriate frequency for those meetings might be, what topics you might want to discuss during those. I think that, I took that as one of the take-always I had from earlier today as a topic we should explore further.

MR. BALAZIK: I guess, this is Mike Balazik again, for expectations for interactions with

the NRC for the environmental review, we're pretty much had a set process. I mean, is there any recommendations on communications that you would like to see in the future?

MS. HAASS: Just want to make sure that the RAIs get reviewed prior to going out final to make sure there's no business sensitive information in there. If you can at all let me know the possible timing when that's going to come in, you know, we have a lot of things going on as well and I need to make sure our resources are there.

And I know when we get into the safety aspect it can get more and more difficult, you know, to get those reviewed, and what resources that means to us as well.

Also from, Nancy, from your perspective, I mean, you'll have another public-type meeting within the NEPA realm. And you know when you're going to be scheduling that. I know that the City of Columbia was asking me that question as well.

I just know, you know, they told me they would really like to help you do that. And I know last time you guys went and did that, you know, independently which is fine, but they're also willing to go help as well. And, you know, you have their

contact information now.

MS. YOUNG: Okay, thank you.

MR. LYNCH: Were there any topics that you've had in mind in addition to that that you would like to focus on in the future?

MS. HAASS: No. I think when you start looking at schedule, the other licensing actions and the same in the public meetings, that's really where we want to focus with you guys.

Obviously, the standing public meetings, you know, we'll assume that there will be some closed portions of those meetings within that, you know, with the appropriate documentation, understand that.

MS. GAVRILAS: Mike, you'll need to elaborate on the process. I think we need the affidavit with sufficient detail --

(Simultaneous speaking)

MS. HAASS: Oh, that's what I just said. Right, no --

MS. GAVRILAS: So that's --

MS. HAASS: I said with the appropriate documentation there would be closed portions as well because there are certain things that, you know, that are technically sensitive as well.

MS. GAVRILAS: Sure.

MS. HAASS: And so any time we have a topic, assume that there's going to be some, there's most likely going to be something business sensitive in there if it has anything to do with some details of the facility.

MR. TIKTINSKY: You don't want to forget, Dave Tiktinsky, the security related information aspects of public meetings with technical discussions which is different because that's a different part of the regulations.

MS. GAVRILAS: Definitely.

MR. TIKTINSKY: So that's always something we want to make sure that, you know, why we close meetings related to discussions of that and information that's the integrated safety analysis or things that are preferably security related.

MR. BALAZIK: Anybody have anything else?

MS. GAVRILAS: Open it to the public I would say.

MR. BALAZIK: All right, we can open up to the public. Actually, I do have one more item. Karen, you mentioned resources. Is there the potential for any impact in the future for Northwest resources for the review of this application, or even future applications? There would be no change or any

fluctuations that could potentially happen?

MS. HAASS: Well, there's no change in our primary subcontractors, no.

MR. BALAZIK: Okay.

MS. HAASS: And they have the people to support this. But, you know, you still have to schedule it.

MR. BALAZIK: Yes, no. I understand, I understand.

MS. HAASS: So yes, but that is not going to change.

MR. LYNCH: I guess maybe just as a closing question, do you feel like your expectations were met today? Did we accomplish what you wanted to accomplish at this meeting, or at least start moving in the right direction?

MR. FOWLER: So we had two objectives as we introduced this meeting from a Northwest Medical Isotopes perspective. The first was gaining alignment around or understanding in common of the licensing application process.

And that one we've I think beaten to death and are in violent agreement now with an understanding from both NRC and from Northwest Medical Isotopes of the options. And the follow up next step on that is

to telegraph to the NRC our intentions. And so I think from a first objective standpoint, we can declare success on that one.

The second, and frankly more important one to the nation and to public health and to public safety is the speed with which we can accomplish a successful review within the guidelines and regulations.

I think this is, we did not have an expectation that that would be solved in this meeting today. Our expectation was that we would have a plan to get to a plan.

What we accomplished in my view today is I've received more granularity in the schedule elements from the NRC and the assumptions behind the schedules, how many iterations of RAIs, how many iterations for the RCS and so forth.

So I think we now have a framework with which we can succeed in a productive conversation on translating the list, Steve, that you've so well-articulated and added to and convert that into an operating plan.

And ultimately, what it comes down to to a company like ours is predictability. Sufficient granularity in schedules so we know what's next, how

do we assess that each one of those milestones whether it's on track or off track, and our ability to predict those next steps, manage accountability, manage schedule, manage budgets.

The risk to any business, the biggest risk to any business is uncertainty. And we've been in an uncertain environment. And this meeting succeeded in helping to remove some of the uncertainty in terms of establishing a framework where we can now discuss the schedule.

And a number of the elements are going to obviously fall right back on us. We have better expectations of what the standard is by which we need to meet. But I think we also can establish a program management plan so we collectively understand when a milestone's been achieved and what the next milestone that we all need to focus on.

MR. BALAZIK: And if there are no more, this is Mike Balazik, again. If there are no more questions in the room, first of all I guess I would like to ask if there's any NRC staff on the phone that has any questions. And then we'll open it up to the public.

(No audible response)

MR. BALAZIK: Okay, hearing no questions

from the NRC staff, so now I would like to open up the phone lines to the public for public comment. Just a couple of items.

Please, speak one at a time and identify yourself in speaking. And also if you're uncomfortable asking a question on the phone, you can submit your question to me via email at mfb@nrc.gov.

Are there any public comments?

(No audible response)

MR. ADAMS: Can someone verify that the phones are still open and working?

PARTICIPANT: Yes, the phones are open.

MR. ADAMS: All right, we just want to make sure silence wasn't something unplugged somewhere.

MR. LYNCH: Thanks, Jenny.

PARTICIPANT: We're here, thank you.

MR. BALAZIK: All right. So I think we are, are we expecting Bill and others to join us later?

MS. GAVRILAS: Yes. I think we'll adjourn until 2:30 when we have an opportunity to interact with two office directors. I think at least one office director, perhaps two. And certainly my boss, Lawrence Kokajko is going to join us.

I don't know if Craig who is the acting director in Shana's organization is also going to join us. So you'll have an opportunity to reiterate, we'll reiterate our action items and you'll have an opportunity to interact with them.

MS. HAASS: And which office directors, potentially?

MS. HELTON: Bill Dean.

MS. GAVRILAS: Bill Dean, our director is coming for sure.

MS. HAASS: Okay.

MS. GAVRILAS: And his deputy might come as well.

MR. ADAMS: So we're going to go mute on the phones until 2:30 and then we'll be back on.

(Whereupon, the above-entitled matter went off the record at 1:54 p.m. and resumed at 2:33 p.m.)

MR. BALAZIK: Mike Balazik, we're resuming the public meeting. Right now we're toward the end of the meeting. And we just want to real quickly go through some closing remarks. Oh, I'm sorry.

Bill Dean, Office Director of NRR is joining us, and Michele Evans has also joined us, and Lawrence Kokajko has also joined is. He's the Director of DPR, for our members on the phone. All

right.

(Off microphone comments)

MR. BALAZIK: Okay, can we just go through everybody, identify themself that's new to the meeting?

(Simultaneous speaking)

MS. EVANS: Sure. Michele Evans, Deputy Director of NRR.

MR. KOKAJKO: Lawrence Kokajko, Division Director, Division of Policy and Rulemaking.

MS. MARSHALL: Jane Marshall, Deputy Director, Division of License Renewal, NRR.

MR. ERLANGER: Craig Erlanger, Acting Director for the Division of Fuel Cycle Safety Safeguards and Environmental Review.

(Off microphone comments)

MR. BALAZIK: Okay. You want to start?

MS. GAVRILAS: Yes, so we had what I would qualify as a productive meeting this morning. And I'm going to ask the Northwest Medical Isotopes to bring their own clarification.

Mike and Steve prepared a few summary points of the meeting that I'll ask them to go through, a couple of action items. And then I know that Bill would like to engage you in some

discussions. And with that, I'm going to ask Mike to summarize.

MR. BALAZIK: You going to go through the points, Steve? You have the points?

MR. LYNCH: Whatever you would like.

MR. BALAZIK: Yes.

MR. LYNCH: I can go through it.

MS. GAVRILAS: One of you two needs to do the summary of this morning, please, and the action items. Thank you very much.

MR. LYNCH: All right. So I guess for everyone's benefit that's in here that was not here in the morning, we had two main objectives that we had set out to accomplish as identified by Northwest, and those were to talk about the licensing approach for the facility. And then the second item was to talk about mechanisms to expedite the review of Northwest's construction permit application.

For the first point, we reached agreement and a shared understanding that there is additional technical information that Northwest will need to provide to meet the Part 70 requirements in 10 CFR.

Whether that's submitted as part of their operating license or as a separate application is up to them, but we are in agreement that regardless of

how the information is packaged, we understand on both sides what technical information needs to be provided. Is that correct?

And then the second point for mechanisms to expedite the review, we went over a number of items that we can do on both sides to make sure that we review their construction permit application as expeditiously as possible.

One of the items we discussed were approaches to request for additional information to limit both the total number of RAIs that we asked and the number of rounds that we go through.

Ways that we can address that are ensuring that the NRC is clear in the questions that we ask and making sure that we have phone calls with Northwest when those RAIs are issued to make sure they understand the question that we are asking.

And also when they are getting prepared to submit their responses, to have additional calls. That may take the form of a public meeting if we need to discuss technical details, or it could be shorter clarification calls to make sure that they're on the right track.

Again, the goal of that is to make sure that we have a shared understanding of the NRC's

expectations and what Northwest's understanding of our expectations is. We also emphasize that quality and completion of those RAIs is important as well.

This fed into a larger discussion of appropriate methods of communication during the review process. We have already established weekly calls following the docketing of the application that Mike and others as needed sit on with Carolyn once a week to discuss the status of the review and then the other administrative details as necessary. And that's consistent with our practices for other reviews throughout the agency.

MR. DEAN: So how long has that been going on? For how long?

MR. LYNCH: Since January 12th.

MR. DEAN: Okay, all right.

MR. LYNCH: So right after we concepted the review and everyone got back from the holidays.

MR. DEAN: Okay.

MR. LYNCH: We discussed the importance of staying up to date on schedule, both from the NRC's perspective as we're doing our review to make sure we communicate how we're progressing towards milestones, and also to get updates from Northwest on anticipations of when, you know, if they have any

delays on the current application, responses through RAIs, and just updates of when they anticipate submitting future applications such as their operating license application.

We discussed, as far as the information at Northwest provides what's the threshold of what's acceptable to the NRC, we went there already following our formatting content that I had provided in NUREG 1537 and the ISG augmenting NUREG 1537.

And as far as the threshold that we set for the information that we're doing our review, we told them that when we do our review we use our standard review plan that is publically available, and that is the threshold we set for the information that we are looking for in their application.

And to maximize the efficiency of our review, the clearer it is to us that they have addressed the acceptance criteria in the standard review plan, the easier it is for the NRC to move forward quickly.

MR. DEAN: Both for the Part 50 and the Part 70 aspects?

MR. LYNCH: Yes, yes. We discussed the guidance for both aspects that they can use.

MR. DEAN: Okay.

MR. LYNCH: We also talked about the importance of reducing administrative time for processing on the NRC side and also preparation of documents on Northwest's side. The goal is through our talks to make sure that there isn't significant debt time where either side is sitting, not doing anything and just waiting.

And this feeds into general program and project management on both sides and making sure that we are identifying clear goals towards working towards the identified milestones that we have in the project.

And the last thing that we went over, or I shouldn't say last thing, I could think of two more things. Looking at past precedents, we have examples of reviews we have done in the past, most recently with SHINE, there are transcripts available from ACRS meetings that they can look through as we go through ACRS to help improve their preparation for those meetings.

Also, they can get a sense from looking at these applications for what the NRC has found acceptable in the past and types of RAIs we've asked in the past and what types of responses we're looking for and similarity of reviews.

As we get ready for their operating

license application, one way we can get ready for that is we explore the possibility of having pre-application meetings to discuss the technical problems or issues that may come up that we need to explore before the application is submitted that there may be questions on.

And also with the current construction permit application, we talked about efficiencies that can be gained from maintaining that document up to date as they respond to RAIs and information in their current PSAR needs to be updated, that they can provide updates to that.

At times it will work out with Mike, it will make it easier for our reviewers to have a single document to look at that has all of the updated and completed information, and also as we go forward to the ACRS and with the mandatory hearing.

We also discussed earlier today the status of our review and our plans going forward. So with all of that, I think with that I think with those topics, that addressed the second main point of talking about ways that we could expedite the review. I think that covers it for that second point.

MR. FOWLER: You did a good job, thank you.

MR. LYNCH: And then between 1:30 and 2:00 we came up with a list of action items to take away to come back to in the future. The first of these was setting up a, exploring the possibility of setting up standing public meetings.

And this, Mike and Northwest will work together on this to see if it's needed. But the idea behind this is to cut down on some of that administrative time.

If we see the need to discuss significant technical information, most likely related to RAIs on a regular basis, instead of noticing public meetings every time we need to have one, we set up a frequency maybe once a month, once every other month, something that's agreed upon between both parties. That was identified as a topic worth exploring in the future to see if it could help in the review.

The next action item we had was in a future meeting discuss when the final design for Northwest will be provided to the NRC. This includes, you know, the final design could be submitted as part of the operating license application, or it could be submitted while we are still reviewing the construction permit.

And understanding Northwest's intent will

help us in our preparations. And then on our side of that, we can discuss with them in the future the impact of their decision to go forward one way or another, without recommending a preference.

The third item that I had here was the NRC could benefit also from understanding any additional licensing actions that Northwest may request in the future.

This could be related to transportation of materials, any exemptions that they foresee needing for their current licensing requests or future licensing requests. Also, license amendments that existing research reactors might need in order to support the radiations of their manufacture targets.

Fourth item that we had as a take-away was making sure that we have clear expectations on both sides. This has to do with, mostly with requests for additional information.

Northwest would like to be able to review drafts of the RAIs for potential proprietary information before they're issued. And also to the extent practicable, we would like notifications of when the RAIs are getting close to being issued so that they can make sure that their resources are ready to receive any begin working on responses to them.

Also, Northwest offered that for future public meetings, that we have it out in Missouri, that the local government there is willing to work with us in getting that set up in the future as well.

And I think the last thing, the last action item I had on here was on both sides, and it's kind of relates to everything else we've just been talking about is just having clear communications on both sides of schedule, NRC making sure that we identify the milestones that we're working towards and our progress towards that and Northwest, again letting us know their schedule and any impacts they may have.

MR. DEAN: Okay, is that it?

MR. LYNCH: Yes.

MR. DEAN: Okay. Good. Sounds like you guys had a productive meeting. So appreciate you guys coming here from Oregon? Both of you from Oregon?

MS. HAASS: The northwest.

MR. DEAN: Northwest? Okay. Go Ducks. No?

MR. FOWLER: Well, we have Ducks and Beavers.

MR. DEAN: Okay, all right. Depends what part.

MS. HAASS: I'm a Husky.

MR. DEAN: Okay, depends on what part of the state that you're from. Well, so I appreciate you guys coming in. And it sounds like it was very productive and useful meeting.

I know that you all were here not too long ago and had expressed some concerns with some of our commissioners and some of our senior management about the process and not having a good understanding of the process.

And so it sounds like, and I certainly would be interested in your all's perspective that today's meeting helped move us forward in terms of establishing better communication and better understanding of what you can expect from us, but also things that we hope that we can engender from your side of it because I view, personally I view this process, and it's a big deal right, moly-99 is a big deal for this country.

And so you guys are pursuing something that is important to public health and safety which is obviously the ultimate mission or objective of the NRC, that we do it in a collaborative way and not in any sort of adversarial way.

I know there's always just sort of dynamic in terms of a licensee or an applicant and the NRC and

we ask a bunch of questions, you got to give us a bunch of answers.

But in reality, I think we're all striving to get to the same point which is can we get licensed for construction and utilization a facility that can be useful in providing moly-99.

So in that regard, I think what we have is a very common end point. So I guess I would be interested in your all's perspective in terms of how you thought today's discussion went, were we able to address perhaps some of the concerns you've had in the past.

And if there's still some open questions, you know, Steve went through a list of action items, but are there still some things that you all have in your mind that are kind of open or areas that we ought to consider.

Like, one thing I didn't hear in your discussion was the benefit of, you know, sometimes when we get an RAI process there's this kind of throwing stuff over the transom and then you all develop and throw it back over the transom.

And sometimes we can make better progress if we do things like, well we call them audits, right, but we actually either send people to wherever the

information is and have face to face meetings as opposed to going into a sort of a writing campaign. Is that something you guys talked about was the audit process?

MR. LYNCH: We did not talk about that today. But we have had an audit on the environmental side as they were preparing information.

MR. DEAN: Okay.

MR. LYNCH: So we have gone through that.

MS. HAASS: And we've had the discussions in the past and we know that it's one of the tools we can use to make things more efficient.

MR. DEAN: Okay. Okay, good. Okay, and then the other one was I didn't hear anything about would it be beneficial for example to set up an electronic reading room where you guys have materials that you developed that are accessible to our staff through some sort of portal or whatever so there's more ready actions instead of you guys having to mail them.

MS. HAASS: Well, and we are setting that up. There's always technical difficulties because you guys have some requirements and you know what they are, you know, about the encryption and the passwords and this, that, and the other. And so those things

are getting set up.

MR. DEAN: Okay. I think we've had some success where the licensee sort of maintains that and then we just get a password for access and it helps maybe avoid some of those, you know, red tape things that we tend to have as a bureaucracy.

But anyway, so we certainly, that would be something that could hopefully improve or increase efficiency.

MS. HAASS: Well, and another thing that could help efficiencies is I know we talked about it a bit offline just standing here. But, you know, some granularity on how, what RAIs are going to be coming because you're not going to throw all of them over at once.

You may be doing them based on subject matter areas and, you know, getting a better granularity in a schedule like that because that helps both your resources and ours and us to be more efficient in responding as well.

MR. DEAN: So I was pleased to hear that you guys have set up weekly calls. So hopefully you're finding those beneficial. I know that we do in terms of being able to ferret out those sort of things.

And I don't know whether, have you guys kind of developed sort of a standing agenda, or has it kind of been sort of ad hoc? I would assume that there's things that week to week that you're going to want to talk about.

MS. HAASS: Yes, there's definitely a standing agenda. But then, you know, you've got things come on and off that agenda as well.

MR. BALAZIK: And this is Mike Balazik. And sometimes we'll share stuff earlier in the week that is to be a great topic to have on that weekly call so that we can take one level deeper into it if it's just Kevin and I talking. Sometimes we'll move stuff on a weekly call.

MR. DEAN: And also to make sure we get the right people there.

MR. BALAZIK: Correct.

MR. DEAN: Okay, all right. So that's good. I think that's a great initiative to do that. So at least what I'm hearing was that it was a constructive, worthwhile meeting, is that --

MR. FOWLER: I do believe it was a very productive meeting. And for those of you who attended our meeting about a month ago in the Executive Director's office, we understand that the NRC has a

mission for public health and takes the production capability this country for moly-99 very seriously.

We understand that, appreciate that, respect that. I hope that you all also understand that we take our mission of providing that secure, reliable supply of moly-99 in the United States extremely seriously. That was part of the intent with the Executive Director's office when we were there.

We also wanted to communicate that while we all know that this is a public health potential issue, sometimes hearing directly from the feet on the street, the constituents and our supporters and investors are public healthcare institutions serving tens of millions of people across the United States.

And so to hear directly from the CEOs of those public health services organizations I think is important to remind us of just how real the mission that we share collaboratively really is. It's extremely important.

This meeting stemmed as a follow up to a couple of outstanding items from the initial meeting, the first being clarification on our licensing application submission process. And that one, declare victory.

We understand it is in good shape. We

all, I think, are in agreement that we understand where to go from here. We will need to telegraph our approach so that the NRC can anticipate. But we're all on common understanding of that first objective. So declare success on that one.

The much broader one is how do we meet the needs of this country in a timely fashion. And what we achieved today was establishment of a very strong framework that we now understand better how the schedule of review is constructed and built within the NRC.

That helps tremendously because we can look at the assumptions, we can compare the assumptions, and we can begin to manage this as a project. It's likely, in fact it's assured, that we'll need a number of follow up conversations to translate that framework into a plan that can be project managed, and we've left with a joint objective to do exactly that.

And Steve did a great job of summarizing some of those actions. And so we can't yet close with full success the second objective on accelerate the schedule to degree possible.

I think we have a pathway to continue a process to get to a mutually agreed schedule, one that

we can both bring back to our supporters and manage against with expectations, identify milestones, identify where we've deviated from milestones, and take remedial actions as appropriate.

And that, to me, is a successful day spent here in the DC area.

MR. DEAN: Well good, I'm pleased to hear that, Nick, in terms of your perspective on how the meeting went because certainly this was one that I felt was very important, you know, the fact that Michele and I and Lawrence wanted to make sure that we touched base with you all before you left to make sure that the meeting met your objective was very important to us.

And so that gives me great confidence that we did have a constructive and productive dialogue. But we need to sustain that.

MR. FOWLER: Exactly right.

MR. DEAN: And I like some of the things you guys have talked about in terms of potential action items. I was interested a little bit more in exploring the topic that Steve raised that when we have meetings in Missouri and the engagement of the local government.

What's the sort of the rationale, what are

we trying to achieve with that. That's a good thing, but I mean --

MR. FOWLER: That was in specific reference to any ongoing environmental public meeting needs where we've had one meeting in Columbia already. If there were needs for others, the City of Columbia and the County of Boone County in Missouri have offered any and all assistance to the NRC if any is requested.

MR. DEAN: Okay.

MR. FOWLER: They stand ready to help.

MR. DEAN: Okay.

MR. LYNCH: And this is consistent with previous reviews, even for the SHINE review we've gone out for the environmental meetings generally, send an email to the city manager and county executives, let them know we're coming, offer any government-government interaction they would like to better understand our process and work our way forward.

MR. DEAN: Okay.

MR. LYNCH: So that's all consistent.

MR. DEAN: Okay. Good, okay. Good.

MS. HAASS: And there's also the ability that they would help you coordinate to make things easier, you know, on you. They have the facilities

available.

MR. DEAN: That's great.

MS. HAASS: And so, and they want to be involved.

MR. DEAN: Super. Okay, that's wonderful. Okay, good. Okay. Anything for me that you would like to convey beyond what you already have?

MR. FOWLER: Well I think that again, we've had a successful meeting. I think in other strategic partnerships that are collaborative in business that I run, we have not only program management at the level of checking all the boxes on the program plan, we have a refreshment at this level to ensure that both parties are in fact comfortable with progress and resource assignments and strategic alignment as we move forward.

Certainly it doesn't need to be a monthly meeting at this level, but probably on a quarterly or semi-annual basis it would make sense for us to touch base at this level to ensure that we're both meeting each other's expectations of moving forward.

MR. DEAN: Okay. And you're comfortable with the 12 to 15 to 1 ratio of members of the NRC? Is that okay? You're comfortable with that ratio?

MR. FOWLER: Well, come out our way and

we'll reverse the ratio.

MR. DEAN: Good, good. Well, anything else that you would like to achieve today?

MS. GAVRILAS: No. I think we met their objectives and we have a good meeting.

MR. DEAN: Okay, good. Good. All right, so who do I point to in terms of is it Mike is the sort of individual that I want to point to as somebody, for SHINE I went to Steve a lot. So is Mike?

MS. GAVRILAS: So that was one of the issues we discussed that even though there are multiple organizations involved in the review, there will be one voice for the NRC and that voice is Mike.

MR. DEAN: Okay, good. Okay, good. Super. Okay, anything else? Excellent. Okay.

MR. FOWLER: Finished the agenda on time.

MR. DEAN: Safe travels. Safe travels back.

MR. BALAZIK: This is Mike Balazik. I just want to thank everybody for attending the meeting today. And we're going to close the bridge line. Thank you.

(Whereupon, the meeting in the above-entitled matter was concluded at 2:58 p.m.)