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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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628TH MEETING

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS

(ACRS)

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THURSDAY

OCTOBER 8, 2015

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ROCKVILLE, MARYLAND

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The Advisory Committee met at the Nuclear Regulatory Commission, Two White Flint North, Room T2B1, 11545 Rockville Pike, at 8:32 a.m., John W. Stetkar, Chairman, presiding.

COMMITTEE MEMBERS:

JOHN W. STETKAR, Chairman

DENNIS C. BLEY, Vice Chairman

MICHAEL L. CORRADINI, Member-at-Large

CHARLES H. BROWN, JR. Member

DANA A. POWERS, Member

HAROLD B. RAY , Member

JOY L. REMPE, Member

PETER RICCARDELLA, Member

STEPHEN P. SCHULTZ, Member

GORDON R. SKILLMAN, Member

DESIGNATED FEDERAL OFFICIAL:

MAITRI BANERJEE

QUYNH NGUYEN

ALSO PRESENT:

ALEXANDER ADAMS, NRR

MARY ADAMS, NMSS

MARISSA BAILEY, NMSS

VANN BYNUM, SHINE

JIM COSTEDIO, SHINE

DENNIS R. DAMON, NMSS

MARILYN DIAZ, NMSS

MIRELA GAVRILAS, NRR

EDWIN M. HACKETT, Executive Director, ACRS

JAMES HAMMELMAN, NMSS

BILL HENNESSY, SHINE

ROBERT JOHNSON, NMSS

CATHERINE KOLB, SHINE

ROBERT LINK, Areva

STEVEN LYNCH, NRR

GREG PIEFER, SHINE

JANET R. SCHLUETER, NEI

ERIC VAN ABEL, SHINE

*Present via telephone

C-O-N-T-E-N-T-S

P-R-O-C-E-E-D-I-N-G-S

(8:32 a.m.)

CHAIRMAN STETKAR: The meeting will now come to order. This is the second day of the 628th meeting of the Advisory Committee on Reactor Safeguards.

During today's meeting the Committee will consider the following: SHINE Construction Permit Application, Interim Staff Guidance on Acute Chemical Exposures and Quantitative Standards, and Preparation of ACRS Reports.

This meeting is being conducted in accordance with the provisions of the Federal Advisory Committee Act. Ms. Maitri Banerjee is the designated Federal Official for the initial portion of the meeting.

Portions of the session on SHINE Construction Permit Application may be closed in order to discuss and protect information designated as proprietary.

We've received no written comments or requests to make oral statements from members of the public regrading today's sessions.

There will be a phone bridge line. To preclude interruption of the meeting, the phone will

be placed in a listen-in mode during the presentations and Committee discussion.

A transcript of portions of the meeting is being kept. And it is requested that the speakers use one of the microphones, identify themselves and speak with sufficient clarity and volume so that they can be readily heard.

And I'll remind everyone in the room to please check all of your little communications devices and turn them off or silence them so they don't bother us.

I'm just going to remind the people up front to turn on their microphones when they speak. But they're notably absent. So, I'm assuming they've heard that.

And with that, unless any of the members -- maybe they're just really small this morning.

(Laughter.)

CHAIRMAN STETKAR: All right. Well, unless any of the Members have anything that you'd like to add, I'll turn the proceedings over to Dr. Dennis Bley, who will lead us through the SHINE Construction Permit Application.

VICE CHAIRMAN BLEY: Thank you, Mr. Chairman. And they do know how the mics work.

They've been here before three times to talk with the Subcommittee about SHINE's Construction Permit Application for an isotope production facility in the city of Janesville, Wisconsin, for producing Moly 99.

We had three fairly long meetings and went through the complete Preliminary Safety Analysis Report and the SER on that report. And covered a great deal of material.

When we looked at how we ought to try to have them present this to the full Committee, what seemed appropriate was to have an introduction by the staff to put the need for Moly 99 and the unusual characteristics of this design into some perspective. And how they addressed -- how this facility ought to be licensed.

And then our -- the folks from SHINE will give us an overview and really focus on the main facilities in the plant. The irradiation facility and the radio isotope production facility. And then a look at the accident analysis.

So with that, I think I'll turn the meeting over to Dr. Mirela Gavrilas. And ask you to introduce this.

DR. GAVRILAS: Thank you. I'm Mirela Gavrilas. I'm Deputy Director in the Division of

Policy and Rule Making in NRR.

And I'm going to talk today about work that we've conducted over the past 20 months in reviewing the Construction Permit Application for the SHINE medical isotopes production facility.

The staff work supports the national policy of relying -- regarding reliable domestic production of Molybdenum-99. Just as an aside, Molybdenum-99 is used in 50 thousand medical procedures daily.

This work was conducted by a large intra-agency group. The key players were NRR, NMSS, Research and OGC. But we have support from just about every other office in the Agency, including OCA.

In my remarks I will highlight two things that are representative of this work. One, the technical review considerations for a construction permit are different from those for a KOLA or an operating license. Two, the risk posed by SHINE is comparable to that from our mid-range research reactors.

With regard to my first point, the philosophy of the review is rooted in 10 CFR 50.35. I'm going to quite a few excerpts and the panel will later place those excerpts in context.

Under Part A of 50.35, the applicant has identified the major features or components for the protection of health and safety -- of the health and safety of the public.

Two under A, further technical or design information will be supplied in the final Safety Analysis Report. Three under A, the applicant has identified and there will be conducted a research and development program reasonably designed to resolve any safety questions.

And under Part B of the same, a construction permit will constitute an authorization to the applicant to proceed with construction. But will not constitute Commission approval of the safety of any design feature or specification.

There's an exception to that that doesn't apply here. It's only if SHINE specifically asks for something to be -- to have a final Safety Analysis.

So, in practical terms, what does that mean to our reviewers? Our reviewers assessed the sufficiency of the design basis, the completeness and clarity of proposed principal design criteria.

During our review we found that there are a number of issues that remain to be scrutinized closely during the operating license review. These

issues were clearly communicated to the applicant. And they are documented in the appendix to the Safety Evaluation Report.

Furthermore, the staff is proposing construction permit conditions where the design basis needs to be refined. These are in areas where parameters need to be finalized before construction is complete. For example, where design features rather than procedure controls safety.

With regard to my second point, in terms of consequences, the SHINE facility is comparable to mainstream research reactors. Therefore, the safety evaluation of SHINE is similar to that for our RTRs.

It has a containment -- a confinement building, not the containment building. We apply NUREG-1537, you'll hear more about that from our panel, not the standard review plan.

A key evaluation criteria is the maximum hypothetical accident which while improbable is devised to have found in consequences. The consequences of the maximum hypothetical accident for SHINE are well within Part 20, which are the limits for normal operation.

I think you'll hear values of 80 millirem to personnel in the SHINE facility. And 18 millirem

to the public in the case of the MHA.

And with that I'll turn it back to the Chairman. We have, you know, apparently Steve is -- oh, he's back. He made us very nervous this morning because traffic around here has been awful.

But here he is. So, thank you.

VICE CHAIRMAN BLEY: Thanks Mirela. Is Steve going to do a presentation?

DR. GAVRILAS: He's going to talk about it.

VICE CHAIRMAN BLEY: While we're waiting, I neglected to put on the record that Dr. Corradini has a conflict of interest with this issue because of previous work he'd done. And will recuse himself from our discussions on the SHINE Application.

It seems to me that that's about right. Also, while we're waiting, I should let all our folks know, we do have to hold tight to the schedule today. We have to finish no later than 11:00 with this session because of other commitments.

MR. LYNCH: Thank you for having us back. We are excited to be here. So we put our presentation structured to be in two parts today.

We're going to talk about first a little bit of background on Moly. Our review process. And

then we'll let SHINE talk about their application and then we'll come back and talk about our conclusions of the review.

So just a couple of quick slides on some background on Moly 99. Just in case anyone in the room is unfamiliar with why we're all here.

While, Moly is what we're producing, what we are really after is gaining technetium-99m. Which is used in approximately 50 thousand medical procedures in the U.S. daily.

Technetium-99 is highly desirable. It easily tags to compounds to be carried to organs for evaluation. And it gives off a nice strong gamma ray.

Methods of Moly production. The three mains ones are neutron captured transmutation and fission. If you come to some of our Moly 99 conferences, some of the people have some very interesting ideas of how to produce Moly as well.

But, what I wanted to highlight here, as far as the NRC is concerned, we're mostly looking at licensing those proposals that are going to be using fission with special nuclear material.

As far as the status of the domestic supply of Moly 99, there are currently no domestic producers. Currently the U.S. relies entirely on

foreign producers, namely Canada. Which is set to cease production within the next year.

Fifty percent of our supply comes from Canada. So, one of the United States policy objectives is to ensure a reliable supply of Moly 99. And this is coming from the Office of Science and Technology Policy.

In conjunction with securing a supply of Moly 99, they are also working to eliminate highly enriched uranium from used Moly 99 production. This is mostly an international concern.

Most of the reactors internationally had been using highly enriched uranium for Moly 99 production. However, all of the U.S. producers will only be using low enriched uranium.

Production is also encouraged by the National Nuclear Security Administration. They've established commercial partnerships with several companies. SHINE being one of them.

Now, as far as how the NRC comes into play here, the NRC is reviewing all applications submitted in accordance with our regulations. We're also working with other Federal Agencies in our reviews.

We are coordinating environmental review work with the Department of Energy. And this is in

accordance with the American Medical Isotopes Production Act.

We're also coordinating with the Department of Homeland Security. Who under the Energy Policy Act has the responsibility to conduct site vulnerability assessments of all new utilization facilities. So that they are also involved in this.

To give a brief introduction to the technology SHINE is proposing, SHINE has requested a permit to construct a new medical radioisotope production facility in Janesville, Wisconsin. If this permit is granted, this would allow them to construct eight commercial, non-power utilization facilities and one production facility.

In the utilization facilities, these would be eight accelerator driven subcritical operating assemblies that would produce Moly 99 through the fission of a uranium solution. After the irradiation, the solution would pass to three hot cells structures that would comprise the radioisotope production facility that would chemically separate the Moly 00 from the uranium.

To go into a little bit more detail on the irradiation facility, in terms of licensing space. Looking at the radiation units, they have a lot of

similarities to our existing research reactors.

In terms of power levels, research reactors that are operating today, operate between five watts and 20 megawatts. SHINE -- these are all heterogeneous solid fuel reactors.

The NRC has licensed 20 aqueous homogeneous reactors in the past. Which are more similar to SHINE. The only real difference between an aqueous homogeneous reactor and SHINE is that SHINE will be operating subcritical in terms of safety considerations.

Safety considerations are the same for a lot of our research reactors and with the previously licensed aqueous homogeneous reactors. We're still concerned about fission heat during operation. Decay heat after shut down. Fission gas release.

And we're also seeing similar accident scenarios. You know, we're considering loss of coolant, reactivity additions and fission product releases.

However, while it looks a lot like a reactor, in license space we had some concern because it didn't meet the definition of a nuclear reactor. How we define a nuclear reactor in our regulations is that you have to maintain criticality.

And if you're subcritical, you can't be a reactor. And if you're not a reactor, we can't license you under Part 50 as a utilization facility.

So, we also looked over to Part 70 and though well, since it's subcritical, can we license it under part 70? Worked with our colleagues in NMSS and SHINE just didn't -- wasn't -- is only just slightly subcritical.

And our friends in Materials did not like that that's a very small margin. And also, most of the fuel cycle facilities don't have a lot of active fission going on. Where the goal is to have a lot of heat.

So, in order to address this issue, we did propose a direct final rule that was issued in October 2014. And what this did, is it modified the definition of utilization facility to add SHINE's irradiation units.

This was a rule of particular applicability in that the rule was intended only to affect SHINE. We actually put SHINE's docket number in the rule.

So, we didn't want to have any unintended consequences with this rule. For example, if you just -- if you were at a university and wanted to irradiate

just a little piece of uranium, we didn't want you to be confused with something like SHINE that actually has a lot, you know, that looks more like a reactor.

Now, a few words on the radioisotope production facility. As I mentioned, it will consist of three hot cells.

One interesting thing to note that this is another part of the facility that we thought, you know, could we license this under Part 70? But if you look at the -- there are three definitions of what a production facility is under Part 50.

Originally production facilities were those that produced special nuclear material, you know, that was used for weapon and safety. Another type of production facility, are any type of facility that are designed or used for the processing of irradiated materials in batches of greater than 100 grams.

So there's our threshold for determining, are we in Part 50 space or are we in Part 70 space. SHINE's proposing to process their batches of special nuclear material in batches greater than 100 grams.

So, that put them into the venue of being a production facility. In the NRC, we've licensed production facilities in the past, but not for a long

time. The last operating production facility we had was West Valley, which ceased operations in 1972.

And also, just looking beyond that, there have only been two facilities that the NRC has licensed that have done similar things to SHINE's production facility. One of those is Cintichem, which was a Moly 99 producer in the '80s. And ceased operations in 1990.

They had a similar hot cell structure that they were separating Moly 99 from irradiated uranium. However, looking back at their license, they happened to be licensed under Part 70. So we didn't have a whole lot of parallels to draw from the licensing process there.

And looking back at West Valley, while this was also a production facility, it was also a reprocessing facility. And reprocessing facilities fall under the second definition of a production facility, which has to do with plutonium separation, as processing facilities were heavily on the PUREX process for their operations.

SHINE is using a similar process. They're UREX process for their processing of the uranium. However, the staff doesn't consider this reprocessing because it does fit under that different definition of

a production facility. They aren't separating to the plutonium.

Also, we have a very specific definition of what we're considering with fuel reprocessing, and that's reprocessing of spent nuclear fuel. And in Part 72 of the Regulations, spent nuclear fuel has a very specific definition as far as fuel that's coming out of a nuclear power reactor. And has sat in a spent fuel pool for at least a year.

SHINE is only processing its targets. And will not be processing any spent nuclear fuel.

So with that, I'll start getting into the licensing process. So as I mentioned, we're going to license SHINE under PART 50.

Their irradiation units are going to be utilization facilities. And the hot cells will be licensed as a production facility.

It's important to note that SHINE has only requested a Part 50 license for their construction permit. They have not yet requested licenses to possess material.

We do expect that as they get ready to submit their operating license that there will be a request for a Part 70, Part 30, and Part 40 licenses. And we will evaluate those when those are submitted.

But, as of now, we are only issuing -- reviewing a Construction Permit Application that will have no material onsite.

As far as the regular reporting requirements for this construction permit, the first of these it's interesting to point out is, under 10 CFR 50.22 that talks about licensing commercial and industrial facilities. This is calling back to the Atomic Energy Act where we have two classes of facilities.

We have commercial facilities licensed under Section 103. And noncommercial facilities or research facilities licensed under Section 104. And our parallels in the Regulations are 50.21 and 50.22.

So while SHINE has a lot of similar safety considerations to existing research reactors, they are solidly licensed at -- all those research reactors are licensed as noncommercial facilities under Section 104.

SHINE is a commercial facility. So they're going to be licensed under 103.

So that means in terms -- in practical stance from our regulations, there's not a whole lot of difference from the licensing requirements we place on a Section 103 versus a 104 license. Most of the

Regulations differentiate between nuclear power reactors and everything else.

So since SHINE falls into the everything else category, most of their licensing requirements are still very similar to how we license our existing research reactors.

One important difference though with commercial facilities is that when they apply for their construction permit, they are required to come before the ACRS. And they are also required to have a mandatory hearing.

So that is interesting. If SHINE had chosen to be a noncommercial facility, we might not be sitting here today.

Some other requirements here. They did submit an environmental report that was reviewed separately from what we're talking about today.

An environmental impact statement was prepared on this and was sent to publishing last week. So we should have a NUREG ready on that in the next week or so.

SHINE did submit a Preliminary Analysis Report which I'll talk about in a few minutes. But I also wanted to highlight here the dose requirements for both occupational workers, the public and even

under accident conditions.

As a non-power facility, SHINE follows Part 20 in all of these cases. The occupational dose limits are a TEDE of 5 rem. The public and accident dose requirements are a TEDE of 0.1 rem.

So, this is a little -- actually following Part 20 by being a noncommercial facility, as I mentioned below, Part 100 accident dose criteria don't apply. So it's actually a little bit more restrictive.

Under Part 100, under accident scenarios, you can have a whole body dose to the public of up to 25 rem. But with SHINE as they're being licensed, they are held to .1 rem.

So that is actually much more restrictive. And looking at their accident scenarios, which we'll get into a little bit more in a couple of slides, they are well below both of these limits.

For occupational limits, under their maximum hypothetical accident, which Mirela mentioned, they are only anticipating 3.59 rem. And for any accident that happens, they're anticipating a TEDE at the site boundary of .08 rem. And to the nearest residents of .01 rem.

So they're only -- they're an order of

magnitude lower then the regulations are setting as a limit.

And I'll also go over later the requirements under 50.35. But talk about the findings that the Commission needs to make in order to issue a construction permit and the staff's findings on that.

I did want to point out here that one of the differences between licensing nuclear power reactors and non-power reactors like -- or other facilities like SHINE, is that some of the appendices in Part 50 don't apply.

For example, Appendix A, the general design criteria, are not directly applicable to SHINE. However, if you look at 50.34 and the requirements that must be in a Preliminary Safety Analysis Report, all applicants for a construction permit must have principle design criteria.

In this case the NRC decided to specifically enumerate what those design criteria are for power reactors. For everyone else, it was left up to the facility to decide.

Also Appendix B for quality assurance, does not apply. However, also under 50.34, SHINE is required to have a quality assurance program.

And, what we do for reviewing quality

assurance is we -- as endorsed by REG Guide 2.5, we do use ANSI standard 15.8. And the only real difference is, the scope of both of these programs is very similar.

But we adjust some of the language to be more appropriate for non-nuclear power reactors. For example, the definition we have, we don't use the definition of safety related structure systems and components as used in Appendix B.

We have a different definition of safety related items. Which is a little bit more generic and not directly tied to nuclear power reactor technology.

For some of the requirements for Construction Permit Applications, the two main components of the application are an Environmental Report and a Preliminary Safety Analysis Report. Today we're focused on the Preliminary Safety Analysis Report.

What I wanted to highlight were some of the requirements that go into the PSAR. They have to have a preliminary design. And need to have principle design criteria.

A design basis. And a general arrangement in approximate dimensions of the facility. They're also looking to have a preliminary analysis of the

structured systems and components. Including the ability of these SSEs to prevent and mitigate access.

What I think is important to emphasize here, is that we see the words preliminary, general arrangement and approximate dimensions. With how the regulations are written, we are not expecting a final design from the facility.

What we are looking to have, is have the preliminary design provide reasonable assurance that the final design will conform to the design basis. And I'll talk more about that in a couple of slides.

We also don't have technical specifications with the Preliminary Safety Analysis Report. What is required is that the applicant identify areas that they think will be subject to technical specifications.

And the applicant has done that. And the staff has reviewed those.

There's also a preliminary emergency plan that needs to be submitted with the Preliminary Safety Analysis Report. This is not a full emergency plan as we discussed at the earlier subcommittee meetings.

But what we did do for our review is make sure that SHINE understands the full scope of what the final emergency plan needs to look like. And has made

adequate commitments to provide that, all of the detailed information in the final Operating License Application.

We still have a quality assurance program. And lastly on here, I wanted to highlight that the regulations also allow for research and development to be ongoing throughout construction.

So, that's interesting too that the Regulations are acknowledging that the sign is not final. And the applicant many identify programs that require additional research and development that do need to be completed for construction.

To contrast that a little bit with the requirements for Operating License Applications and the operating license. We will have your final Safety Analysis Report. This will be in your final design.

And all those things that were preliminary originally, we finalize. We get your plans for operation and other procedures that were not submitted and were necessary to issue a construction permit.

We get the full emergency plan. We see your technical specifications. And we get a physical Security plan as well.

Now to highlight a couple of differences in philosophy from issuing a construction permit

versus an operating license. The construction permit as Mirela mentioned, only allows the licensee to proceed with construction.

It does not approve, as described in 50.35, of the safety design of any feature of the facility. That is saved until the Operating License Application, which under 50.57 allows operation.

And at this time, one of the requirements before we can allow you to operate is that you -- that we do have reasonable assurance that the activities authorized by the license will not endanger the public health and safety.

So, and I'll talk -- as I'll talk a little bit in our findings, while we're not approving the safety of any feature, and we understand that SHINE's continuing to define their design.

What we did look at was, you know, do we have adequate margin for safety in the preliminary design? And is the desi -- do we have confidence that they will be able to conform to the design basis that they set forth.

In terms of how we specifically reviewed the application, we primarily relied upon the guidance in NUREG-1537. Which is the standard review plan for reviewing applications for non-power reactors.

Recognizing that SHINE and other applicants for Moly 99 applications would not necessarily be traditional non-power reactors, the staff did develop interim staff guidance to review more technology specific features of these facilities.

So we fit interim staff guidance that provided additional guidance on how to -- for the applicants to prepare and the staff to review radio -- production facilities and aqueous homogeneous reactors.

MR. COSTEDIO: Excuse me. This is Jim Costedio. I think there's 15 people on the bridge line that can't hear the meeting right now.

MR. ADAMS: You can go ahead.

MR. LYNCH: Okay. I think I wanted to make another comment here.

MR. ADAMS: I just want to make one comment. When we were developing the ISG, for example for the ISG for the radioisotope production facilities, we were fortunate enough to have on the research test reactor licensing staff, the gentleman who was the last operations manager at Cintichem.

And also in develop -- while we were developing the ISG -- we had under contract working for us --

VICE CHAIRMAN BLEY: Back up just a little.

(Laughter.)

MR. ADAMS: Should I start over again?

VICE CHAIRMAN BLEY: Yes.

MR. ADAMS: So when we were developing the interim staff guidance in the area of the radioisotope production facilities, we were fortunate enough to have on our staff, the gentleman who was the last operations manager at Cintichem.

So, you know, we had that knowledge of actually how Cintichem operated. And also we had under contract to us while we were developing the ISG, the gentleman who was the last facility director at Cintichem.

So, you know, it wasn't theoretical knowledge we were gathering. It was the actual how. You know, how Cintichem did this. So, that reflected in our -- in the guidance development we put together.

MR. LYNCH: Thank, Al. Yes. We also relied heavily on NMSS to help us -- to help inform our interim staff guidance to incorporating appropriate guidance from their standard review plan on licensing fuel cycle facilities.

Other guidance was used as referenced in

both the ISG and NUREG-1537, referring to REG guides, other NUREGS and ANSI Standards as appropriate.

VICE CHAIRMAN BLEY: Steve?

MR. LYNCH: Yes?

VICE CHAIRMAN BLEY: You're running a little bit behind. You got about ten more slides to go. So, --

MR. LYNCH: What I was hoping -- I was going to break those up. So I was only going to cover about three -- let me see, I'm --

VICE CHAIRMAN BLEY: You're on track then. Go ahead.

MR. LYNCH: Yes. I'm going to only talk about three more slides right now. And then we'll cover the rest when I come back up.

So just real quick. I'm going to highlight the review chapters that we -- the areas of review that we went over in our standard review plan.

Site characteristics, structure systems, components, cooling systems, engineered safety features, instrumentation and control, electrical power systems, accident analysis, financial qualifications. Those were some of the highlights.

I did star a couple of chapters here that were not applicable to SHINE. That were more specific

to other types of facilities. For example, for the construction permit, we weren't looking for decommissioning plans.

SHINE also is not converting a previously existing facility from high enriched uranium to low enriched uranium as indicated in Chapter 18. And there is -- also Chapter 16 was not applicable as by other licensing considerations we're looking at facilities that are using components that have been used in previous facilities.

Or we're looking at some of the more unique facilities that are used in direct medical therapy. As in your irradiating someone with the reactor. SHINE is not doing that either.

To quickly go over how the staff applied this guidance. Since the construction permit only allows construction, the level of detail that we needed in the application, in the staff's SER, is different from that for a combined operating license or even for an operating license for example.

And this gets back to what I had said earlier. That we're not necessarily looking for a final design. We're looking for, did SHINE apply the appropriate methodology in their thought process to get to the final design?

That's what's important to us now. And, did they identify the full scope of what needs to be in the final design?

We want to make sure that they understand what we will be looking for come the operating license. And not have that be a surprise. Because that will inform how they continue to improve and refine their design going forward.

And as we mentioned earlier, for the purposes of issuing a construction permit, the facility may adequately be described at a functional or conceptual level. And as such, SHINE has elected to defer many of the design and analysis details in the submission of its Final Safety Analysis Report.

The staff is -- for these areas the staff either has that documented in the PSAR, those areas that are specifically SHINE is going to defer. Or we are tracking those as regulatory commitments in an appendix to our SER.

So every time SHINE told us that they were going to provide information later, we have that documented. And we're tracking that to make sure that they actually do that.

In using this guidance that we have in our ISG, it's a lot just to tailor our review to the

unique and novel technology that's in SHINE's application.

As far as resolving the technical deficiencies in the application, so these are the areas. We reviewed the application, decided we wanted more information.

There are three categories when reviewing a construction permit of these types of deficiencies. Some of those we may decide that we need right now in order to issue the construction permit.

And these are issues related to establishing the design basis of the facility. Other issues, we may decide can be left completely until the Final Safety Analysis Report.

And then there are other issues that we think we have enough information to issue the construction permit. But we still believe that the applicant needs to resolve those before the completion of construction.

So in all three of these cases, the staff can issue, and it did issue request for additional information. For the first option, we're expecting those RAIs to come to completely satisfy the information we need to support issuing a construction permit.

In the second and third cases, the staff can track this information as either regulatory commitments or necessary license conditions in the application or in our Safety Evaluation Report.

And I think this is where I'll pause for right now and let SHINE talk about their application. But I'm happy to answer any questions you may have right now.

VICE CHAIRMAN BLEY: Thanks Steve. That was just the overview that we were looking for. Anything from the Committee?

Then we'll move onto the design.

MR. LYNCH: Okay. Thank you.

VICE CHAIRMAN BLEY: Please, go ahead.

MR. HENNESSY: Good morning everyone. You're here today to discuss the SHINE Medical Technologies application to construct a medical isotope plant. This presentation will summarize the main points of the previous three meetings with the ACRS subcommittee.

And I would like to say that we're as excited as the NRC is to be here. It's been quite a process for us. It's very interesting. And a lot of twists and turns.

But we think we see the light at the end

of the tunnel. So, we're very happy to be here. Next slide please.

VICE CHAIRMAN BLEY: It's probably an oncoming train.

(Laughter.)

MR. HENNESSY: SHINE Medical Technologies is a private corporation based in Monona, Wisconsin. As Steve mentioned, the purpose of our plant is to produce the medical isotope Moly 99.

The plant will be comprised of two main processes. Irradiation and processing, which are located in two separate areas of the facility that we identify as the irradiation facility, IF, and the radioisotope production facility, RPF.

The facility is located in a previously undeveloped 91-acre parcel of land in the southern boundaries of the City of Janesville, in Rock County, Wisconsin. Next slide please.

The map on the right side shows the general location of the SHINE facility in the extreme south-central Wisconsin. Close to the border of Illinois.

On the left, we show the 91-acre site just south of the main part of the City of Janesville. Next slide please.

This image illustrates the site layout. The two main processes are designed to occur within the main building. Other outlying buildings include a waste staging and shipping building, a maintenance building and an administration building.

I would like to note that these structures take up a relatively small area on the site situation in the middle of the site, which allows us to have a large buffer to the site boundary. Next slide please.

This drawing shows a plan view of the main building with the two main process areas. The blue area, the area outlined in blue, is the irradiation facility.

And the area in green is the radioisotope production facility. Eric Van Abel will discuss these processes in more detail in just a few moments.

SHINE system designs are based on defense in depth practices. We prefer engineered and passive controls over administrative controls.

The single failure criterion is applied to our safety systems. Where a single failure of an active component in conjunction with an initiating event does not result in the loss of that system's ability to perform its intended safety function.

Safety related system structures and

components can withstand earthquakes. And non-safety related SSEs are designed to not degrade the function of a safety related system -- structure or component as a result of an earthquake.

The SHINE quality assurance document describes the administrative and engineering controls we will use to ensure compliance with the Regulatory requirements.

MR. VAN ABEL: Hello, I am Eric Van Abel. I'm going to first give a brief overview of the actual processes that we use to produce medical isotopes.

In the figure here, we show a high level schematic. We begin at the bottom by producing the target solution. We prepare it by dissolving uranium oxide into sulfuric acid.

And then the target solution is transferred over to a target solution hold tank. That hold tank is unique for each for radiation unit cell. So there's one hold tank per TSV.

When we want to begin filling the TSV, we transition to state up mode. And begin transferring that target solution in discrete increments over to the TSV.

Once we've filled it up to our target fill volume, then we begin the irradiation process. We

transition to irradiation mode. Irradiate for five and a half days. Produce our medical isotopes from fission.

And then we transfer that target solution over to a super cell, which is just a larger hot cell where we extract the medical isotopes. And then most of the time the target solution is returned to a target solution recycle tank.

We have three target solution recycle tanks that are a buffer before we can move that solution back into one of the eight target solution hold tanks. And then the process would normally just be repeated.

Occasionally we go through a cleanup process where the target solution is directed to the UREX processes as was mentioned before. And the associated cleanup processes there.

Following UREX, we remove the fission products from the uranium. As well as the plutonium. We produce uranium oxide again

And then we can re-prepare the target solution again in the target solution preparation process. And then that's just reinjected back into the target solution hold tank. Next slide.

First, let me begin by talking about the

irradiation facility. Your irradiation unit has a subcritical assembly, a neutron driver, a variety of supporting systems that support the radiation process.

There's eight of those in the facility. Each in their own individual concrete shield itself.

Supporting system include biological shielding, the light water pool, the off gas system, which manages hydrogen and oxygen concentrations.

And the primary coils to the cooling system that provides cooling as well as a tritium purification system that supplies clean tritium to the accelerator so they can keep performing at full output.

The primary system normally is not a pressurized system. It operates at subatmospheric pressures to minimize potentials for leakage of fission product gases or other radioactive materials.

When we want to shut down the process, the TSV is drained to a subcritical, passively cooled dump tank that's in the light water pool. And that's through two redundant fail-open dump valves.

The TSV itself is an annular vessel constructed of Zircaloy-4. We don't have any mechanical mixing while we're irradiating the solution.

The target solution is just naturally convected inside the vessel. Next slide.

On this slide, on slide nine, there is a schematic. A rendering of the subcritical assembly. The subcritical assembly support structure is shown in the center there as the main vessel.

Inside of that vessel -- it's a vessel inside of a vessel concept. There's the TSV and the neutron multiplier.

So the TSV is what holds the solution during irradiation. The dump tank is located directly blow it connected by dump and overflow lines. Next slide.

The irradiation units all have one neutron driver that sits directly above that. That's the accelerator that produces the fusion reactions that drive the fission process.

It's an electrostatic accelerator with a gas target that produces the D-T fusion. Which generates 14 MeV neutrons in the center of our subcritical assembly.

Those 14 MeV neutrons are multiplied to a neutron multiplier and through subcritical multiplication inside the TSV.

The driver itself performs no safety

related function. Therefore, it is not safety related. If the driver shuts down, the fission process in the TSV is automatically terminated.

The TSV off-gas system is connected to the TSV and continually sweeps gas over the TSV head space. That maintains the hydrogen concentrations below the LFL.

It brings the hydrogen to a catalytic recombiner to recombine it with oxygen. And then return any produced water back to the TSV.

It contains the fission product gases that are release during irradiation. And maintains the system at a negative pressure while we're irradiating.

The whole lower portion of the IU cell there, below that IU cell floor grading is a light water pool. So, that's all filled with water.

Those flow vents are under water. And that water provides shielding and decay heat removal.

The purity and purification systems is not shown on this figure. But it connects to the neutron driver and supplies the clean tritium to the accelerator.

The accelerator mixes the tritium and deuterium. And the tritium purification system separates them back and returns them to the

accelerator.

The tritium lines in the processing equipment are in glove boxes and double walled piping. Which is inerted with nitrogen.

When we want to start up the TSV, we begin by measuring uranium concentration and any other assay parameters of the target solution such as temperature and pH of the solution. We then begin filling the TSV in discrete batches.

We move a discrete amount of uranium to the target solution vessel. We monitor the flux change. And begin the one over flats that are typically done with research reactors.

The difference is, we stop early. We don't go to critical. We -- our final fill level is approximately five percent by volume below the critical volume of the TSV.

And during the fill process, there are automatic safety systems that are monitoring and ensure that the TSV will trip and dump the target solution should we exceed the expected fill volume.

Or something else unexpected occurs such as low PCLS temperature. Then we can transition to irradiation mode. Next slide please.

So in the irradiation mode, we isolate

that batch of target solution in the TSV. We close the isolation fill valves so you can't add any more fissile material to the TSV.

We energize the driver and begin supplying tritium. And that slowly ramps up the driver output. And we irradiate then for approximately five and a half days.

As we irradiate, the reactivity drops significantly in the TSV due to the heat generation and void from the radiolytic fission product gases. The temperature in the TSV will increase from approximately 20 degrees C to nominally 60 degrees C during full power irradiation at our licensed power limit.

During the irradiation process the two TOGS system is continuously sweeping gas over the TSV head space and recombining hydrogen PCLS. And light water fuel cooling loops are removing head from the fission process.

Those cooling loops are only necessary for operations. They're not required for shutdown cooling. And then following shut down, the light water pool is a sufficient heat sink.

Even if we lose after cooling, temperature rise in the light water pool is approximately 12

degrees after 90 days eval in the active cooling of the pool in decay heat.

MS. KOLB: I am Catherine Kolb. I'm going to -- I just have a couple of slides here on the radioisotope production facility to go into more detail. This is the part of the facility where we prepare the target solution as Eric mentioned before.

The low enriched uranium metal that we plan to receive from the DOE's wide well facility, is first dissolved in nitric acid. That uranyl nitrate solution is converted to uranium oxide by a heating process, by denitration.

And then we use sulfuric acid to dissolve the uranium oxide and produce our uranyl sulfate target solution. After the target solution is irradiated, it is transferred to the radioisotope production facility, the RPF.

It first goes to a super cell that is a hot cell. It's divided into three portions for the extraction, purification and packaging of the molybdenum-99 products.

The first part is the extraction parts where the target solution is passed through an extraction column. And that is then sent to a recycle tank as was depicted in one of the earlier slides.

The second portion is the purification portion where we do the Cintichem process to purify the products. And it is then transferred to the third portion where it is packaged in small bottles and then into larger shipping casks for distribution.

The RPF is also where we perform the recycling and cleaning of the target solution. We use the UREX process, or uranium extraction solvent extraction.

Then that is done on a uranyl nitrate solution. And that is converted back into uranyl sulfates using the same equipment as used for preparing target solution in the first place. The next slide.

The RPF is also where we do many of our waste handling activities. Solid wastes such as miscellaneous equipments and trash is consolidated and packaged.

The aqueous liquid wastes are concentrated by evaporation. Processed and held for decay for a time. And then solidified for shipments offsite.

The gaseous wastes are treated onsite prior to release. The Noble Gas Removal System stores the TSV off gases from the TSV Off Gas System from the irradiation for at least 40 days in gas decay tanks

prior to sampling for release.

These decayed off gases are released to the Process Vessel Vent System. This system also receives gases from the various process vessels in the RPF, the hold tanks and other things.

The caustic scrubbing is also part of the PVVS system where we remove acid gases and some iodine species. The off gases are passed through charcoal and HEPA filters and monitored to ensure radioactivity levels are below regulatory limits prior to discharge through the facility vent stack.

VICE CHAIRMAN BLEY: Before you go on. Will this be the largest scale application of UREX to date?

MS. KOLB: I believe so. It was --

VICE CHAIRMAN BLEY: It's mostly been laboratory work before, right?

MS. KOLB: That's correct. They've done some laboratory work, UREX, on spent fuel from a commercial reactor. But I believe that was as far as well.

VICE CHAIRMAN BLEY: Anticipating areas where you're going to have to prove it at the production level, where things are kind of worried about that might crop up? Since this is the first

really production kind of operation.

MS. KOLB: So it's very similar to the PUREX process, which is --

VICE CHAIRMAN BLEY: But not quite, yes.

MS. KOLB: Yes. But not quite. But with the main difference is that the plutonium goes with the waste products, which raffinates. With the fission products.

MEMBER POWERS: PUREX hasn't been trouble free.

(Laughter.)

MS. KOLB: We understand. But, there is a good operating experience that we can utilize.

VICE CHAIRMAN BLEY: Well get some more, okay.

MR. VAN ABEL: All right. SHINE uses engineered safety features in our facility to mitigate consequences of potential accidents. I'll discuss potential accidents in a moment.

But, first a little bit on the ESFs. It's important to note that our radio nuclide inventory in any one confinement area is approximately ten thousand times less than a power reactor.

Also, our processes are generally low temperature, low pressure processes. Not like a power

reactor, which minimizes disbursal forces that you would expect to occur during a potential accident.

We do have confinement areas. And the figure on the right here, this shows the ventilation zones. And I bring this up because it's a good layout of cells and shows the differential pressure ventilation zones.

The right areas are the lowest pressure zones. That's where we had the highest potential for contamination. That's where our actual processes are occurring.

For instance, the hot cells, the irradiation unit cells and all the gas cells. And those are the pressure zones. And the yellow is the next highest pressure above that.

And it's cascaded out again to the green and the blue. So that minimizes our potential release of radioactive materials outside the cells during normal operation.

And those red areas principally are confinement, active confinement areas that we have in the plant for potential releases.

CHAIRMAN STETKAR: Eric, just for clarification.

MR. VAN ABEL: Yes?

CHAIRMAN STETKAR: The blue is actually a separate ventilation system, right?

MR. VAN ABEL: Yes. The blue is --

CHAIRMAN STETKAR: It doesn't communicate with the red, yellow and green?

MR. VAN ABEL: Except for when you open the doors and expel material, yes.

CHAIRMAN STETKAR: Except, well yes.

MR. VAN ABEL: But yes, the blue is outside the RCA, yes.

CHAIRMAN STETKAR: He's getting more careful.

(Laughter.)

VICE CHAIRMAN BLEY: After several years, you'll learn.

CHAIRMAN STETKAR: And you're leaning quickly. Okay. Thanks.

MR. VAN ABEL: The confinement functions are provided by the walls of the biological cells, by the biological shielding in the cells themselves, the IU cells, the hot cells, the tank faults and trenches.

We also have isolation valves on the piping systems. And the -- active isolation dampers on the ventilation systems that close in response to an isolation signal.

The RVZ1 duct work and the RVZ1 and RVZ2 -- sorry, the RVZ1 and RVZ2 duct works and the RVZ1 and RVZ2 filters are also part of the confinement process.

The ESFAS system, Engineered Safety Features Actuation System actuates ESFs in the IF. And in the RPF, they're actuated by the Radiological Integrated Control System, the RICS.

CHAIRMAN STETKAR: Eric, before you leave this, and I know that we need to be careful about proprietary versus nonproprietary information. So if I go over that line, alert me and we'll see how we address it.

The areas that are color-coded in blue on this drawing, we've had some discussion about those areas for a variety of reasons.

MR. VAN ABEL: Um-hum.

CHAIRMAN STETKAR: And they contain things like the main control room and the electric, AC switch gear rooms, the DC power supply rooms, the instrumentation, and as I said, assuming -- if I get too far, just tell me.

Instrumentation control power rooms and protection rooms for all eight irradiation units. So they're common to the entire facility there.

And I wondered, they're categorized as non-safety related, as is their ventilation system. And I didn't know if you wanted to -- could you address that a bit?

Because we've had some discussions about why those particular areas are not characterized as safety related parts of the facility.

MR. VAN ABEL: When you said they are characterized, you mean the areas are?

CHAIRMAN STETKAR: The areas and hence the equipment inside those areas are characterized as non-safety related.

MR. VAN ABEL: So there is the portion of the building extending, drawing south on this figure to the bottom is actually safety related. That part of the structure that's in blue there.

CHAIRMAN STETKAR: That part of the structure that's in blue? Okay.

MR. VAN ABEL: At the bottom.

CHAIRMAN STETKAR: At the bottom. Well, thank you. Okay.

MR. VAN ABEL: So these --

CHAIRMAN STETKAR: Yes, just use the mouse so that -- yes. So that the -- the second of the blue that we see on this slide that has the darker black

outline --

MR. VAN ABEL: Yes. That's a seismic boundary.

CHAIRMAN STETKAR: That is a seismic boundary?

MR. VAN ABEL: Yes.

CHAIRMAN STETKAR: Okay. Thank you.

MR. VAN ABEL: That is a safety related structure, yes.

CHAIRMAN STETKAR: It's a safety related structure although the --

MR. VAN ABEL: The question I figure you're asking about --

CHAIRMAN STETKAR: The things inside of it aren't necessarily characterized as safety related equipment?

MR. VAN ABEL: Some of them are. Some of them are not.

CHAIRMAN STETKAR: Some of them --

MR. VAN ABEL: Yes.

CHAIRMAN STETKAR: Right. Some of the protection cabinets are.

MR. VAN ABEL: Yes. Like the UPS system that's there, that is safety related.

CHAIRMAN STETKAR: Yes. Okay.

MR. VAN ABEL: It has equipment inside that.

CHAIRMAN STETKAR: Thanks. That helps. That helps, thank you.

MR. VAN ABEL: Next I'm going to discuss --

VICE CHAIRMAN BLEY: Before you do.

MR. VAN ABEL: Yes?

VICE CHAIRMAN BLEY: Just a couple of things. One, you haven't had a lot of comments from the Committee, but I noticed that almost everybody on the full Committee here today was at some or most of our Subcommittee meetings. This drew a lot of interest.

Which is part of the reason you haven't heard a lot. I also noticed, at least I didn't see, that you included anything here and in the safety analysis that's coming up, that looked at external events and environmental events.

We may have some questions about those again. I mean, we talked about those early on in this process.

So, is there a reason you didn't include them? Or just because of time constraint?

MR. VAN ABEL: I didn't include them in

the slide just because of time constraints.

VICE CHAIRMAN BLEY: Okay.

MR. VAN ABEL: That was the only reason.

VICE CHAIRMAN BLEY: We may still raise them. Go ahead.

MR. VAN ABEL: Okay. The basis for the design basis accidents and initiating events, in our PSR Chapter 13, was the Hazard and Operability Study, the HAZOPS that we performed. As well as the Preliminary Hazards Analysis.

Both of which were wrapped into our Integrated Safety Analysis or ISA. We also used the initiating events and accidents that are enumerated in the finalized, augmenting NUREG 1537.

And the expedience of our hazards analysis team, which included folks with experience in nuclear criticality safety and nuclear process operations in operations of nuclear power plants, management of nuclear power plants, and people familiar with the accident analysis methodologies themselves.

We used the current preliminary design information of the facility as it was to date. And we plan to reevaluate the accident analysis with detailed design and make sure that we are including all the potential accidents.

The qualitative evaluations were performed of each of the accident scenarios to identify the bounding and most limiting accidents or scenarios. And then we performed quantitative evaluations for those DBAs with consequences.

The MHA was postulated for the IF and RPF. And I think we've discussed the only share. A couple of times here, I'll just mention that it's a non-mechanistic failure. And it's not credible.

It does -- not necessarily credible. So it's a little different then a power reactor where you can just have a non-credible event just around those events that are considered credible. And this is what is done with the research reactors.

So we looked at an MHA in both the IF and RPF. And the RPF MHA was the most limiting.

CHAIRMAN STETKAR: Eric, I have to ask you this, because I promised that as long as I'm on the Committee, I will do this in every meeting. What is a credible event?

VICE CHAIRMAN BLEY: That's good. We had a long discussion on this at the last Subcommittee meeting, yes. It wouldn't hurt to do it again.

MR. VAN ABEL: We looked at events that were credible essentially as anything that was

physically possible. So we threw out some things that we didn't feel were physically possible, which as we didn't see a way for there to be multiple IU cells to be damaged from a single TOGS failure.

You know, we didn't -- because of the four foot thick reinforced concrete shielding between the TOGS cells, we could -- and the low pressures of those systems, we couldn't envision them affecting it.

And there were no interconnecting cells.

CHAIRMAN STETKAR: Yes. I mean, I don't need examples. I'm trying to get the philosophy.

What you said is that an event is not considered credible if it's judged to be not physically possible. Is that my -- is my understanding correct of that?

MR. VAN ABEL: Yes.

CHAIRMAN STETKAR: Okay. Do you want to add anything, Bill?

MR. HENNESSY: Oh, I'd like to add just a little bit. Yes, generally that's true. If you look at our MHA accidents, they're multiple failures of passive couplers.

So not just a single failure of a passive coupler. But multiple barriers that have reached without reason. So, multiple passive failures.

CHAIRMAN STETKAR: So, I'm trying to distinguish between -- is there a numerical threshold for what is considered credible? Or is it a physical concept?

And what I heard was, it's a physical concept. It's not because of the laws of nature, physics and whatever. It's not possible.

MR. VAN ABEL: Yes.

CHAIRMAN STETKAR: That's not a numerical argument. It's --

MR. VAN ABEL: Yes.

CHAIRMAN STETKAR: Fundamental science?

MR. VAN ABEL: Correct.

CHAIRMAN STETKAR: Okay.

VICE CHAIRMAN BLEY: But before you leave this, this is the position SHINE took and the way they've interpreted it to my understanding.

CHAIRMAN STETKAR: Right.

VICE CHAIRMAN BLEY: The staff also referred back to NUREG-1520 where they used their definition of not credible from the NUREG, which is three things. Either it's less than a 10 to the minus 6 event.

It includes multiple unlikely human failures. Or three, it's physically not possible.

But I don't think SHINE relied on that.

But we haven't seen their ISA.

CHAIRMAN STETKAR: Right.

VICE CHAIRMAN BLEY: Is the other piece of this.

CHAIRMAN STETKAR: Yes, I heard -- the third one seems to be consistent with what we just heard. The first two, not so much. Okay.

MR. VAN ABEL: All right. Next slide. We can go to slide 17, please.

VICE CHAIRMAN BLEY: Before you get into the details of the maximum hypothetical, I wanted to put something on the table. And I think John may have a question or two here because he was not at that last meeting for other reasons.

We raised lots of questions about all of the accident analysis. And I think most of that are issues that are reasonable to be resolved before the operating license application.

We were also trying to think of things that might not be easy to resolve once the building is in place. And to my memory, we raised two of those.

And one was this issue of lay-up. Being able to take a disabled process system and put it into a safe condition for a very long time if it need be.

Including all kinds of failures that might occur to get you there. And the other one -- and then if you've poured concrete, it might be hard to solve a problem like that.

And the other one was the aircraft crash analysis. Where there were some questions about definition of aircraft size, categorization and some others. And if the building's not built to match your analysis there, it might be very difficult to take care of later.

And so any questions we had in those areas were ones we thought really need to be pretty well put to bed before you actually start building this thing. For both, you know, it's economic things for you.

But it's availability of probably 99 for society and it's a worker risk if you get in some spot with people in the plant here. And maybe for the airplane crash there's some public risk side of that as well.

I don't know if you have anything John, to pursue on that. But we raised a bun -- many questions on the aircraft analysis back in I think it was the first meeting.

CHAIRMAN STETKAR: Yes. And actually we've had some communications from SHINE in the

interim since that meeting.

VICE CHAIRMAN BLEY: There were two letters I think, yes.

CHAIRMAN STETKAR: And there was the little report also on the --

VICE CHAIRMAN BLEY: Oh, on the aircraft, yes.

CHAIRMAN STETKAR: Aircraft crash screening probabilities. This is an area where the reason I wanted to ask you about what the boundary of the safety related structures were on the previous slide, was to get on the records something for this comment actually.

The aircraft crash analysis used -- do use numerical screening criteria. And we've had some discussion about those numbers. And I honestly don't want to dwell on the numbers.

The correspondence that we've had after that -- the first meeting, seems to support the notion that the frequency of a so called large aircraft crash -- firs of all, for the record, the frequency of small -- so called small aircraft crashes is judged to be above whatever numerical screening criteria we use.

And again, I don't want to get into the specific numbers. Questions came up about what is the

frequency of a large aircraft crash into the facility?

And there seems to be some general agreement at least from what I've seen more recently that the frequency is probably greater then a 10 to the minutes 7 event per year. And very likely 10 to the minus 6 per years.

So, it's somewhere in that decade. There might be different opinions of where it is in that decade. But it's probably somewhere in that decade.

And again, I don't care too much about the frequency for the moment because we can work out frequencies later in terms of understanding the risk. The question is that the safety related structures, it is my understanding, are designed to withstand the impact from a nominal aircraft that's in that small aircraft category.

It looks like a business jet to most people. And I wanted to make sure that the -- if we go back to your slide that had the ventilation systems on it.

It was only a couple -- it's slide 15.

MR. VAN ABEL: Hit the left arrow key.

CHAIRMAN STETKAR: That the -- the part of the blue on the bottom of this slide that is outlined by the black line so that the immediate south end of

this facility drawing.

Is that -- are those -- is that structural boundary also designed to withstand the impact of that design basis aircraft crash?

MR. VAN ABEL: Yes.

CHAIRMAN STETKAR: It is?

MR. VAN ABEL: It is.

CHAIRMAN STETKAR: Thank you. I wanted to get that on the record. Thank you.

MR. VAN ABEL: We're on 17 now. One back. So the IF postulated MHA was a loss of integrity of the Target Solution Vessel, the TSV. We've seen both the TSV and the SASS, the Secondary Vessel around that had breached and the target solution spills into the IU cell.

At the time of the event, we assumed the maximum inventory is in the TSV, operating ten percent above licensed power limit. Maximum carryover of fission produces between cycles. It occurs at the end of the cycle with no decay assumed for the radio nuclides.

The non-credible aspect of this is that we assume that there is no pool present. So we assume the pool is not present. Therefore, the target solution just spills directly onto the floor.

Which generates the mode of force for disbursal as that generates air results as well as the release of the gaseous products. The radio nuclides are airborne and then drawn into the HVAC system.

And the high radiation in the HVAC system initiates high radiation alarms and confinement isolation signals. The radioisotopes that get into the duct work are filtered through HEPA filters and charcoal ad servers in the RVZ1 exhaust duct work with 99 percent credit assumed for particulates with the HEPA filters and 95 percent credit assumed for halogens with the charcoal.

Next slide please. The calculated dose consequences from this event were a 3.1 rem worker TEDE, which is below the 5 rem regulatory limit specified in 20.1201.

And the dose at the fence to the public was 17 millirem. Which is less than the .1 rem regulatory limit specified in 20.1301, which the staff discussed before, is the normal dose limit as well as discussed in 20.1301. Significantly less than a power reactor.

The calculation for the MHA contained significant conservatism. Normally the TSV is at ambient or below ambient pressure. So there's not a

large driving force for this release to occur.

The pool is normally present. And would prevent direct generation of aerosols as the liquid would mix into the pool water and not generate aerosols immediately. And the pool will dilute the target solution as well. Which would reduce releases.

The Nobel gases are assumed immediately. Leave the target solution to evolve from the solution as it spills. Which is also conservative to assume that it's -- the Nobel gases are contained and then just immediately leave as soon as it spills.

The mishandling or malfunction of a target system event. What I mentioned is similar to this event other then the fact that it did not ignore the presence of a pool.

So, the -- that event looked at a release of target solution in the IU cell, had a very similar mitigating factors and sequence of events following the release. But that release was from a dump tank type rupture as it's being -- as the solution is being moved to the RPF.

The calculated worker dose from that event was 1.5 rem TEDE. And the dose to the public at the fence was 2 millirem.

The next event category we looked at was

mishandling or malfunction of equipment affecting the primary system boundary. This DBA looked at equipment that handles gaseous produces from irradiation, which is principally TOGS.

And the most limiting event was a rupture of the TOGS system inside of the TOGS cell. For the event we assumed the maximum inventories were in the TOGS system, similar to before.

And we assumed that the off gases released into that cell with a Z like that in TOGS being credited for retaining 95 percent of the iodine in the gas stream. The gaseous products in the ventilation system are detected by the RAMs in the ventilation. And that initiates alarms and confinement isolation signals via SFAS.

Twenty-five percent of activities that enters the shield itself is assumed to enter the shield itself before evacuation. Which occurs in ten minutes in the assumed accident analysis.

And ten percent of the material that's released into the cell leaks through the penetrations and exposes workers. One percent of the materials assumed to bypass the isolation dampers before they close.

And that accounts to leakage to the

dampers after they close as well. And again, the charcoal ad servers and the RVZ1 exhaust are credited for removing 95 percent of halogens.

The doses from this event were 1.99 rem worker TEDE. And at the fence 16 millirem to the public.

Next event. We looked at unique events. We have a couple of unique systems in the irradiation facility that a normal research reactor wouldn't have. So we looked at those events.

And specifically the tritium purification system design basis accident was included in our PSAR. That looked at potential failures of piping, process equipment malfunctions, fire and human errors with that system.

As I mentioned before, the tritium supply and return lines are all in double-walled pipe. And the tritium is maintained subatmospheric in those lines to prevent a release should a pipe actually rupture, there would be an in-leakage.

The TBS glovebox and double walled piping are inerted with nitrogen to reduce flammability concerns should there be a leak. And automatic isolation valves isolate the tritium supply. They sectionalize the system and a loss of system

integrity.

The learning event was determined to be a loss of the inventory of all eight neutron drivers. This event has the tritium released into the IU cells.

And a high radiation or other actuation signals such as the pressure differential in the tritium lines, activates the confinement isolation functions and high radiation alarms. Up to one percent of material bypasses the isolation dampers similar to before.

And the confinement features of the IU Cell would significantly reduce exposure to the workers as the workers are not in the IU cells normally. But that confinement function is not credited at all for the workers for this scenario.

So, which would provide a significant margin. The worker TEDE is calculated to be 2.4 rem. And the dose at the site boundary is calculated to be less than 1 rem -- 1 millirem, excuse me.

Next slide please.

VICE CHAIRMAN BLEY: Before we finish up, you've only got a few more slides, I know. But going until 11:00 without a break is a little hard.

I think we'll take a ten minute recess and then come back. And we'll still be pretty much on

time. And then we won't have people drifting in and out.

You're the boss now.

CHAIRMAN STETKAR: You could have done this. So we'll recess until 10:00. Yes.

(Whereupon, the above-entitled matter went off the record at 9:51 a.m. and resumed at 10:04 a.m.)

VICE CHAIRMAN BLEY: Okay, we're in business.

MR. VAN ABEL: All right, the next accident we looked at was the MHA in the radioisotope production facility, and as I mentioned before, this is more limiting than the IF MHA, so it was deemed a facility MHA. The most limiting event that we found was a simultaneous rupture of the five noble gas decay tanks shown in blue on the figure on the right there. At the time of the event, we assumed that the tanks were all at their maximum inventory, they're filled to capacity, they're instantaneously released into the storage cell, the high radiation levels are detected in the exhaust duct work again, and the RICS actuates the high radiation alarm and the cell isolation. We have redundant bubble tight isolation dampers on the inlet and outlet of the cell, and 10 percent of the activity that's released into the cell is assumed to

bypass those dampers and make it into the exhaust duct work of RVZ1, and 10 percent of the activity is assumed to leak out of the penetrations in the cell and leak into RVZ2, where the workers are present. Next slide, please.

The calculated dose from the rupture of these five tanks simultaneously is 3.6 rem for the worker, and that's below the 20.1201 limit, and the dose to the public is 82 millirem, which is at the fence, I should note, which is below the 20.1301 limit. Should we know that this analysis is conservative; we assume these five tanks instantaneously, simultaneously rupture with no mechanistic cause, these tanks will be seismic safety related tanks that will contain isolation between the tanks, but we do not expect more than one tank to be able to rupture at one time and release its contents. We also assume that 100 percent of noble gases from the TSVs leave the target solution and are transferred to the NGRS. The five tanks are completely filled at the time of the event, which is beyond how we plan to normally sequence and operate those tanks, and the isolation dampers in the RVZ1 would also close, the main isolation dampers, so there's another set of dampers by the exhaust filter train that would also

close, and that would trap the majority of the fissile products likely in the duct work, but we don't credit those here.

On slide 23, we looked at inadvertent nuclear criticality accidents in the RPF through preliminary evaluation of some areas were looked at through the HAZOPS and the ISA process, including leaks in process equipment, accumulation of material in systems, vessel overflows, misdirection of fissile materials to unintended locations. For each of these scenarios, we identified engineer controls and administrative controls to make sure that each scenario is highly unlikely. The nuclear criticality safety evaluations will--the NCSEs will look at each system and process in detail, and look at all the potential failures, and that will be performed with detailed design. And that will augment and ensure that the necessary features to make the event highly unlikely are comprehensively identified.

The preference at SHINE is to use passive engineered designs, such as the geometry of the tanks, the geometry of the piping to ensure that nuclear criticality safety is maintained. Each of our process tanks that are handling fissile material, with the exception of the liquid waste processing tank are

criticality safe by geometry, so those tanks are sub-critical even if you put in uranium concentrations that are far beyond what we would expect to put in. We searched for the most reactive uranium concentration and ensured that it's sub-critical for even that uranium concentration.

The absence of appreciable quantities of fissile materials in the waste processing tanks is through measurement and independent verification of that measurement prior to transferring that material to those tanks. The pipe runs that transfer fissile material around the plant are sub-critical by geometry; they are less than the sub-critical cylinder diameter, and all the tank faults that have fissile materials have criticality-safe sumps and got drained to a criticality-safe sump catch tank, and those are, again, criticality safe by geometry. The combination of safety-related SSCs and activities ensure that criticality in the SHINE facility is highly unlikely.

MEMBER REMPE: So Eric, just because this is full committee as to the subcommittee meeting, I think this is a good time, since you have the integrated safety assessment mentioned in this slide to mention that it has not been submitted yet to the staff for review, and the ACRS obviously didn't see

that. And so again, just to make sure it's on the record that these are a bit preliminary; that we have not seen that yet. I just wanted to bring that point up. Thanks.

MR. VAN ABEL: Next slide, please. We looked at fires in the radioisotope production facility; fire-initiating events could damage the SSCs and lead to the release of radioactive materials. We looked at normal maintenance operations in the RPF within and outside of our filed of processing closures. The most limiting fire scenario we identified was a fire affecting the Moly eluate hold tank inside the supercell. The fire affects this process while we're processing radioactive materials; the hot cell fire detection activator which alerts operations personnel to the fire; the ventilation system is automatically isolated, the hot cell fire suppression system would be expected to be activated through automatic or manual means, although we don't credit it in the safety analysis, and indeed the thick shielding of that cell, nominally four feet thick reinforced concrete, the consequences of a fire are limited to the hot cell interior.

The RVZ1 filters the exhaust from the release, and HEPA filters remove 99 percent of

particulates, and the charcoal are credited for removing 95 percent of halogens, and the calculated dust consequences are .58 rem to a worker TEDE and less than one milligram to the public at the fence.

MR. HENNESSY: In summary, the preliminary designs described in the PSAR shows the SHINE facility can be constructed such that it meets the applicable regulatory requirements. Radiological consequences to workers and the public during normal operation and postulated accidents meet the limits, and robust engineering and administrative controls have been identified that ensure the protection of the public, the environment and our workers. The plant is being designed with safety as our primary criteria.

MEMBER REMPE: Sir, I have a question if you don't mind. It's a little more--my microphone is on. It's a little more detailed then; it's a follow up from the last subcommittee meeting that I wasn't quite able to attend or even call in on. With respect to the red oil event prevention table that you provided, which I appreciated your response to, but there were four controls mentioned, and if you look at the DNFSB report, they actually are very explicit about saying all four controls should always be used in conjunction, not independently. And I was curious

about the slide because there are a couple of places where you mentioned control not used in certain locations, and this could be my ignorance on the process, because I'm a nuclear engineer not a chemical engineer, but could you explain why you are not using the control at certain locations?

MS. KOLB: Yes.

MEMBER REMPE: Okay, this slide isn't really necessary--

MS. KOLB: Okay, well we have the slide; if it gets open that's okay. So in some of the locations where we said control not used was, for example, a temperature control is not used in the denitration process because the purpose of the denitration--I mean the way to carry it out is it's at a temperature about 300 degrees Celsius, so it is above the limits by its nature. The other controls are sufficient to prevent red oil in that case because --oh there it is. So it would be like that in the next slide, Jim. So the--I was talking about the denitration; by its nature, it's above those controls, so they can't--they don't physically apply, but the sampling of organics, it'll be during independent sampling, so that prevents organics from being in that process in the first place, and it'll also be

ventilated according to the recommendations of this document, the Defense Nuclear Facility Safety Board documents so that if there were carryover, it wouldn't become a runaway reaction.

MEMBER REMPE: Okay. And the concentration, is that also why it's not used?

MS. KOLB: So the concentration, there's --as you're evaporating and as you're denitrating, you're both driving off water and driving off nitric components, so the concentration is varying, so it's not really something we can--are planning to control as far as nitrate going from a liquid to a solid, and they're varying.

MEMBER REMPE: Okay. Thank you.

MEMBER SCHULTZ: Question. The staff has indicated in the licensing process that we have ongoing you have the opportunity to do research and development between the construction permit and the operating license in order to demonstrate capability for operations. Could you highlight those R&D programs, the key R&D programs that you have ongoing to address safety issues?

MR. VAN ABEL: Yes, there are two are R&D programs that we have identified that are necessary to ensure safety of the facility. One is evaluating

the materials that are in contact with the target solution to ensure that they'll be compatible for irradiation damage in the TSV during its lifetime and chemical corrosion effects. That work is being done with Oak Ridge National Laboratory; they're doing irradiation corrosion tests to ensure that that will be-- the vessel designs-- the materials will be okay for 30 years, the plant lifetime. The second R&D activity is to look at uranyl peroxide precipitation in the target solution during irradiation and verify that there will be any problems with uranyl peroxide precipitating during the irradiation process. we are working on this with Argonne National Laboratory; they did some initial preliminary tests that show that it can be prevented, and they're going to do some more comprehensive, complete tests before we say that that box is checked.

MEMBER SCHULTZ: Thank you.

CHAIRMAN STETKAR: I had one more question, and here again I'll try to keep it as generic as possible. During subcommittee, you mentioned fire analysis, so that triggered some neurons. During the subcommittee meeting when we were talking about the fire analysis and the fire areas, I noted that it seemed to me that some sets of

safety-related cabinets were located in a single fire area rather than separated--and again, stop me if I get too far off. I know that for example, the safety-related uninterruptible power supplies, train A and train Bare in separate rooms. I know that the ESFAS, safeguards actuation cabinets train A and train B are in separate rooms, but it seems to me that the radiological integrated control system, RICS, and Target Solution Vessel Reactivity Protection System, TRPS, which are both characterized, they have safety-related functions. All of those cabinets seem to be located in a single room. In other words, to be clear, all of the RICS cabinets were in one room, and all of the TRPS cabinets are in one room. They're in separate rooms, but they don't provide redundant functions. The only reason I bring this up as a question is that in the sense of a construction permit, that may affect the configuration of the rooms and the necessary footprint of the rooms and perhaps separation walls among the rooms. So do you have any further information about that?

MR. VAN ABEL: Those PLCs that we're doing, some of those functions, the TRPS and the RICS were in individual fire areas and the original thought process has been that if those components fail, then

shut down; that's the safe state. If they lose the capability to perform their functions, they would shut down and those systems would go to a safe state. We understand that there are potential other failure modes that we're going to look at and ensure that the system will fail the safe state or if we cannot prove that, that we'll have proper separation.

CHAIRMAN STETKAR: And you don't feel that that would affect the fundamental design of the structures?

(Simultaneous speaking.)

CHAIRMAN STETKAR: You have enough room to move things around and reconfigure interior walls or stuff like that?

MR. VAN ABEL: On the drawings it just shows little dotted boxes and they sort of look the same, so--

CHAIRMAN STETKAR: Okay. Thank you. Jim had some--

MR. COSTEDIO: Yes, we covered this in the follow up to the--I don't think--

CHAIRMAN STETKAR: I wasn't here during the subcommittee meeting--

(Simultaneous speaking.)

MR. COSTEDIO: Yes, this is what we

presented at the previous--

CHAIRMAN STETKAR: Okay, thank you Jim. I knew it was covered; I couldn't remember how. Okay, thank you, sir.

VICE CHAIRMAN BLEY: You were almost finished or done? You are done?

MR. VAN ABEL: We are done.

VICE CHAIRMAN BLEY: Anything else from the committee? Okay, thank you. We'll hear from the staff, and we will maybe have a little discussion near the end on a couple of issues.

MR. LYNCH: Okay, to conclude the staff's presentation, I'm going to go over the results of our review for SHINE, but a quick status of where we're at with the overall process of reviewing the construction permit application. As of September, the staff has completed its' review; SHINE has responded adequately to all requests for additional information. We did publish our environmental impact statement, or it's been sent for NUREG publishing, so that will come out this month. Our Safety Evaluation Report is also in concurrence and expected to be published later this month or early in November, and we do have a mandatory hearing scheduled for this review on December 15 of this year.

So when reviewing the construction permit, the ultimate findings that we have to make and be able to support are those under 50.35, 50.40 and 50.50, and over the next slides, I'm going to go through these points individually. So under 50.35(a)(1), we're looking to see has the facility been described, do we have design criteria and other major features that are components that have been identified that are important to safety. So we did look--we've essentially used 50.34 as guided by our guidance to evaluate the sufficiency of the preliminary design, making sure that the work design criteria identified, there was a design basis, do we have SHINE identified in the materials of construction, do we have a general arrangement, approximate dimensions, and in those areas that we needed additional information, we did ask that of the applicant.

With the second finding here, as far as technical information that may be left for the FSAR, these are those situations where I talked about earlier that maybe we asked an RAI but SHINE had said that we're not going to provide it now; they gave us a reason why it does not affect the design basis or construction and said that they'll follow up in the FSAR. The staff evaluated these commitments and we

are tracking these independently as regulatory commitments in our SER to make sure that SHINE does implement these in the FSAR for the operating license. So the finding that we had to make here was that there was reasonable assurance that we will get this information later in the Final Safety Analysis Report, and we believe that by SHINE making these commitments to us explicitly in writing in their application or in responses to requests for additional information, that we do have that reasonable assurance.

For the third finding here as part of safety features and components that require additional research, making sure that those have been adequately identified to resolve any safety questions, SHINE as they did mention, they do have two ongoing research and development activities related to irradiation and corrosion testing and precipitation studies that are being performed by Oak Ridge National Laboratory and Argonne National Laboratory respectively. In response to requests for additional information, SHINE did describe these research programs to the staff. In addition to these research and development programs, the staff did determine that there was information needed with respect to nuclear criticality safety and radiation protection, and these were items that the

staff felt we didn't necessarily need them to allow SHINE to begin construction, but they were issues that we felt needed to be resolved before construction was finished.

So as such, we are recommending to the Commission that the permit be conditioned. To give an idea of how we're approaching this, we want--the permit conditions are confirmatory in nature. We're not going to be approving of anything that SHINE sends in; we are asking that they submit periodic reports updating us on their status, and there are certain things they need to demonstrate in these reports and with the design of the facility, and if they do not design the facility or construct it as it's described in the PSAR or as provided in the permit, then the staff will be able to intervene.

But to give an example of the conditions that we've put in place, for example, SHINE has proposed in their production facility to have a criticality alarm system. One of the concerns the staff has is what's this thickness of shielding that's going to be surrounding this system? If it's too thick, it might not be able to perform as functioned; if it's too thin, we could have shielding concerns. So as such, we do have--we are recommending a

condition that SHINE update us periodically on the status of this design so that we can make sure that the system will perform as designed.

For our next finding here, for those safety questions and SHINE's research programs, we need to make sure also that they're going to be able to complete those before the latest date of construction. SHINE has proposed that the latest date of their construction would be December 31, 2022. Based on the schedules that SHINE gave us for their research programs, we're expecting that their research programs will be completed well in advance of this. And also for the additional permit conditions that were placed on the construction permit, we also, you know, one of the conditions that those must be satisfied prior to the completion of construction as well.

I'll also mention here too, in addition to the technical permit conditions that we're placing on SHINE, we have added additional conditions for change control process; there's two aspects to this. We've created a 50.59-like screening process for SHINE, so if you look at 50.59 as far as setting a screening process for when you do and do not need an amendment to your license, that only applies to final safety

analysis reports. But there are situations where if SHINE decides to substantially change their design during construction, they may need to amend their license. So what we did is we took 50.59 and modified that to fit what would be appropriate for construction, and we've included that into the construction permit, or we're recommending that it be included in the construction permit so that SHINE has the adequate screening process to determine when an amendment should or should not be applied for.

And on top of that, we also looked to the combined operating license applications being implemented there as a preliminary amendment request as well. The staff also --well, if an amendment is needed during the construction process, while we do need to approve those changes, we also don't want to stand in the way of construction and have it stopped indefinitely. So also in the permit, we've included a provision that if SHINE does decide they need to apply for a license amendment, they may also request to proceed with making the change prior to the staff's approval. But the understanding with this is if the staff ultimately does not approve of the change, they must return the facility back to the way it was. So it is kind of proceeding construction at risk, but it

also allows SHINE to continue with construction with the understanding that the staff is approving of a change to the facility, and if the staff does not approve, they need to go back.

Our other finding here, taking into consideration the site criteria in Part 100, can the proposed facility be constructed and operated without undue risk to the public? As I mentioned earlier, our consideration of the site criteria of Part 100 is that the site criteria are specific to nuclear power reactors and testing facilities. That being said, we do look at very similar things in our--in Chapter 2 of our SER for site considerations. We are looking at meteorology, geological concerns, seismic concerns, and other siting considerations. So while we're not directly using Part 100, we do look at those same aspects. We did look at radiological releases; as I discussed earlier, those are all--are expected to be well within Part 20 limits, and we discussed this in greater detail in Chapter 11 with radiation protection and in Chapter 13 of the SER in our accident analysis. We also believe that SHINE has demonstrated that they will have a sufficient emergency plan in the operating license after our review of their preliminary emergency plan.

And to conclude, looking at 50.40 and 50.50, based on our previous findings that I just discussed, we don't believe that construction will endanger the health and safety of the public. One of the things with this is also during construction, SHINE will not--there will not be material on site. We do believe that SHINE is technically and financially qualified to engage in the construction; their application to us and our review and their demonstration of understanding of the concepts and what needs to be finalized for the FSAR. They're showing us that their technical qualifications; financial qualifications while they have not been a specific subject of these meetings, SHINE did submit information on how they're funding through construction.

And one of the things too SHINE, as far as on the financial side, they are receiving some money from the Department of Energy through the cost sharing agreement that they have through NNSA. And based on these other findings, we do find that the construction of the facility would not be problematic to the common defense or security or to the health and safety of the public, and that the application meets the standards of the AEA and the Commission's regulations. I'm

happy to answer any questions.

VICE CHAIRMAN BLEY: Yes, I'm going to have a question for you in a minute; I'm going to go back to something I mentioned earlier, that we thought we found two areas that related to worker safety and public health and safety that could be affected if the construction didn't account for certain things. One was the aircraft crash issue, and I think our discussions earlier today resolved the remaining point we had on that one. On the lay-up issue and being able to safely go to lay-up no matter what events have occurred, SHINE put a letter on the docket recently that shows that they have ample storage capability; that's half of the problem, and at least two facilities I know of ended up being shut down because they didn't--permanently, because they didn't have that. The other half of that is do they have the physical ability to move the fluids to those storage locations for all of the failures that might put you in this kind of spot. Perhaps the ISA has addressed that; I don't know if it has or not since we haven't seen it, but that's the one thing I think we're still struggling with. We didn't hear if you--actually, if the staff reviewed that letter they sent, and what the staff's opinions were and we'd be interested in

hearing them.

MR. LYNCH: Sure. Yes, I did look at that letter, and to me when I was looking at this letter for the purposes of issuing the construction permit, the big thing was you mentioned was physical storage, you know, is that planned for because that should be accounted for up front. They've got their dump tanks, their hold tanks, their recycle tanks, and I think as they mentioned in the letter, that they'll have twice the storage capacity for the material that they anticipate having on site. So that was part of it, and I was looking at the procedures that they listed for what they're looking at. So to me, as far as what are they thinking about, what are they going to do to --are they looking at procedures to test the material while it's being stored to ensure that it remains in the states they expect it to, and are they looking at making sure that the systems that it's taken out of are cleaned. And they had quite a list of the different procedures that they anticipate implementing. To me, looking at that it seems like there was thought put into that, and given that most of that was procedural in nature, and that they made a commitment to fully develop this for their final safety analysis report, the action that I took was 1)

I think they had the physical storage; and 2) I made sure that in our safety evaluation report, I am tracking this as a commitment they've made to fully develop these procedures, and that we'll take a hard look at this come the final safety analysis report.

MR. ADAMS: Okay. Can I--

MR. LYNCH: Yes. Sure. Please.

MR. ADAMS: --one thing. As far as the long term ability to retain these materials, I guess part of it depends what's the reason they would have to retain them for a long period of time, and one reason that isn't on the table is there's no pathway to remove these facilities from the--the material from the facilities. The American Medical Isotope Act directs DOE to develop a lease take back program, so if it became a case where they shut down before the end of the life and they knew they weren't going to run again, DOE would basically--the U.S. Government would come and get their stuff back, you know, SHINE would never retain title to the material, similar to the research reactors. So at least for the reasons why the material would have to be maintained on site for a long period of time, I just want to point out that's not one of the reasons that would be on the table, you know, assuming that DOE successfully

completes the work that they need to do to develop a lease take back program.

MR. LYNCH: Thank you, Al.

MR. ADAMS: Thank you.

VICE CHAIRMAN BLEY: Anybody else on the Committee have something at this point? John, you started to say something? Okay, I think at this point we should open the phone lines, and I'll ask is there anyone in the meeting room who would like to make a comment? If so, please come to the microphone, state your name, and give us your comment. We'll wait for the phone lines, and--phone lines open? Somebody on the phone line just say hello so we know that we've got it working right.

PARTICIPANT: Hello.

VICE CHAIRMAN BLEY: Thank you. Is there anybody on the phone line who would like to make a comment? If so, please state your name, affiliation and we'd love to hear your comment. Going, going, gone. Thank you very much. I had one last question, I'm sorry. The letter they submitted, the letter was submitted and now you've got it in the SER or some aspect of it that has it as part of the application, so that covers it.

MR. LYNCH: Yes.

VICE CHAIRMAN BLEY: Okay. Thank you very much. Mr. Chairman, back to you.

CHAIRMAN STETKAR: Thank you, and I'd like to thank the staff and SHINE for covering an awful lot of material very efficiently; good job by everyone. And with that, we are recessed until 1:00.

(Whereupon, the above-entitled matter went off the record from 10:38 a.m. and resumed at 1:02 p.m.)

CHAIRMAN STETKAR: We're back in session; the next item on our agenda is the review of interim staff guidance for the Acute Chemical Exposures and Proposed Quantitative Standards, and Dr. Powers will lead us through this session. Dan?

MEMBER POWERS: I will do my best; we're in for a treat today. This is a distinctly different but a troublesome issue that has plagued us in the past. What members may well recall that when we were considering the BOX Facility, that we recognized that for these facilities we have to consider not only the radiological hazard, but we also have to consider the toxic chemical hazards. And by and large, we focus heavily just on the inhalation hazard, but there are other pathways. When we just looked at the inhalation hazard, we had enough trouble trying to find good

sources, reliable sources for data on what the hazardous levels are; well I had similar kinds of problems by the other pathways. So the staff is going to take us through and show us some of the stuff that they've been trying to do, which is really, as I understand it--and I'm perfectly prepared for you to correct me on this--they're trying to help both the reviewers and the licensees in this work. So I'm going to ask Marissa Bailey to give us an introduction to this subject, and then Marilyn, you're the boss then, right? So Marissa, tell us what we can expect here.

MS. BAILEY: Okay. Thank you, Dr. Powers. I should mention I'm Marissa Bailey, I'm the Director for the Division of Fuel Cycle Safety Safeguards and Environmental Review in NMSS. And first of all, I'd like to thank the Committee for your review of this interim staff guidance on key chemical exposures. We are requesting a letter from the Committee which we hope will endorse issuance of this ISG. Marilyn will be giving you a detailed presentation of the ISG, but before they do, I'd like to just raise three points that highlight why we think this staff guidance document is important.

So the first point that I'd like to bring

up is that chemical hazards at fuel cycle facilities are real. In fact, chemical accidents at fuel facilities, including the one at Sequoyah Fuels in 1986 that killed one worker and injured several others are in part what prompted the NRC to require licensees to conduct integrated safety analyses for their facilities, and to include in those integrated safety analyses the evaluation of chemical hazards.

Second, the regulation of hazardous chemicals that are produced from or commingled with licensed material is within NRC jurisdiction. 10 CFR Part 70 has very specific requirements for acute chemical exposures, including a requirement that licensees must provide in their ISA summaries a description of the proposed quantitative standards used to assess the consequences to an individual from acute chemical exposures. And what we found, primarily due to a series of chemical exposure events around the 2006 and later time frame, what we found is that licensees have not fully analyzed all acute chemical exposure hazards in their integrated safety analysis, which is what's required by the regulation. So we see a gap in regulatory compliance, or I should say a potential gap in regulatory compliance.

Which brings me to my third point, which

is that this is more than a regulatory compliance issue. We see safety implications in an incomplete integrated safety analysis. Bear in mind that the purpose of the ISA is to identify all facility hazards, their likelihood and consequences, and then put in place measures that would either mitigate or prevent those consequences. So the ISA is fundamental to a licensee's safety program, and hazards have to be analyzed and understood before they can be effectively managed. This is why we believe it's important that licensees consider all exposure pathways when it comes to chemical exposures. Developing the standards, or those quantitative standards would allow them to categorize the consequences of the exposures, which in turn would allow them to properly manage the risks associated with the chemical processing of licensed material. So I just wanted to just highlight those three points to you in terms of why we believe this guidance for how the staff would review chemical-like hazards at fuel cycle facilities is important. So I'll now turn it over to my staff--

CHAIRMAN STETKAR: Marissa, before you do, may I--I hear, you know, the needs and things like that; why not pursue regulatory guidance, development of a reg guide rather than interim staff guidance?

MS. BAILEY: Do you want to answer that?

(Simultaneous speaking.)

MS. DIAZ: So when we started this, we started back in 2007 when there were a couple of exposures events at fuel cycle facilities. We sent out an information notice telling licensees that--it was a particular HF exposure by dermal and inhalation exposure. And we told the licensees that they need to evaluate all exposure hazards, including all pathways. After that, it came to multiple letters from industry, from the nuclear energy industry, and NRC trying to--discussing on that this, the evaluation of all routes, it's not a new requirement; it's required by the regulations. We started working with them, with industry on doing a proposed approach for complying with the requirements, but then we received a letter claiming that our staff's position was back then. And since then, we this path to develop a staff guidance for evaluating this chemical exposures and so it was our way to try to address the problem.

CHAIRMAN STETKAR: Okay. I hear that, but I still labor under this perhaps naive notion that interim staff guidance is intended to be perhaps somewhat more expeditious method to address evolving concerns that require some sort of timely input to the

staff and information, more formal information to the industry in lieu of the time that it takes to develop a formal regulatory guide; that they are not substitutes for regulatory guides, they're simply, as I said, an expedient way of getting some of that information out there. So let me ask my question this way. Are there plans to develop a regulatory guide for this issue? Because if there are not, then I see interim staff guidance becoming perpetuated as the staff guidance, which I don't think is what interim staff guidance was originally intended to do.

MS. BAILEY: I think that we are open to developing a regulatory guide for this issue. You're right, we saw the interim staff guidance as maybe a quicker way to get the guidance out there, and it is-- because it's an issue that has been brewing, developing for several years now, and as a first step we felt that we needed to provide guidance for our staff, which is what an interim staff guidance is. We are open to in the future developing a regulatory guide for this.

CHAIRMAN STETKAR: Well if the issue is important enough from a safety perspective, from a regulatory perspective in terms of compliance with the interpretation of the regulations, then it would seem

that the development of a formal regulatory guide according to the process used would be the way to eventually document this guidance in the form that's traditionally used throughout the agency. I guess my concern personally, and this is throughout the agency, that we seem to be developing things that are called interim staff guidance that then get revised, and you have Rev 7 of the interim staff guidance, and that was never the intent of interim staff guidance. It was intended to address issues which might not be fully addressed in a timely manner through the formal regulatory guide process. And from our perspective, I mean we obviously are reviewing this one in particular, but we've had difficulty at ACRS in the past in terms of recognizing when even interim staff guidance is being developed. We do formally have the opportunity to review all regulatory guides, so I'll just make that--

MS. BAILEY: And I appreciate that comment, but I--and we will--we haven't closed the door to a reg guide, but I just--

CHAIRMAN STETKAR: But I think what I'm saying Marissa, and this is my own opinion, that promulgation of interim staff guidance without the goal of producing a regulatory guide is something that

I don't understand, because that says that the interim staff guidance will be a permanent set of guidance, and that's not my interpretation of the intent of interim staff guidance.

MS. BAILEY: And I do--this interim staff guidance is not intended to be a permanent guidance. As with our other interim staff guidance, we--in the next revision of the Standard Review Plan, we will incorporate this interim staff guidance into the standard review plan.

CHAIRMAN STETKAR: Okay.

MS. BAILEY: We did that with the recently issued Rev 2 of the Standard Review Plan, where we incorporated--

CHAIRMAN STETKAR: That's another way to get it into the process.

MS. BAILEY: So we would envision in a couple of years the Standard Review Plan would be updated and we would incorporate this interim staff guidance into the SRP.

CHAIRMAN STETKAR: Okay. Thank you.

MS. BAILEY: And if there are no more questions, I'll turn it over to Marilyn.

MEMBER POWERS: There will always be questions, but we're dying to hear from Marilyn.

MS. BAILEY: Marilyn and Robert and Jim Hammelman will be happy to answer them.

MS. DIAZ: Thank you Marissa, and thank you Dr. Powers for those opening remarks. My name is Marilyn Diaz, I'm a Chemical Safety Reviewer for the Division of Fuel Cycle, Office of NMSS, and I'll let Jim--

MR. HAMMELMAN: Jim Hammelman, also a Chem Safety Reviewer.

CHAIRMAN STETKAR: Jim, make sure you turn your mics on when you're talking, and turn them off when you're not. It's--I'm not going to go through the monologue.

MR. JOHNSON: It has nothing to do with the communication; it's just a fetish he has.

CHAIRMAN STETKAR: I like to see green lights go on and off; it's just something--it's me.

MR. JOHNSON: Okay and good afternoon, my name is Robert Johnson, I'm the Fuel Manufacturing Branch Chief, I have the chemical reviewers and I'm in charge of doing these--conducting these reviews.

MS. DIAZ: Okay, so let's start. During this presentation, we'll be going over some background information, I will provide a quick overview of the fuel cycle facilities, and I will talk about NRC's

responsibility for regulating chemical hazards. We'll also go over the chemical safety requirements that are relevant to this ISG, then we'll get into the ISG and end up with a brief summary. Next slide. So fuel cycle facilities are those non-reactor nuclear facilities that convert, enrich and fabricate uranium into nuclear fuel. This map shows the locations of fuel cycle facilities throughout the U.S. 10 CFR Part 70 only regulates the enrichment and fuel fabrication facilities, shown as the red dots here in the map. Facilities regulated under Part 70 are B&W, Westinghouse, Columbia Fuel Fab, Nuclear Fuel Services, Areva Richland, Global Nuclear Fuels, BOX Facility, and LES. Fuel fabrication facilities' predominant hazards include criticality chemical hazards and fire hazards.

So here, since most of the Part 70 licensees are fuel fabrication plants, I decided to put this slide here. This figure shows the general process and steps for manufacturing fuel. We have here that the UF-6 comes in, and then goes through several chemical processes to convert UF-6 to UO-2 powder, uranium oxide powder. Then it gets into pellet form, they then insert it into a fuel rod and then they make the fuel assemblies. The important

thing here is that a fuel cycle facility like this one can be similar to a chemical processing plant, and like other chemical plants, many manual operations are involved. Because of the manual labor, a worker is often very close to the process chemicals involved in the process.

Also, these types of facilities go through a number of changes and modifications per year; they may need to make some changes in the process line to accommodate new feed material or a new fuel type, a new fuel design. Due to the dynamic nature of these facilities, staff believes that chemical hazards are better managed by analyzing all potential hazards and all potential accidents through a process hazard analysis, or an Integrated Safety Analysis. Like I was saying, numerous chemicals used at fuel cycle facilities--there are numerous chemicals used at fuel cycle facilities, and some of the chemicals are uranium hexafluoride, hydrogen fluoride, which is produced and also used, ammonia, nitrogen oxides, nitric acid, other acids and other solvents.

So the Memorandum of Understanding between OSHA and NRC, this MOU was establish after Sequoyah Fuels accident where a worker died due to an overexposure of HF. The MOU was developed to clarify

each agency's responsibility for regulating fuel cycle facilities. The purpose was not to have a dual regulation, but just clarify their lines. As the MOU states, NRC is responsible for radiation risk of licensed materials, chemical risk of licensed materials and plant conditions that affect or may affect the safety of licensed materials that would present an increased risk to workers. This basically means that any chemical hazards that may affect the safe operation of licensed materials, it's NRC responsibility. In addition to the MOU, the OSHA Act, Section 4 prevents application of OSHA regulations to areas regulated by other federal agencies. This highlights that if it's a chemical hazard that will affect the safe operation of licensed materials, OSHA is not looking at it. If we don't regulate those hazards, nobody will.

CHAIRMAN STETKAR: That's what I was going to ask, because I'm not--you're talking to someone who basically can make a clay pot out of clay in terms of knowing the chemical processes. In terms of now your example of exposure of a worker and injury to a worker from, let's say HF, I'm assuming that you're making the argument that that source of risk comes under the third sub-bullet under NRC responsibility; is that

correct? Because it's obviously not a chemical risk of a licensed material.

MS. DIAZ: So it depends; in a fuel cycle facility, they can produce HF from the process from converting UF-6 to UO-2 powder; they can produce HF--

CHAIRMAN STETKAR: Oh okay, okay.

MS. DIAZ: --or if they have it in their facility and it's outside in a tank and they only add that HF to the process, then that comes--

CHAIRMAN STETKAR: Yes, I was thinking more of the second example.

MS. DIAZ: Oh, the tank outside?

CHAIRMAN STETKAR: Right.

MS. DIAZ: OSHA regulates that.

CHAIRMAN STETKAR: OSHA's that. Okay.

MS. DIAZ: When it comes into the process of processing fuel, that's where it gets to NRC's responsibility.

CHAIRMAN STETKAR: Okay. Got it. Thank you.

MEMBER SCHULTZ: But I want to explore that one more time so I understand it, because in the first bullet, NRC responsibilities focuses on licensed materials, one two, except you get to the third one, plant conditions affecting risk to workers. But then

the second bullet says OSHA is not responsible for working conditions where another agency exercises the authority. So what about the chemicals that are not licensed material, which are inside the facility?

MS. DIAZ: So it depends. If those chemical hazards--

MEMBER SCHULTZ: Where does the facility start and end I guess? I'm kind of confused as to why there would be--

MS. DIAZ: --they--kind of confusing, I guess. But once the process of processing the fuel, processing the uranium starts, that's where NRC comes in. Any chemical hazards resulting from those processes, then it's our--it's within NRC jurisdiction. Anything that doesn't affect that process, or it's in a tank outside--

MEMBER SCHULTZ: So take the fuel cycle facility--I didn't mean to interrupt. But a fuel cycle facility then that has licensed materials must abide by regulations and inspections for both NRC and for OSHA; they're responsible for both because they will have the chemicals if you will with and without licensed materials.

MS. DIAZ: They will have to comply--

MR. JOHNSON: But I think they're not in

a overlapping manner. I think the facility has both--the purpose of--yes, the purpose of the OSHA-NRC MOU is to divide that--make that line; define the industrial chemical hazards associated with the storage of the bulk material outside or even inside the facility--

MEMBER SCHULTZ: Even inside the facility.

MR. JOHNSON: Even inside the facility. The regulations define--70.4 defines--

MS. DIAZ: The hazardous chemicals associated with the process.

MEMBER SCHULTZ: So there's an event and it doesn't involve licensed materials, just chemicals--

MR. JOHNSON: It would be industrial.

MEMBER SCHULTZ: --then NRC would not feel they had a responsibility, OSHA would have the responsibility in terms of--

MR. JOHNSON: OSHA would have the responsibility, but they also, because we've been working together with them and we have the MOU, they would--we would be talking back and forth about the hazard. If we identified a purely chemical hazard, we would maybe communicate that to OSHA, but it's not under our jurisdiction.

(Simultaneous speaking.)

MEMBER SCHULTZ: I thought the Memorandum of Understanding would have OSHA say NRC, the licensed material is there, there's chemical hazards there, why don't you take this one, and that would be the facility. But that's not the way it works is what I'm hearing; it's still divvied up as to what tank has what materials within it.

MR. HAMMELMAN: Which portion of the plant, at least in my experience, you know, if you've got the chemicals intimately mixed with the licensed material, NRC worries about that. The tank farms out back, OSHA worries about that. You know, before NRC becomes involved with it, they have to see a linkage between--that hazardous material either has to come from the licensed material, or has to have some potential impact on the ability to control and manage that licensed material. So the calls--

MEMBER SCHULTZ: I understand, it's just hard for me to agree that that is an effective way to manage the risk, the chemical risk.

MR. HAMMELMAN: Well, I guess--

MEMBER SCHULTZ: To have two organizations that have overlapping responsibilities in a way.

MEMBER POWERS: It's also not subject to

what we're talking about today.

MEMBER SCHULTZ: Okay.

MR. HAMMELMAN: Well that's what was worked out in the MOU.

MS. DIAZ: Okay, moving forward. Next slide. So in 2000, NRC amended its Part 70 regulations adding the Subpart H regulations, which established the performance-based requirements. In there, that's where we required an applicant or licensee to conduct and maintain an integrated safety analysis. It has the performance requirements; the performance requirements are one of the most important requirements in here because all licensees need to meet the performance requirements, and we'll go over the performance requirements in just a second. The new Subpart H requires an applicant to identify the items relied on for safety, the controls to prevent or mitigate a potential accident; we call it the IROFS, and also requires an applicant to submit an ISA summary that must include a description of the quantitative standards used to assess the consequences. Next slide.

So here, this risk matrix that I present here represents the different category's agents in the performance requirements. The performance

requirements states that a risk of high consequence here, here's the high consequence, must be limited to a highly unlikely, and the risk of intermediate consequences here must be an unlikely event. Here, the performance requirements are describing what an acceptable risk is. If a high consequence is less than highly unlikely, if it's unlikely or not unlikely here, then that creates an unacceptable risk here, the gray shaded areas, which a licensee would have to prevent or mitigate and identify controls to mitigate it. Now this table also helps you visualize the need for the quantitative standards used to assess those consequences. The quantitative standards required by 70.65(b)(7) helps categorize or bin the severity of the consequences.

For example, if we have--if we're dealing with hydrogen fluoride, and in my ISA scenario, I've determined that the exposure to HF is unlikely, so it's in this category, then by establishing a quantitative standard of let's say 50 ppm, that's AGL 3 for a worker, a life-endangering--endangering life of a worker, then it will help me categorize the event as high or intermediate consequences. So if you have the quantitative standards of 50 ppm, anything above it will be considered a high consequence. If it's

less than 50 ppm, then it's an intermediate consequence. So that kind of shows the importance of the quantitative standards; it helps you categorize the severity of the consequences.

CHAIRMAN STETKAR: That's half of it; you didn't give us the example in the horizontal axis in terms of what is--

MS. DIAZ: I just provided one example.

CHAIRMAN STETKAR: --likely. You will get to that?

MS. DIAZ: Huh?

CHAIRMAN STETKAR: Will you get to that?

MS. DIAZ: No; do you have any questions on that?

CHAIRMAN STETKAR: Yes, because in risk, risk is determined by both frequency and consequences. So simply making a determination that the--the consequences of us being hit by a meteorite are very, very dire, so that would be like the most unacceptable thing that I could think of. Maybe. On the other hand, the frequency is exceedingly low, so we accept the risk. So I'm curious about how you make the determination of which of the columns you fit into. I mean you've given us a very specific example of 50 ppm as some sort of threshold between acceptable and

unacceptable; what are the thresholds between the horizontal determinations, the highly unlikely, unlikely and not unlikely?

MR. HAMMELMAN: When the licensee does their ISA, they are required to put it into one of those frequency bins.

CHAIRMAN STETKAR: What are the frequency bins in terms of--

MR. HAMMELMAN: They use those terms highly unlikely and unlikely and they're required to define those; regulations require them to define it for their particular site.

CHAIRMAN STETKAR: But does that mean--

MEMBER POWERS: He's not going to let up until we tell him--

CHAIRMAN STETKAR: No, that's right.

MEMBER POWERS: --10 to the minus 4, 10 to the minus 2--

(Simultaneous speaking.)

MS. DIAZ: Those are not regulatory requirements, it's just provided in the guidance, in the standard review plan.

CHAIRMAN STETKAR: I just wanted to get it on the record what the numbers were.

MEMBER POWERS You fish around and you

fish around instead of just saying what you want.

CHAIRMAN STETKAR: But they are--they are--the important thing is, because in the response there was the implication that each licensee could establish those numerical bounds on a site-by-site basis, which is not necessarily what I'm hearing, because they didn't have complete latitude in terms of determining numerically what is highly unlikely, like 10 to the minus 90 versus 10 to the minus 1.

MR. HAMMELMAN: That is correct.

CHAIRMAN STETKAR: Okay, thanks.

MEMBER POWERS: Well, I mean all these things are subject to negotiation, but the way the regulation is written, it's exactly what he said it was, that the licensee defines those things, but they better conform roughly--

MS. DIAZ: It may vary from site to site, but the SRP will provide guidance on well highly unlikely will be 10 to the minus 5, 10 to the minus 10, and those numbers.

MEMBER POWERS: Thank you.

MS. DIAZ: So here we have the actual regulations, the language of the regulations, and these are specific to chem safety, to chemical safety. These are the two regulations that we're focusing our

interim staff guidance in. We have 10 CFR 70.61, which requires an applicant or licensee to limit the risk of high or intermediate consequence events resulting from acute chemical exposure. So the regulations speak out or talks about acute chemical exposure; that's where it also comes into our NRC responsibility to regulate the chemical hazards, not only the MOU, but also the regulations talk about evaluating acute chemical exposures. And then we have 10 CFR 70.65(b)(7), which requires a description of the proposed quantitative standards used to assess the consequences to an individual from acute chemical exposures. Next slide.

Here, I provided a simple diagram of the ISA process. First, the licensees identify the hazards, identify all hazardous materials per our definition of 70.4. Anything commingled, mixed with the processing of fuel and those kind of materials. Then they have to identify the accident sequences caused by process deviations, routine, non-routine operations, or other events internal to the facility and credible external events. Then they evaluate if the event is credible based on past events, operating experience or new information that they have. Then they identify the consequence and likelihood; they

identify the consequences for that chemical hazard based on toxicity information, exposure, time, exposure area, and then if the occurrence of the event is likely or unlikely.

Then they assess the consequences using kind of a risk evaluation or a risk matrix that I just showed you to gain insights of what are the acceptable risks and what--which ones are the unacceptable risks to see when they have to control or prevent or mitigate. And then we have to identify the IROFS, which are the controls to mitigate or prevent the accident sequences. Now the quantitative standards comes into play on the third and fourth step when you are assessing the consequences and likelihood, and that plays an important role to help them categorize or help them bin the high or intermediate consequences. So it is--I want to emphasize it is important to analyze all exposures, all pathways, because you are in a better position to identify preventive and mitigative controls so you can effectively manage the hazard and provide adequate protection. Next slide.

MEMBER SKILLMAN: Please before you move to the next slide, the fourth block from the left, "the consequence likelihood for compliance," does that

suggest there is a human behavior element that is considered? If you go to block three, I can understand consequence and likelihood being very quantitative. When the thought is introduced in the next block, the likelihood for compliance, that suggests that one might say only 10 percent of the people are ever going to even listen to the administrative prohibition for going into that compartment, or the procedure that says don't mix too much of this with that because you might have an adverse chemical reaction. So is the fourth block attempting to point to human behavior attributes?

MS. DIAZ: I'm going to try to answer that. First, that fourth block is basically the demonstration of the facilities of the licensee to demonstrate that they complied with the performance requirements, the 70.61 and the description of the proposed standards. It's basically taking their analyses, the evaluation from the one two three steps and then moving on to how does it comply with the regulations, with the performance requirements of high or intermediate consequence. Are they doing that? How--what is that number that allows you to bin or classify high, intermediate consequence? So it's not about the human factor, it's more about how do they

provide assurance that they are evaluating all hazards and that they are meeting the performance requirements. If anyone wants to add to that--

MR. HAMMELMAN: What I would say is you're taking the results of likelihood of frequency, putting it on that matrix and saying am I in an acceptable region or not. I think that's what that block is talking about. So you have already made some assessment of an exposure, of an event likelihood and consequence; you're putting that data point on that matrix and saying is it in an acceptable region or not. That's what compliance is talking about.

CHAIRMAN STETKAR: To help me out, the third box on this is where you actually should assess the likelihood that somebody might not follow the process and could go into a location when that person ought not to.

MR. HAMMELMAN: Right.

CHAIRMAN STETKAR: Okay. Thanks.

MS. DIAZ: So that fourth box provides assurance to the regulators that they are in an acceptable risk and they are doing the mitigation and prevention.

CHAIRMAN STETKAR: In effect, in Regulatory Guide 1.174 space, it's kind of those

thresholds of where you meet various--I don't want to call it acceptance criteria, but measures of relative assurance that they've evaluated everything and that they're within some regime of risk. Thank you.

MS. DIAZ: Thanks. So next slide. So now we're getting to the interim staff guidance that we've developed. So this slide just presents the sections of the ISG, and we'll go over them in more details. So the ISG begins with an introduction discussing the scope of the ISG, and also referencing the sections of the NUREG 15.20® Standard Review Plan that this guidance is supplementing. The next section opens the technical discussion and provides guidance to the reviewer to ensure the completeness of the applicant's submittal by reviewing that they've considered all exposure pathways, all credible exposure pathways. The next section, the review of chemical hazards and accident sequences, in this section we guide the reviewer to review the description of the hazards, if it consistent with scientific data or toxicological information based on historical events or historical experience, and has the applicant's ISA identified credible scenarios for routine as well as non-routine operations.

The next two sections talk about the

review of chemical accident consequences and likelihood; in this section we describe a reviewer's multi-step process for reviewing accident sequences and consequences. First, the NRC staff needs to review the exposure estimate and determine that all factors and parameters considered by the licensee or the applicant are reasonable, and the same for the consequence estimate. The NRC reviewer should also ensure that the applicant identifies exposure events that will produce effects comparable to those defined in the performance requirements, the high or intermediate consequences. Then we have Section B4 that discusses the review of proposed quantitative standards. And in this section, we provide guidance to the reviewer of when the quantitative standard is necessary. We don't expect to see a quantitative standard for every single chemical a fuel cycle facility has on site; we just needed to see to--when the consequences are high or intermediate, to help them bin or classify the events on those two categories defined in the performance requirements, not for every chemical they have on site. We don't want to see that. The other thing that we look at is that the quantitative standards are based on information, scientific information on the physical

and chemical properties of that chemical, and that it is consistent with available information.

In the Interim Staff Guidance, we have one general criteria for the proposed quantitative standards, and that is that it provides a reasonable estimate of the consequences. WE also provide guidance on publicly-available, useful information sources that the reviewer can use to evaluate the proposed quantitative standards. For inhalation, we have identified the AEGLs, ERPGs, the TEELs and others. We also have identified the Globally Harmonized System of Classification and Labeling of Chemicals, the GHS system that provides hazard statements on the different chemicals, and also we've identified NIOSH key notation for dermal exposures. And again, this is used for helping the staff reviewer evaluate the quantitative standards.

CHAIRMAN STETKAR: Again, I know nothing about chemical risks, so--

MS. DIAZ: So this table--

CHAIRMAN STETKAR: --he does. Let me-- before we get into this table, which has got a lot of stuff in it, when you say "reasonable estimate of consequences," are we talking solely about fatal consequences, or are we talking about skin burns or

are we--you know, what are we talking about? If I start to draw the analogy with radiation effects, without trying to get into it--

MR. HAMMELMAN: The two effects that are mentioned in the regulations are--I don't know the precise words, but one is sort of life-threatening--

CHAIRMAN STETKAR: Life-threatening I get.

MR. HAMMELMAN: --is one, and the other one is an irreversible effects, some serious irreversible effect. So those are the--

CHAIRMAN STETKAR; That's sort of the level that I needed, thank you.

MR. JOHNSON: And that's tied to the high and intermediate and the--

MS. DIAZ: Exactly.

MEMBER POWERS: I mean the--it depends on what chemical you're talking about; the databases that we have for chemicals is not as comprehensive as you would maybe like--

CHAIRMAN STETKAR: I was just trying to get a metric--

MEMBER POWERS: --as the chemical gets more and more extensively used, you get more and more discrimination in the effects. So some chemicals only tell me that yes, it'll kill the hangnails on your

little finger if you stick it in there, and some of them it says well, don't take a bath in it. You know, I mean it just depends on what chemical.

MS. DIAZ: Also not all chemicals are dermal hazards or inhalation hazards or ocular hazards; it does depend on the--

CHAIRMAN STETKAR: No, I understand, you know, on a chemical--by chemical; I just wanted to get that high level in terms of--

MEMBER POWERS: The other problem is that there are multiple databases and they don't use consistent nomenclature.

CHAIRMAN STETKAR: Okay. Thanks.

MS. DIAZ: So this table kind of talks about what we were just discussing. This table is taken directly from the ISG, so it identifies some of the common chemicals used at fuel cycle facilities, and we have identified here four information sources where a reviewer could go into those information sources and be able to get information to evaluate that proposed quantitative standards that the applicant or the licensee has submitted. This table number 2 talks about the information sources we have identified for inhalation exposures only that provide information, good information on how to evaluate the

high and intermediate consequence. Here, we provide a comparison with the language in the performance requirements that talks about could endanger the life of a worker or could lead to irreversible or other serious, long-lasting health effects, and that's to describe the high consequences. For intermediate consequence, Part 70.61 defines an intermediate consequence as "could lead to irreversible or other serious, long-lasting to a worker," and then "could cause mild transient health effects to the public."

MEMBER POWERS: This is real useful because it provides a translation of these various designators that people have invented in the various data and relates it to the language in the regulation. I found that incredibly useful because I've never tried to do that.

MR. HAMMELMAN: Yes, you're exactly right. We're just trying to map up language in the regulation with language that's used in some of these data sources.

MEMBER POWERS: Yes, and that's actually worth retaining because you see the designators they used in the database mean nothing to you relative to the regulation.

CHAIRMAN STETKAR: But again, in terms of

my personal education, if you can bear with me here, from a staff's perspective, and I'll just use the AEGL column as an example, is the staff concerned with AEGL-1, despite the fact that it's under the broad thing of intermediate consequences? I get the irreversible, I get--so AEGL, something that would fall in the mild transient health effects to someone outside the controlled area is not part of the staff's concerns; is that correct?

MR. HAMMELMAN: No, I think AEGL-1, I think what that's saying is AEGL-1 maps up closely with the threshold for intermediate for somebody outside the controlled area.

CHAIRMAN STETKAR: But is--okay, I was trying to be too specific. Is the staff concerned with that subset of--I see on this matrix intermediate is divided into two subsets; one is irreversible or other serious long-lasting health effects to a worker. I get the fact that the staff is concerned with that under the regulations. Is the staff concerned with the other subset that says cause mild transient health effects to any individual located outside the controlled area?

MS. DIAZ: Yes.

MR. HAMMELMAN: That's the definition of

intermediate--

MS. DIAZ: Yes.

MR. HAMMELMAN: --for somebody outside the controlled area in the regulations.

CHAIRMAN STETKAR: In the regulations?

MR. HAMMELMAN: Yes.

CHAIRMAN STETKAR: Okay. I'm not as familiar with the regulation as I should be.

MS. DIAZ: So there's two being used that you see in the--

CHAIRMAN STETKAR: So a release that causes my eyes to burn for a few hours is of regulatory concern?

MR. HAMMELMAN: Yes.

CHAIRMAN STETKAR: Thank you.

MS. BAILEY: So an intermediate consequence like that needs to be in an unlikely or--

MS. DIAZ: Unlikely.

MS. BAILEY: --unlikely category for it to be acceptable. That's the way the regulation is defined.

CHAIRMAN STETKAR: That's where I'm headed.

MS. DIAZ: It goes back to the acceptable or unacceptable risk of what--but those two meanings

that you see here cite to the high consequence and intermediate consequence, they're divided to worker, the description that life injury to a worker, and then for the public. So you see two binning because one is for the worker, and one is for the public, member of the public.

CHAIRMAN STETKAR: I get that; it's just --and I understand from a consequence perspective life endangering or irreversible health effects to me sound fairly important. Mild irritations to people sound-- there seems to be a distinct difference there.

MEMBER POWERS: Of course there is because the person outside the controlled area has not assumed risk.

CHAIRMAN STETKAR: That's true. I get that too. Thanks.

MS. DIAZ: So next slide, here we have kind of the same table, but for dermal and ocular exposures, and what we found in the GHS hazard statements that are compared to the high consequence in the regulations and the intermediate consequence. And also for dermal, we've identified the NIOSH skin notations to be useful when evaluating the quantitative standards for those exposures. And then we have the ocular exposure descriptions that we have

identified the GHS hazards statements to provide comparable information on the hazardous characteristics and to cc information for that chemical.

And to summarize, the ISG will provide guidance to ensure--to staff to ensure that the ISA review considers all exposure pathways, verifies that the applicant's ISA analysis for all phases of operation, including routine operations, non-routine, maintenance, that it ensures that the proposed quantitative standards are identified when necessary and ensure proposed standards are consistent with available scientific information. Do you have any questions?

MEMBER POWERS: We didn't ask enough?

MS. DIAZ: I think--yes.

CHAIRMAN STETKAR: You didn't get a full quota?

MS. DIAZ: My opinion, yes, but we just wanted to ask, be polite.

MEMBER POWERS: She didn't fair warn me that she had a ton of questions. You never ask this committee if they have questions, Marilyn.

(Simultaneous speaking.)

MEMBER SCHULTZ: I have a question, or

perhaps just a comment. These seem very useful, but not being experienced, it looks like you work to organize a lot of information that's probably been scattered into an approach that can be used in a review, and you've got the combination of tables that lays things out logically. There's still though, in my view, it seems like there's still perhaps some missing pieces in terms of--there must--you mentioned so many standards or data sources that are out there, you've picked the most prevalent ones in the slides preceding, and some of those are not fully represented here, or are they all?

MS. DIAZ: So as Dr. Powers was saying, when you've got a chemical, if it's used in the chemical plant, as it gets more and more used in the chemical plant, you'll get more and more information available to add on about that chemical. So some of them will have a lot of information out there; we just identified the ones that have been approved or endorsed by OSHA that have been developed by--

MEMBER SCHULTZ: And are they the most commonly used then, or the most familiar in the processing facilities?

MS. DIAZ: --and they are the most used according to AEGL CRPGs; they're widely used. The

Global Harmonization System is now being endorsed by OSHA, so that is--

MEMBER SCHULTZ: When you say now being, it means at current time it's endorsed or it's going to be, it's in the process of--

MS. DIAZ: It's coming; I think 2016--

MEMBER SCHULTZ: Okay.

MS. DIAZ: --they're supposed to implement it, and that was an effort done by the international community to try and standardize the toxicity information that is all over the place in the U.S. and internationally, and it's just come back to having everyone the same information, like Material Safety Data Sheets, they're now called Safety Data Sheets, and they're going to keep it in that Global Harmonization System to be consistent on the different manufacturers, different facilities and it will be kept--all that information, all that hazardous characteristic will be kept under one simple database.

MEMBER SCHULTZ: And tables 2 and 3 have this note indicating that the reviewer should take a current look at information that's available; there's no similar notes on the other tables. Is there any meaning that should be taken from that? In other words, table 1, is this--

MR. HAMMELMAN: I think that note is on the table--

MS. DIAZ: I think it is.

(Simultaneous speaking.)

MR. HAMMELMAN: I'm just going to make a mention--

MEMBER SCHULTZ: That's the intent, to make sure--this is--

MR. HAMMELMAN: Yes.

MEMBER SCHULTZ: --all coming together, very organized here; I really like--

MS. DIAZ: The higher level will--

MEMBER SCHULTZ: I like the intent and it does provide a much better approach to organize the information and make it meaningful.

MR. HAMMELMAN: Okay, I'm just going to just say a few words on that Global Harmonization Standard. That was a UN-initiated effort where they were trying--where all the countries were trying to standardize on their hazards statements so that when this chemical moves across the boundaries, we don't say this one is a little hazardous, and the other one says well it's a little more hazardous, or another one a little less. They developed some standardized hazard statements, and then some standardized test

protocols for running your chemical through those tests and then developing the appropriate hazard statement. And what OSHA has done, they have had a historical requirement for these MSDS, Material Safety Data Sheets, and what they're saying now is you're going to start using these hazard statements in your next generation of MSDS sheets.

MEMBER SCHULTZ: Okay, now I've got a benchmark I can connect to; thank you.

MEMBER POWERS: But you still have to recognize there are an awful lot of MSDS sheets that will say we don't know what the hazards are--

MEMBER SCHULTZ: That's right--

MEMBER POWERS: --of these chemicals.

MR. HAMMELMAN: And sometimes you know, when we're reviewing it, we would use these data sources; we also go back to the literature too, you know, medical reports, you know. A lot of times there's surveys, I mean I've done a lot of reviews of HF toxicity and there are people--

MS. DIAZ: So there's a lot of information out there; we just identified the ones that we think are acceptable, and the licensee and applicants are free to propose quantitative standards based on the literature--

MEMBER SCHULTZ: And this guidance.

MS. DIAZ: --and this guidance, but they don't have to use this guidance. But they can propose the quantitative standards, and this is what we'll be using to evaluate those hazards.

MEMBER SCHULTZ: Right, I understand.

MEMBER POWERS: And on top of that, there's the other thing that some people are just more sensitive to these chemicals than are other people, and it just makes getting a uniform declaration of hazards impossible.

MS. DIAZ: It would have been difficult, yes.

MEMBER POWERS: Coupled with the fact that you really don't how the guy is going to be using this, I mean we do in our facilities, but when they make up the sheets, they really don't know how people are going to be sloshing this stuff around. It does become very nightmarish, I understand that, and a little clarification for the guys that have to review it, who typically won't be specialists in any one of the chemicals that they're looking at is just a big help.

MEMBER SKILLMAN: I'd like to ask for clarification. I thought I understood the thread of

discussion, but as I think back I--it's not clear in my mind what the answer is, and so I would direct my question at Marissa. John asked, I think, why not a reg guide, and at least in part the answer was there was some push back because of the concern about backfit. May I ask you please to explain that a little more clearly?

MEMBER POWERS: We'll get there.

MEMBER SKILLMAN: Oh, we're going to get there?

MEMBER POWERS: Yes, we're going to get there. We have more presentations.

MEMBER SKILLMAN: Thank you. I'll wait.

MEMBER SCHULTZ: Just a question for clarification. You've got one additional slide, and it has to do with events; I just wanted to know is that a complete listing or is that a sample listing?

MS. DIAZ: It's an--well, those are past events.

MEMBER SCHULTZ: Right.

MS. DIAZ: But just focusing on dermal and ocular exposures. So it's--

MEMBER SCHULTZ: Is it derived as an example or is it--

MS. DIAZ: It was derived if we got a

question about backfit.

CHAIRMAN STETKAR: What he's asking is, is this an excerpt of all history, or is this the complete history?

MR. HAMMELMAN: It's the history that we're aware of--

CHAIRMAN STETKAR: In the U.S.?

MR. HAMMELMAN: --yes, from fuel cycle facilities since about 2006 or something like that.

CHAIRMAN STETKAR: Thank you.

MS. BAILEY: Can I just answer your question about as to why that came up. When we first reviewed the licensee's ISA summaries, starting in I would say 2003, 2004, 2005 time frame, our focus of the review were on those I would say the hazards that provided the highest risk. And so when it came to chemical exposure, it was really the inhalation pathway that provided the high--that we understood provided the highest risk at the time. And so we didn't focus on how licensees may have considered the other exposure pathways; we really just focused on the inhalation pathway. And as I mentioned earlier, starting around 2006 and later on, there was a series of dermal exposure events that caused us to reconsider--caused us to focus more on other pathways

besides inhalation pathways. So the operating experience is really what got us into making sure that we were also looking at other pathways for chemical exposure, not just the inhalation exposure.

So the question of backfit comes, you know NRC, when you first reviewed and approved the ISA summaries, you accepted those summaries knowing that only the inhalation pathways were considered. And so now that you're looking at other pathways, isn't that a backfit, haven't you changed your position? So that's where the backfit question comes up. And so we are very sensitive to that backfit comment, and so for that reason, we are going to be going to the CRGR, the Committee for Review of Generic Requirements, so that you know, we do our due diligence and the backfit issue is addressed.

CHAIRMAN STETKAR: Marissa, thank you. But if backfit is applied to regulations, and the regulation--regulatory guides don't change the regulations; regulatory guides alert the staff to what they should be reviewing, right?

MEMBER POWERS: Yes.

CHAIRMAN STETKAR: Okay. I look to you because you know everything.

MEMBER POWERS: Thank you Marilyn.

MS. DIAZ: Thank you.

MEMBER POWERS: Now we're going to hear--Janet, you're set to go?

MS. SCHLUETER: Uh huh.

MEMBER POWERS: Okay. Janet, the floor is yours.

MS. SCHLUETER: Okay. Thank you.

CHAIRMAN STETKAR: We like to see little green lights. Yes, just do--the reason we do that, if you're not familiar with this--

MEMBER POWERS: This is a speech that he gives seven times during a average meeting. So it's his moment in the sun; he likes to do this.

CHAIRMAN STETKAR: And I only get two more months to do this, so humor me. All of our transcripts are picked up off the microphones and if they're on constantly, the microphones are so sensitive that everybody hears paper rustling and things like that, so we've gone to this turn it on/turn it off thing.

MS. SCHLUETER: Sure. Okay well good afternoon, and thank you very much for the invitation to participate in the discussion. It's an interesting one as you know, and one that's been going on for quite a few years. As the slide indicates, I'm Janet

Schlueter, I'm the Senior Director for Radiation Material Safety at the Nuclear Energy Institute, and my group is responsible for addressing, identifying and addressing generic radiation safety and environmental protection issues for all the different categories of our facilities. I happen to personally spend a lot of time working with the fuel cycle facilities on regulatory issues.

For the record, I'm compelled to let you know that NEI is the organization that's responsible for establishing some unified policy across the industry for generic regulatory and operational issues. Our members include entities that are licensed to operate commercial nuclear power plants, nuclear power designers, major architects and engineering firms, fuel cycle facilities, uranium recovery operations, materials users, and other organizations and entities that support the nuclear industry globally. Next slide, please.

So before I'd like to begin, I think that I want to just clarify a couple of important things that came out in some of the opening remarks, and that is that the ISAs as Marilyn had indicated is the tool that the licensees use to evaluate the hazards from chemical exposures in all pathways' manner. The

second part I think Marissa very helpfully clarified was on the backfit issue; it in fact is focused on whether or not the staff is interpreting the current Part 70to actually require a quantitative standard now versus in the past when that was not the impression that the industry had when the ISAs were developed and they were approved by the agency. So the backfit issue is about the rule itself, and it's not focused on the all pathways issue; that's separate and distinct and one that I think the licensees feel confident that they're working and doing in the right manner today.

So first and most importantly, I'd like to emphasize that all of the fuel facilities certainly do place great import on a comprehensive chemical safety program in place at their facilities that complies with the OSHA standards and the NRC requirements. After all, as Marilyn has indicated, these are manufacturing plants that are primarily chemical plants that handle licensed material. So it is a complicated regulatory mosaic if you will, but I think the NRC and OSHA and the licensees have all worked together very carefully to ensure that those lines of regulatory jurisdiction are relatively clear.

As I trust will be evident from my

remarks, the development and imposition of any sort of new quantitative exposure standard for the worker is unnecessary from a safety standpoint, it's impractical, and it does constitute an analyzed backfit. Our letters go into great detail on those issues; most recently, the letters you see at the bottom of the screen, the March 2014 letter went into a great level of detail on the backfit discussion as well as the other two did. We firmly believe, and these messages are not new that I'll be relaying to you today; the staff is certainly familiar with our position and I have no new information to shock the staff with, and their information on their slides is not new to us. We've had a very open dialogue about this, but we firmly believe that our issue, our resources both in the industry and at the NRC should probably be focused on some other regulatory issues or either and also other initiatives that even the licensees maybe have identified as operational improvements at their facilities that would yield a higher safety return than an imposition of a new quantitative standard that I hope you'll see I believe is--or we believe is unnecessary. Next slide, please.

So I have a couple of slides on the point about exposure standards being unnecessary, and then

we'll move to impractical and backfit. We firmly believe and the NRC has discussed this with us in the past and given us some assurance, and they do that through their inspection program as well, that our safety programs are currently designed and implemented in a manner to provide protection of the workers and the member of the public. So they're adequate today, and I think we have a lot of evidence as far as their operational experience to demonstrate that. More specifically, the fuel cycle industry does have to follow the OSHA standards as we've discussed already, and it's regardless of the exposure pathway that the licensee is obligated, required and certainly holds very important the idea of protecting their workers from any--whether it's ingestion, inhalation, dermal, ocular, it's still a chemical exposure. It's not something that they obviously want to have occur at their plant. So their chemical programs are very comprehensive in order to try to prevent these and to mitigate those events should they occur.

They typically use a three-layered approach in their chemical safety program, and the first layer is equipment integrity, and that's to contain the chemicals and to reduce the potential for exposure. And in some cases as Marilyn alluded to ,

the integrity of those program elements might actually be identified as an item relied on for safety or an IROF within the ISA. The second layer is personnel protective equipment, or PPE that employees wear to protect them while performing routine tasks or in upset conditions.

MEMBER POWERS: Do you really give credit for personal protective equipment?

MS. SCHLUETER: Yes.

MEMBER POWERS: I don't know of anybody that does that.

MS. SCHLUETER: As part of a chemical safety program.

MEMBER POWERS: We never give credit for that. In all the chemical facilities that I've ever worked in, personal protective equipment was never credited; that was--I mean they had it, we required it of them, but we didn't give credit--in analyzing the facility, we did not give credit to that personal protective equipment because you can't anticipate that the guy has it on correctly. I've never seen that done. I'll be darn. Okay.

MS. SCHLUETER: Well as you very well know that can include in many cases respirators, safety goggles, gas masks--

MEMBER POWERS: Yes, respirators and goggles, but you can never guarantee that the guy's got it on correctly. I mean, you can fit them, you can test them, you can train them. At the time that event occurs, you cannot guarantee that the face shields are tight, the goggle are actually on and things like that. I mean, it's just a fool's errand to try to say I can guarantee that this is here, so we never give credit for it. In any chemical facility I've ever worked in.

MS. SCHLUETER: Well, I think it's just a part of the defense in depth approach that the facilities use with regard to prevention and of course then mitigation with your equipment being that first layer that I was describing.

MEMBER POWERS: We do the ISAs, and we identify the high consequence or intermediate consequences; we don't look at personnel protective equipment there, do we? I don't think so.

MR. JOHNSON: Just to clarify, the licensees are conducting and doing the process hazards safety analysis and the ISAs; they are--they have the latitude to identify the equipment, the protective, preventive or mitigative equipment, and actually I should let you reply to that.

CHAIRMAN STETKAR: Curiosity though, you've looked at--

MEMBER POWERS: We haven't. I haven't certainly.

CHAIRMAN STETKAR: --looked at the details of ISAs, certainly for these types of facilities; do you find licensees identifying personal protective equipment as IROFS? I mean, the analogy here--

(Simultaneous speaking.)

MR. POWERS: That's what you'd have to do, and I don't know how you do that.

CHAIRMAN STETKAR: But what I'm asking is do you see people actually doing that? If they're not doing that, then they're not--essentially they're not taking credit for it.

MS. DIAZ: So I think Jim and Dennis--correct me if I'm wrong--when reviewing the ISA safety analysis, they do have a description that they do say that they provide protective, the PPE, but they do an unmitigated analysis to the consequences and likelihood, and then they have--but I don't think I've seen IROFS as--we don't encourage it. We've seen all the things related to the training of PPE, of how to train a worker to wear their mask, to work with the goggles as IROFs, as an administrative of IROFs, but

I don't believe I've seen PPE as IROFs.

MEMBER SCHULTZ: All of that is necessary but not sufficient. In other words, you look at the data on your backup slide, two-thirds of those instances are failure of PPE one way or another.

CHAIRMAN STETKAR: I get the notion of administrative IROFs, that you have to have a training program, you have to have, you know, fitting masks and stuff like that, because that's something that it's programmatic that you can hold people accountable, but--

MS. DIAZ: So we do see, but we don't encourage identifying an IROF as PPE.

CHAIRMAN STETKAR: Well I was going to say don't encourage, but--

MS. DIAZ: I think there are other things, like the equipment and other controls that they can identify as preventive or mitigative strategies.

CHAIRMAN STETKAR: But saying you don't encourage is something different than saying nobody takes credit for it, nobody has identified PPE as an IROF.

MS. DIAZ: Well it's--we've heard it from NEI that getting into the dermal and ocular exposures they might need to identify PPE as IROFs; NRC staff

believes that that's not necessary.

CHAIRMAN STETKAR: You haven't seen--

MS. DIAZ: But again, it's a disagreement between the industry and staff.

CHAIRMAN STETKAR: Let me see if I can twist it a little bit. Have you seen it in terms of radiological hazards, people taking credit for PPE as an IROF?

MS. DIAZ: I don't believe so.

CHAIRMAN STETKAR: Okay. Thank you.

MR. DAMON: This is--my name is Dennis Damon, I'm in the same division as Marilyn. Yes, I mean I can't speak for all the licensees because I haven't looked at every single process design at every plant, but typically as Janet says, the licensees have PPE and a very typical way of treating the PPE in an ISA is because dermal exposures were not typically included as an exposure pathway, when the PPE is the gloves, the things that protect the skin or the eyes, the goggles, those things are there and they're not IROFs because they're not protecting against one of the hazards that the licensee was considering within the scope of the ISA, so they didn't make them IROFs; however, the licensees also had a concept of defense in depth, which means that they have controls in

addition to IROFs, and so they're usually considered a defense in depth.

CHAIRMAN STETKAR: I get that, and I was trying to pull you back away from what has been analyzed in terms of chemical hazards and what has not, but if I go back to the radiological hazards, do you see people identifying filters and breathing apparatus as an IROF against inhalation of radiological hazards, the dose due to inhalation of radiological hazards? Particulates, for example or something; I don't know what they analyze.

MR. DAMON: Well, not--the one facility that has that issue is the BOX Facility.

CHAIRMAN STETKAR: Okay.

MR. DAMON: Okay. The other ones don't; they're not radioactive enough material in order to hit the thresholds of intermediate radiological consequences because it's 25 rem. But BOX, yes, they have all that, all those protective measures there in BOX, and many of those things are IROFs.

CHAIRMAN STETKAR: Protective--personal protective equipment is what we're talking about, and I'm talking about--

MR. DAMON: Yes, I don't--personal protective equipment, I don't know about BOX.

MEMBER POWERS: I think they were running ventilation--

CHAIRMAN STETKAR: That I get; I'm trying to find out where--

MEMBER POWERS: All I can say is that I have no experience relying on personal--

CHAIRMAN STETKAR: I have never heard of it either, but this is something gray out on the periphery of my experience.

MEMBER POWERS: Please continue.

MS. SCHLUETER: Okay. So we talked about the first layer being equipment and its integrity and the second layer being the PPE, and of course the third layer being those mitigating actions that a worker would take in the event that there was a chemical exposure, whether it's running to the full shower and eye wash station, onsite medical treatment, what have you; those steps that you would take immediately, since dermal exposure is self-evident, to--

MEMBER POWERS: No, it's not. HF is the classic example where it's not. The worst HF exposure I've ever seen is where a guy was wearing gloves, had a pin hole leak, and because it anesthetized the skin, he was unaware that he was getting exposed to HF, and

consequently he exposed himself for a long time. And it was extremely devastating. So dermal exposures need not be self-identifying. Similar, osmium tetroxide on the eyeball is not self-revealing; it's found only when you start losing your sight the next morning.

MS. SCHLUETER: As the next bullet points out and has been acknowledged, the chemical programs do follow OSHA standards, and they have been approved in the past or accepted at least by the NRC through the ISA summary, which we discussed earlier, which were developed about four or five years, all of them were approved by that time line, about four or five years after the final order went into effect in 2000. So they've been in place for quite some time. I think the important point here on this bullet is the fact that, you know, a new quantitative exposure standard is certainly not necessary for licensees or the NRC, in our opinion, to adequately categorize the consequences from an exposure event under the performance objectives of Part 70 or make a report under Part 70, Appendix A. In other words, regardless of what the exposure standard, the quantitative standard might be for such an exposure that would vary by chemical, if you have exceeded the performance

objectives in Part 70, you would file a report regardless. So the existence of such an exposure standard is not going to help you make that decision of categorizing the consequences of the event, of an intermediate or a high consequence event. It's simply a standard that would exist.

And I would like to give credit to the at-large chemical industry, which have applied their practices and their programs for, in this case at the field facilities for many of them for more than four or five decades, which have been maintaining chemical safety despite the presence of a large number of chemicals and hazardous materials at these facilities, and it's a wide variety across the fleet. It's not a large fleet, but there's a lot of variety in the chemicals that have been used. And as such, there's been a low number, a very low number of reportable acute exposure events and none I would point out that would be prevented by any quantitative exposure limit on the books. That's simply, as you know, not how it works. A standard does not prevent an event.

MEMBER POWERS: A standard has never prevented anything.

MS. SCHLUETER: Right, exactly. Exactly. And in that regard, I know the staff is aware of our

comments back on the Federal Register Notice from April of this year, where there's what, about 10 events or so, 10 or 12 that are in the Federal Register Notice, and we did have concerns over two of them with regard that we think that they have been mischaracterized based on the NRC and the licensee's own medical consultant reports, that they in fact were not high-consequence events. So that's a concern we have over a recent characterization of a couple of those very few events that have occurred in the last-- I think that was over 20-some years; the chart is-- next slide, please.

So for our next slide here on why we believe the exposure standards are unnecessary, we believe that the industry has again, as I've mentioned, has worked very hard on ensuring that its chemical safety program is adequate, and they go to great lengths to share operational event information amongst the fleet, and we do that in several different ways, whether it's in the biweekly calls that I facilitate, or within the corporate structure, bench marking against their peers. We also of course support continuous improvements to identify and apply the lessons learned, not only from the fuel cycle fleet, but other industries at large from any sort of

similar exposure event for the purpose of preventing recurrences.

The industry did also consider the NRC Information Notice that Marilyn mentioned in 2007 as operating experience, and many of them did, from what I have been told, did implement corrective actions directly as a result of that information notice, for the purpose again of preventing recurrence. So effective preventative measures were implemented, and they continue to evolve; obviously there are learning organization and a chemical exposure event is obviously the last thing that they want to have happen. So any efforts to derive what we consider to be a pretty elusive quantitative exposure standard would just simply represent an unnecessary burden that would probably yield no commensurate safety benefit as far as the existing chemical programs and how they naturally evolve and improve.

I would also add that imposing a new quantitative standard for such an exposure actually provides sort of a false sense of security. A new standard is not necessary as I mentioned for either the licensee or the NRC to actually categorize the consequences of the event or to report it under Part 70; those requirements already exist. It's clear that

a new standard which is an attempt to measure exposure after the fact would not result in any changes, improved or new chemical safety programs out there. A new standard, putting a new standard on the books is not going to change the way that licensees effectively manage, evolve, implement, and modify their chemical safety exposure programs in response to events. It's not going to make a difference to them.

MEMBER SCHULTZ: So Janet, is--there's the reportability requirements for the facilities, and then you mentioned the phone calls that you have; is NEI an informal clearinghouse for communications?

MS. SCHLUETER: We're a forum. We provide a forum; we facilitate the discussions between the different categories of fuel cycle facilities; our members, you know, they don't have another forum that's available to them to get on the phone and talk about operational events, generic licensing and inspection issues. We run those calls every two weeks, and additional ones as needed.

MEMBER SCHULTZ: Would you characterize it as an informal forum? In other words, are there any requirements for their participation or--

MS. SCHLUETER: It's informal in the sense that if they're our members, they participate.

MEMBER SCHULTZ: They have the opportunity to participate?

MS. SCHLUETER: They have the opportunity to participate and do.

MEMBER SCHULTZ: But you're not requesting them to provide any particular information on a--you're not an INPO--

MS. SCHLUETER: Yes, that's right. I'm not an INPO, I'm not a WANO, I'm--right? Yes.

MEMBER SCHULTZ: Okay. Thank you.

MS. SCHLUETER: We are a policy organization that provides those sorts of opportunities and forums and facilitates the exchange of information and helps to try to identify regulatory issues, for example, and build consensus and then represent those back to the NRC, EPA, DOT, whomever it may be. Can I have the next slide please? Thank you. So our second important point, which is stress in our letters of course is that a new exposure standard is simply not practical and none actually exists today in industry that we can draw upon.

In the last two years alone, many industry representatives, one of whom is on the phone with me here today, Bob Link, who has been with Areva for many years, have spent considerable time and resources

working with their senior facility experts, including industrial hygienists, to try to develop or try to determine the feasibility of developing quantitative dermal and ocular exposure standards for workers that are exposed to the chemicals that are on site. And this has proven to be a very exhaustive effort that has not yielded a standard that is readily identifiable for every chemical that they have on site. And I know Marilyn and others at the NRC are certainly aware of that effort; we've been very open in communicating our difficulties in trying to develop those chemical-specific standards, and they have used a lot--well, the industry has looked back and that's where the draft ISG as you noted on the slides has a lot of resources of information with regard to data. But our facilities have gone and done similar level of research, and have not been successful for a whole variety of reasons of coming up with a quantitative standard for these exposures.

MEMBER REMPE: Could you be a little more specific and cite some of those reasons?

MS. SCHLUETER: Well I think it gets back to some of the--and I want to look here at my notes here for just a moment--some of the same reasons that OSHA had indicated that it was very difficult to

develop a standard and why they have not. First of all, just the difficulty in and of itself of actually quantifying the actual dermal exposure, what occurred at the time, the inability to select a reliable biological indicator, and the difficulty in correlating the amount of absorbed dose with a precise adverse health effect is extremely difficult. Acids versus non-acids--I'm not an industrial hygienist or a chemical engineer, but that's why I also mentioned Bob Link is on the phone and he and his staff, along with industrial hygienists did spend an inordinate amount of time attempting to do this. So if the Committee would be so gracious as to allow him to perhaps elaborate on that, it might be useful for you.

MEMBER POWERS: I think we can open up the line and ask Mr. Link to speak if he would like to, but I don't know how to do it.

MS. SCHLUETER: Yes, if you can I think that would be helpful because he has spent a lot of time and effort on this issue.

MEMBER POWERS: It may take us a minute or two.

MS. SCHLUETER: Sure.

MEMBER POWERS: It's open; Mr. Link are you there?

MR. LINK: Yes, I am. My name is Bob Link, and I've been in the industry for 40-plus years; recently with Areva, I've been the Environmental Health Safety and Licensing individual, and as Janet said, I want to preface though my remark, I am not a certified IH expert, but I have had those individuals on staff, and we have worked diligently as Janet has mentioned over the years to investigate--to try to strike and be timely in my response, the real challenge with dermal and ocular exposure as compared to inhalation pathways is that as Janet not4ed and OSHA has also acknowledged, the complexity of the transport phenomena and the impact is a very complex one. It really is a dose approach, but dose is affected by the normal things, you know, concentration, time, area of exposure, but then you get into the further complexities of the transport phenomena through the tissues, the buffering agents that are naturally available that the body has, and with the complexity of the what I call chemical cocktails. It's actually more commonplace that it's not a pure chemical like nitric acid or HF that we've discussed which are commonly used, but it's a cocktail of chemicals that are actually--or the exposure is caused by.

So OSHA's approach, which we and the chemical industry have used for decades as Janet said, is essentially to prevent the exposure, and I can comment on the PPE. Actually PPE is acknowledged by OSHA and the NRC to have protection factors afforded it, especially in the respirator use category. In fact, recorded doses are mitigated or adjusted based on those protection factors. So the use of PPE in the safety realm in both OSHA and NRC is well established. That's not to say that we rely on it heavily, and in fact we do not prefer to take credit for it, but in the situation we have and the practice we have, in essentially the ISA application, there are cases that PPE would have to be accredited, albeit at a reduced value from a risk assessment perspective, because it is an administrative, we acknowledge it's an administrative control. So I can elaborate on more if you want, but I want to keep my comments concise.

MEMBER POWERS: Okay, did that cover what you wanted him to say?

MS. SCHLUETER: If it answered her question.

MEMBER POWERS: Thanks Bob.

MS. SCHLUETER: Okay thank you, Bob.

MR. LINK: You're welcome.

MS. SCHLUETER: And some of the phrases that I was using I should have referenced was from the 1992 OSHA Rule on Occupational Exposure, where OSHA declined to adopt a quantitative dermal standard by stating that it was unable to establish the standard and allowable limits for the reasons--additional reasons than the ones that I mentioned, but those are the ones that were in the quote. And to the NRC's credit, you know when we first had this discussion or began these discussions back in the fall of 2009 at one of those meetings, NRC actually asked some representatives from OSHA to come in and participate in that discussion. And during that time, they had stated that OSHA had not and wasn't attempting to and didn't plan to develop quantitative dermal exposure standards because of some of the difficulties that we just discussed. So the staff brought in some OSHA reps and they confirmed what we believed was the understanding at the time.

So as I stated on slide 2, or I may have failed to state now it's running through my head; I don't remember saying these words. In one of our letters, in the June letter, we commented on the draft ISG because the NRC had solicited comments on it and wanted input, and we certainly weren't going to pass

up that opportunity. But that being said, in the letter and since then, we wanted to make sure that the NRC certainly understood that our comments should not be interpreted as a concession to or endorsement of the draft ISG or its contents, or the staff even moving forward to finalize it. And I think that's simply consistent with our position as I've discussed on these slides that we do not believe that the quantitative exposure standard is necessary or it's even practical to develop and implement.

So despite the staff's reasonable effort to develop the ISG, it remains clear, and I think it's obvious from the charts that were shown, that uniform quantitative standards addressing dermal and ocular exposures to the wide variety of chemicals that are in use have not been developed by expert organizations, and will not be the outcome of licensees applying these methods which are described in the ISG. The ISG, as the NRC recognizes, doesn't provide standards, it provides methods that could be used to create the quantitative standards for various chemicals. But it should be recognized that if you implement the draft ISG as written, it would more than likely result in different facilities developing different chemical standards, and I'm not sure that that's an outcome

that the staff is after.

But again, I think it sort of draws back to this main point of why are we doing this? Has it been required from the get go? We don't believe so; that's part of the basis for our backfit analysis. Will it prevent a chemical exposure? No. Does it have any part in mitigating it? No. Will it make a difference as to the chemical safety programs that are in place today? No. So what is the benefit of imposing some new standard on industry that won't make a difference from a day-to-day operational safety perspective?

MEMBER POWERS: Isn't differences, I mean aren't difference inherent in the whole ISA approach?

MS. SCHLUETER: Yes, they're facility-specific.

MEMBER POWERS: Yes, I mean inevitably, you're going to have different standards for different operations, I mean it's just unavoidable because of the way the ISA is constructed.

MS. SCHLUETER: True.

MEMBER POWERS: Okay.

MEMBER SKILLMAN: Janet, let me ask this. Does NEI see any benefit to some action on dermal and ocular exposures?

MS. SCHLUETER: I'm being measured in my response because of the way you phrased it when you said any action. By the regulator? Is that really what you're focused on?

MEMBER SKILLMAN: If you wish.

MS. SCHLUETER: No, I'm speaking on behalf of the industry and our discussions to date that no, the industry does not see value, increased safety or anything measurable or commensurate with the imposition of a new quantitative standard for workers for dermal and ocular exposures. And I think that's mainly because they have comprehensive chemical safety programs in place, and they have stated repeatedly amongst themselves and to me, you know, when I'm part of those discussions, that it's not going to change what they're doing. Their programs are all about prevention and mitigative and they take the layered approach, it's a defense in depth approach; it doesn't matter the source or the chemical that is of concern. Now of course that the event occurs would be of great concern and all of the root cause analysis and actions that are taken to prevent recurrence and so forth will still go on. But trying to determine what's an acceptable standard for a dermal or ocular exposure to the worker, they ask themselves what is the purpose

from a safety perspective on a day-to-day basis, what will I do different as a ES&H or radiological safety manager, ISA manager, regulatory compliance manager. Will I do anything different if NRC imposes a new standard in this regard? And the answer they come up with every time is no, it won't change what I do, so what is the value added? And it is a fundamental--we are in two different places with regard to what the rule does and does not require, and the licensees have been under one impression for many years, and the NRC has a different interpretation of what the rule requires, and this is the foundation of our backfit.

MEMBER POWERS: You speak to current facilities which have established programs that have operated pretty well. I mean we had a list of events, but that's a pretty short list for a long time of operation. Now speak to me about I'm building a new facility, we're going to make Moly 99 or something different. Now how do things square?

MS. SCHLUETER: I'm sorry now, what?

MEMBER POWERS: Now how do things square? I'm designing a new facility, and I'm using this ISA process that I'm openly abusive of because I don't really like it simply because it doesn't go far enough; it should go all the way to PRA. But given

that that's what we have, and it's written into the regulations, we're going to use it. Now speak to me; does it change the kind of program that I would set up, having this guidance as the staff's promulgated it?

MS. SCHLUETER: Well, I think you have to ask yourself if there's some--let's just take an example of a 10-centimeter square standard on your hand or something. I mean, whatever that standard is, whatever that quantitative standard is, is that really going to make a difference as to how you design your chemical safety program? Aren't you still going to have the same fundamental, integral components, whether it's equipment, how you maintain it, its integrity, what you identify as an item relied on for safety or not, the PPE we discussed, and then of course the other elements of your facility that are all involved in the mitigative actions that a worker or the next to worker is going to take to assist that worker whose been exposed; the eye wash, the stations and so forth. It's not going to change how they design their facility or design their chemical safety program. It is an after-the-fact type of standard. You're trying to measure what happened; it's not going to prevent what happened; that's what your chemical

safety program is all about, is designed to do.

MEMBER POWERS: Could it possibly move me to automate or mechanize things that now in our older facilities we do manually?

MS. SCHLUETER: I'm probably not the best person to ask that question. Honestly, I wouldn't want to misspeak for someone who may be designing or--

(Simultaneous speaking.)

MS. SCHLUETER: I would say common sense would say no, not necessarily, but--

MEMBER POWERS: I'm not coming up with a real good example, but it strikes me that that's where I would look if I were--I'm designing one from scratch, and I could imagine having this guidance might move me to say okay, I would prefer not to get into a fight with Marilyn because she's tough and mean and hard to get along with, and I will automate this or mechanize this instead of having a manual operation. I'm right, I don't know.

MEMBER SKILLMAN: Well I would weigh into this because I watched feed cylinder at a centrifuge facility being connected, and I don't know if any of you have seen that process, but a feed cylinder is a pretty hefty piece of equipment, and hooking that onto the header that is the feed header involves bringing

that feed cylinder in about 15 centimeters, then hooking up what looks like a compression fitting or a refrigeration fitting by hand. And when I watched this, I was kind of presuming the tech would use a face shield, gloves, because this is hex. And what surprised me is the guy did it the way I would do it at home. And it was a guy; I'm not trying to be gender-specific here, but the gentleman took the coupling nut and he tightened it down by hand, then he took a non-sparkling wrench and he pulled it down a couple of times, a flat or two like you would on any other mechanical hook up, and he was done. But that was an area-likely situation; that gentleman could have been exposed, had the valve just tear off its seat, he would have had live hex on his hands. He could have breathed that, he could have gotten it onto his face or his skin.

That's not to poo-poo, Janet, what you've said. But it seems like the NRC staff is saying hey, when you do an ISA, there's more to it than just the inhalation; there is the ocular and there is the dermal, and that deserves attention. And what I'm really interpreting from what you are saying, the industry says you know what, we don't even need that. There needs to be--well, I don't know. It seems

there's probably a middle ground where the potential for the skin and the ocular has been taken into consideration appropriately, and maybe the industry's response is you know, we already do that because our programs are so robust, which is I think what you're saying. But there seems to me the need of salute to the NRC for saying the ISA really needed these two other components, and there needs to be a way to factor those in that is reasonable. At least that's what I'm carrying away, and I appreciate your direct answer; that was a good answer. Thank you.

MS. SCHLUETER: And if I--may I ask for my lifeline again? Okay. Perhaps if Bob could take a minute or two and just discuss how the other pathways are considered within the ISA, that might be useful.

MR. DAMON: Yes, I'd love to. Thank you.

MS. SCHLUETER: Great, I knew you'd love to.

MR. DAMON: First of all, we did take and do take the pathways into consideration, dermal and ocular. The nexus or the--the specific concern we have is in the interpretation by the staff that we do take exception to, to require a quantitative standard, that is a number, that is--and hopefully or if they have good science, and I believe they understand this

and the ISG does represent a very good amount of work, but in reality, as already mentioned, the ISG is not the quantitative standard. It's a methodology approach; there are no values in existence to my knowledge and after extensive research in the same context as IRPGs or TLDs and what have you. Those are I think industry standards of exposure that are quantitative.

We do take into account dermal and ocular potential exposures as required by the rule in our methodology; we do it in a qualitative context, and we credit the different barriers per our methodology and per the ISA rule in explicit ways. So it's not that we don't take them into account; we do, and they are done in a qualitative approach, which is the basis of the ISA. I also would add in terms of the, you know, what would we do if we built a new facility. Well even though my facility is over 40 years old, we have added new processes, we have added new buildings, we have added new technology. In every case, we have improved. I enjoyed the example the gentleman used relative to we call it hooking up a pig tail to a cylinder. Yes, 40 years ago, I'll admit we had individuals doing the similar thing that you did. Today, we don't allow that to happen. The person is

on supplied air, in an acid suit, and with all the right PPE to prevent in case an isolated leak occurs. So we evolve and improve our overall programs to assure the safety of our individual workers.

MEMBER SCHULTZ: Bob, just for the record, you mentioned you're from Areva; I presume you're at the fuel cycle facility?

MR. DAMON: Yes, I'm at the Richland Fuel Cycle Facility.

MEMBER SCHULTZ: Thank you.

MS. SCHLUETER: Did that help? Okay.

MEMBER SCHULTZ: Yes thank you; that was helpful.

MS. SCHLUETER: Next slide, please. So obviously the issue of backfit was sort of brought up before I got up here, but I did feel I would be remiss if I didn't at least mention the fact that it is our third fundamental concern with the staff's new expectation that licensees develop a quantitative dermal and ocular exposure. We believe it does constitute an unanalyzed backfit, that the licensee programs through the ISA summaries were approved by the NRC for quite some time, that this explicit interpretation and expectation for a quantitative dermal and ocular exposure standard did not exist

since the rule went effective in 2000. This has been an issue that was raised in the 2007-2008 time frame, and so we have a very exhaustive legal argument, and I'll have to take the fifth again that I'm not an attorney, either; you'll start to wonder what I am, but I won't begin to explain the exhaustive, 20-page discussion that we have in our letter.

But at a high level, I do feel compelled to best summarize our fundamental concerns, and that is that the backfitting issue associated with the staff position of the development of standards is not, as I think I tried to emphasize, a question about whether the chemical exposure via the dermal and ocular pathways must be addressed; they do that. As explained in our letters, the chemical safety programs use the three-layer approach, and as I've discussed, for all pathways of exposure. The backfitting question is whether the staff's re-interpretation of 70.65(b)(7), after approving the ISA summaries, requires the creation of the quantitative standards to gauge the severity of the dermal and ocular chemical exposure, and that's really fundamental--that's the fundamental premise on which our backfit claim is built. And those letters that you saw in the first slide and here go into great detail about that.

And so we do not believe the standard is needed and therefore, as I've mentioned, we've had a lot of conversation with the staff; I think they've been extremely open and forthcoming and transparent about where they're at and why, and we have as well, but we're just fundamentally in different places. So as the recap slide will say, I trust that my remarks--

MEMBER POWERS: Could we come back to the where you're going to get to the analyzed backfit. We're talking about interim staff guidance here, which is not regulation. Backfit is language we use in connection with backfit, so I'm not sure how backfit and ISG exactly fit here.

MS. SCHLUETER: Well the staff has made it clear through discussions and the letter exchanges that we've had back and forth, which are on the docket, that they are interpreting Part 70, Section 65 in a manner different than we are, and that's where it fundamentally comes down to. And you know as well as I do the NRC has the opportunity during license amendments or renewals to impose certain expectations.

MEMBER BROWN: So we're concerned with the way they're interpreting the rule different than what you--what the industry has envisioned it over the years, that they would then use this ISG to then

impose standards as opposed to just being in the broad context of some guidance that people could use if they so desired?

MS. SCHLUETER: Well I think they've made it clear in their letters, you know. We have letters that date back to 2008-2009 time frame that explicitly describe their interpretation of Part 70, and this is part of our concern, that it's coming through letters, that's it's part of the ISG, that it's an expectation. We think there's a word clarification in the rule that could be made that perhaps would have solved the issue a long time ago if we could agree what and was not actually required.

MEMBER SCHULTZ: Could you describe what that is specifically, or have you done so in your letters?

MS. SCHLUETER: It's been some time since we looked at the specific sections of Part 70; I think part of it stems from the use of the word "individual," which is used to refer to the public in some cases, and the worker in some cases. There's some ways that we have thought about on our own that would help clarify this issue. One is as simple as making sure that the word "quantitative" versus "qualitative" is used appropriately and consistently

in Part 70. We're just in fundamentally different places with regard to--

MEMBER POWERS: Well I sympathize with your concerns over the wording of the regulation itself. It's not my favorite regulation on the books. Let's continue.

MS. SCHLUETER: So in recap, I hope that my remarks have established that the importance the licensee places on chem safety at their facilities and the fact that OSHA standards are very important and meeting the NRC's expectations in this regard is also important to them. Based on an exhaustive consideration of this issue over seven years, and as I've mentioned, a lot of open dialogue with the staff on it, we firmly believe and we've documented our basis for our continued position that the imposition of a new quantitative standard, and again, as Bob alluded to, the imposition of an actual number for certain chemicals at different facilities across the fleet is not the answer from a safety perspective or anything else. It's unnecessary with regard to the chemical programs that are in place today, it's not practical to do, and it does constitute an unanalyzed backfit as we've discussed with regard to the rule language in Part 70 as it exists today. So we firmly

believe that in this era of limited resources, both for the NRC and us, and within the context of the agency's Project 20/20 Aim Re-Baselining Initiatives, that our resources should be focused on other issues of higher import than continuing to develop the elusive standard.

MEMBER POWERS: One other question. Without a quantitative standard, does the exposure limit become zero?

MS. SCHLUETER: Well we have the performance objectives of course in Part 70 and 61 in place, and that's the slide that Marilyn had up with the intermediate and high consequences, yes. So those thresholds remain for categorizing an event and potentially reporting on an event. So I would say nothing would change in that regard.

MEMBER POWERS: I look at those, I think they go--the exposure limit becomes zero. If you don't have an exposure number--it doesn't have to exactly be a number, but something more quantitative than nothing, doesn't it become zero? I think it does. If I go back to the Rosetta Stone chart that they had, I think the number becomes zero in there without a quantitative standard. I mean it strikes me it does.

MS. DIAZ: I mean if there's no quantitative standards, the interpretation will be that the exposure would not occur. I mean the quantitative standards, they're required by 70.65(b)(7), so it's not something staff is imposing on, it's a requirement.

MEMBER POWERS: I'll go back to your what I called the Rosetta Stone chart, because it has multiple languages and it translates them. I think it becomes is there an exposure or not? Without a--I mean it becomes a qualitative standard; is there an exposure or is there no exposure? Unless you have some threshold in there, then that's what it becomes, doesn't it?

CHAIRMAN STETKAR: We could interpret it that way certainly, because you have no measure of the consequences, right?

MEMBER POWERS: Right.

CHAIRMAN STETKAR: I mean I think you have no way to measure.

MR. JOHNSON: Well then guess I think to a broader concern. It seems we recognize that there's a compliance issue here, but I think it's broader than that. When you start to look at the ISA and how you're identifying hazards, how you're identifying

consequences, categorizing them, identifying whether you need additional protective measures to prevent or mitigate, in order to qualify or quantify where the boundaries are for high and intermediate consequences, you need to have some type of standard. And I understand your question, but it feeds to the next level for the staff is are the ISAs complete?

MEMBER POWERS: What you're going to do is assure that the facility does not enter into the forbidden zone of unacceptable risk, okay. You have a frequency axis--

CHAIRMAN STETKAR: I knew you'd get there eventually.

MEMBER POWERS: --and you have a consequence axis here. Without something on that axis, it strikes me that the axis says did it occur or did it not occur. That is the only judge on that, and so consequently the exposure limit promptly becomes zero. If you get any exposure at all, then it happened and you are into the forbidden zone.

MS. SCHLUETER: Thank you.

MEMBER POWERS: Do any of the members have any additional questions for Janet or for Marilyn?

MEMBER BROWN: Yes, I had looked at the background info that was provided, and you had

commented on exposure occurrences, and yet the only--and maybe I missed something; I'm not a chemical guy, okay, other than taking a lot of it in college when I was forced to.

MEMBER POWERS: There's no real exposure limit on that.

CHAIRMAN STETKAR: That was--yes, but you were using the Gestetner, you know--

MEMBER BROWN: I was looking for more definitive data, yet the only data that was in the background info or in these other things was this table in the very, very back on almost the last page about 10 events over 31 years, and not being a risk-informed person and noting the severity of some of these, which seem to be "I shouldn't be playing with matches anymore" type style of things, where we used to--I hate to say this, as a kid we would take a clothespin and reverse it, you could take a wooden match and shoot the match; it would light and hit your buddy. We used to shoot matches at each other in elementary school. So I mean I--you can tell I'm playing a little bit of a devil's advocate here in that you can regulate and regulate and regulate until the cows come home, and it gets kind of ridiculous after a while. And I'm not saying this is ridiculous,

I'm just--it just seems that these were not--minor burns, a little bit of this, a little bit of that; and if you have to take a bottle of nail polish remover or acetone, smear it on your hands and leave it, you'll get a minor burn, but the regulation is the percentage of stuff that's limited by FDA or whoever--it's not FDA--

MEMBER POWERS: HF burns are a circus thing.

MEMBER BROWN: I'm not arguing. HF is nasty stuff as we're all well aware of; that's for sitting in laboratories, chemical laboratories. So I'm just playing a little bit of a devil's advocate, and it seems like with 10 quoted events over a roughly 31-year period that this is--plus I listened to the gentleman from Areva, and they have obviously evolved. I have no doubts if you go back to the '40s and '50s, there were very, very, very low standards for anything--or not for anything, but for many things. Is there another large table where there's 4,000 of these type events, or is this--

MS. DIAZ: This only looks at dermal and ocular--

MEMBER BROWN: Yes, that's the title.

MS. DIAZ: --and not all chemical

exposures; we're not including--

MEMBER BROWN: Well that's all the ISG applies to, isn't it? Is just the--

MS. DIAZ: No, the ISG applies to all exposure pathways, including inhalation.

MEMBER BROWN: Oh, my false write up; I'm sorry. I included that in my thought process.

MS. DIAZ: But this table that I provided here, it's only relevant for dermal and ocular exposures. I do want to point out that Sequoyah Fuels, a worker died because of inhalation exposure and also dermal exposure. It was a respiratory tract and the burns that he had from overexposure of HF that caused that fatality. Also, we see this as precursors. When we analyzed this data, when we took that table and analyzed the data, we evaluated the event and we came up that if a worker had been there for five more minutes, or if the exposure area had been a little bit more, or if something of the factors, the parameters in that event change, it could lead to intermediate or high consequences. So it could be much worse. So we take this as precursors; we don't want--we don't want anything to happen; we have been good enough and I think lucky that nothing else has happened, but I think we want to make sure

that the ISA analyzes all exposure pathways just to prevent anything like Sequoyah Fuels happening again.

MEMBER POWERS: One of the things--

MS. SCHLUETER: The ISA takes an all pathways approach, and a standard would not have prevented any of those events that Marilyn just mentioned.

MS. DIAZ: The standard is a requirement. OSHA--

MEMBER BROWN: She's got a point. I mean if the standard is not going to prevent anything, then that's--I've heard that argument somewhere recently. You can issue standards, but they don't result in prevention, so--

MS. DIAZ: So what would the licensee or applicant use to determine if it's high or intermediate? What would they use? They need something to categorize that as high or intermediate, even if it's not a rule. Even if it's not a regulatory--

MEMBER BROWN: Were they doing it without a regulatory requirement--

MS. DIAZ: --they do have to have something that--

MEMBER BROWN: My point was are they in

fact actually doing those types of evaluations?

MS. SCHLUETER: Yes.

MS. DIAZ: Not apparent in the ISA; that's what we're saying.

MEMBER BROWN: Two different answers. She says yes, and you say no. I've milked this to the full extent it's necessary right now. I just wanted to try to get somewhat other than a more esoteric perspective that was flashing around via the view graphs, that's all. Thank you.

MS. DIAZ: And I also want to add that a fuel cycle licensee has come in with an HF exposure standard for dermal and ocular exposure, and the staff has evaluated that and accepted such standards. So the ISG is just to document current practice that we are already doing. But again, we've seen the ISAs summaries and facilities and licensees, they have only analyzed for HF exposures.

MEMBER BROWN: Okay, well they obviously think of this as a camel's nose in the tent, where if they're--like you say, they've already done certain things, so you're only implementing what's already in practice; therefore, it's okay and that toe in the water is out of date history of immersing the foot, the leg, the ankle and on and on and on. So anyway,

that's--I'll stop.

MEMBER POWERS: Any further comments or questions? Okay. I will also ask is there anyone in the room that would care to make a comment? I don't see a mad rush to my microphone. And in that case, we have a procedure for allowing people on the phone to make comments that I never quite understand, so I'm delegating to my esteemed colleague, Mr. Stetkar, to walk through that protocol.

CHAIRMAN STETKAR: You just want me to hear--to hear me say is someone out there.

MEMBER POWERS: Yes.

CHAIRMAN STETKAR: But we know someone is out there. Quinn, did we have one or two lines? Did we have one or two lines open though for the public?

MR. NGUYEN: We had one line.

CHAIRMAN STETKAR: Okay. If that's the case, I will indeed go through said procedure. We know that the bridge line is open; are there any members of the public on the bridge line who would like to make a comment, and if so, please identify yourself and make said comment. Hearing none, I'm assuming you're turning this back over to me, or do you have final closing comments that you would like to make, kind sir?

MEMBER POWERS: Not on the record.

CHAIRMAN STETKAR: Thanks, thanks very much. I think this was a really interesting discussion for me certainly because as may have noticed, I know nothing about this, and I really appreciate, you know, both--there's obviously a difference of opinion here, which we're always interested in hearing. And with that, we will go off the record for today, and we will recess until--I sure hope--I'm going to say 3:30, because I have to figure out what the heck we're doing next. So we're recessed until 3:30.

MS. SCHLUETER: Thank you.

(Whereupon, the above-entitled matter went off the record at 3:11 p.m.)

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

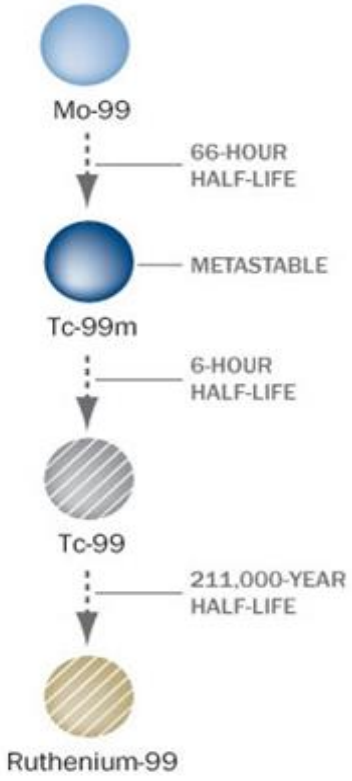
Advisory Committee on Reactor Safeguards
Meeting on SHINE Construction Permit Application

Medical Radioisotope Production and Construction Permit Application Review

Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
October 8, 2015

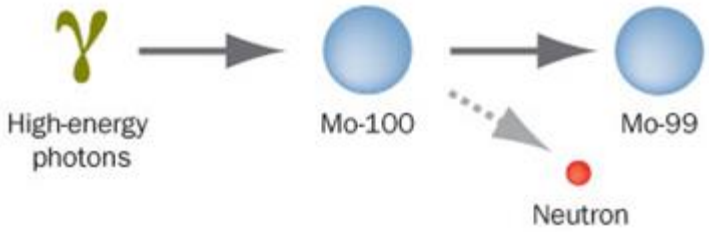
Molybdenum-99 (^{99}Mo) Production

- ^{99}Mo decays to Technetium-99m (^{99m}Tc)
- The life of ^{99m}Tc is long enough for effective diagnosis, but short enough to minimize radiation exposure
- In the U.S., approximately 50,000 scans performed daily
- Compounds readily tagged with ^{99m}Tc and carried to specific organs under evaluation

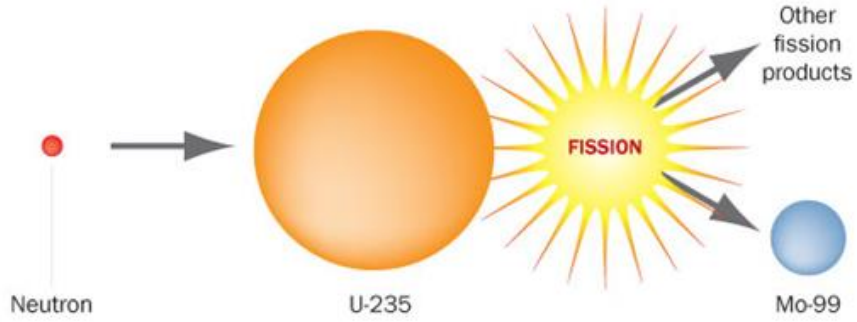


Methods of ^{99}Mo Production

Neutron Capture



Transmutation



Fission

Status of Domestic ^{99}Mo Supply

- Currently, no domestically-produced supply
- Aging international reactors, dependence on foreign suppliers, and extended repairs jeopardize and disrupt international supply
- The United States ^{99}Mo policy objectives are to 1) ensure a reliable supply of ^{99}Mo, 2) eliminate highly-enriched uranium use in ^{99}Mo production, and 3) eliminate market subsidies
- Domestic production encouraged by cost-sharing cooperative agreements between National Nuclear Security Administration and commercial partners

Supporting Domestic ^{99}Mo Production

- NRC is prepared to conduct reviews on all applications submitted in accordance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR)

- NRC is coordinating environmental review work with the Department of Energy (DOE), in accordance with American Medical Isotopes Production Act

- NRC is supporting the Department of Homeland Security's (DHS) site vulnerability assessments for utilization facilities, in accordance with the provisions of Section 657 of the Energy Policy Act of 2005

SHINE Medical Technologies, Inc.

- SHINE has requested a construction permit for a medical radioisotope production facility in Janesville, WI
- If granted, permit would allow construction of eight commercial non-power utilization facilities and one production facility
- Eight accelerator-driven subcritical operating assemblies comprise the irradiation facility (IF) and will produce ^{99}Mo through fission of uranium solution
- Three hot cell structures comprise the radioisotope production facility (RPF), which will chemically separate ^{99}Mo from uranium solution

SHINE Irradiation Facility

- Irradiation facility houses eight subcritical irradiation units, which are comparable in power level and safety considerations to existing non-power reactors licensed under 10 CFR Part 50

- However, due to subcriticality, irradiation units did not meet the existing definition of utilization facility in 10 CFR 50.2 and could not be licensed under 10 CFR Part 70

- To align licensing process with potential hazards, NRC issued direct final rule modifying 10 CFR definition of utilization facility to include SHINE irradiation units
  - Published October 17, 2014
  - Effective December 31, 2014

SHINE Radioisotope Production Facility

- Radioisotope Production Facility consists of three hot cells for ^{99}Mo separation and purification
- Based on batch size (i.e., greater than 100 grams), facility meets the definition of a production facility as defined in 10 CFR 50.2, “Definitions”
- While NRC has historically licensed production facilities, no such facilities currently operating
- Only two previously-licensed facilities have conducted similar activities as SHINE
  - Cintichem (licensed under 10 CFR Part 70)
  - West Valley (licensed as a reprocessing facility)

SHINE Licensing Process

- SHINE facility will be licensed under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities”
  - Target irradiation performed by *utilization facilities*
  - Fission product separation in *production facility*
- Special nuclear material will be licensed under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material”
- Byproduct material will be licensed under 10 CFR Part 30, “…Domestic Licensing of Byproduct Material”
- Source material will be licensed under 10 CFR Part 40, “Domestic Licensing of Source Material”

Construction Permit Regulatory Requirements

- Regulatory considerations for SHINE construction permit:
  - 10 CFR 50.22, Commercial and industrial facility licenses
  - 10 CFR 50.30, Environmental Report
  - 10 CFR 50.34(a), Preliminary safety analysis report
  - 10 CFR 20.1201, Occupational dose requirements
  - 10 CFR 20.1301, Public and accident dose requirements
  - 10 CFR 50.35, Issuance of construction permits

- Note: 10 CFR Part 50 Appendices A, “General Design Criteria…” and B, “Quality Assurance Criteria…” are only applicable to nuclear power reactors.

- 10 CFR Part 100, “Reactor Site Criteria,” siting and accident dose criteria are only applicable to nuclear power reactors

Construction Permit Application Requirements

- Consists primarily of environmental report and preliminary safety analysis report (PSAR), as required by 10 CFR 50.30 and 50.34

- Contents of PSAR include:
  - Preliminary design of the facility, including principal design criteria, design bases, general arrangement, and approximate dimensions
  - Preliminary analysis of structures, systems, and components, including ability to prevent and mitigate accidents
  - Probable subjects of technical specifications
  - Preliminary emergency plan
  - Quality assurance program
  - Research and development

Operating License Application Requirements

- Consists of final safety analysis report and supplement to environmental report, if needed
- Application includes final design and analyses that conforms to the design bases of the facility
- Other application elements include:
  - Plans for operation
  - Emergency Plan
  - Technical Specifications
  - Physical Security Plan

Construction Permit vs. Operating License

- Construction permit (10 CFR 50.35)
  - Allows licensee to proceed with construction
  - Does not approve of the safety of any design feature or specification unless specifically requested by the applicant
- Operating license (10 CFR 50.57)
  - Allows licensee to operate the facility
  - Issued when there is reasonable assurance that the activities authorized by the license will not endanger the public health and safety

Regulatory Guidance and Acceptance Criteria

- NUREG-1537, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors”
- Interim Staff Guidance Augmenting NUREG-1537
  - Radioisotope production facilities
  - Aqueous homogeneous reactors
  - Incorporates relevant non-reactor guidance from NUREG-1520, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility, Rev. 1”
- Other guidance (e.g., regulatory guides and ANSI/ANS standards) and engineering judgement used, as appropriate, to determine what is necessary for construction permit

NUREG-1537 Review Areas

1. The Facility/Introduction
2. Site Characteristics
3. Design of Structures, Systems, and Components
4. Facility Description
5. Coolant Systems
6. Engineered Safety Features
7. Instrumentation and Control
8. Electrical Power Systems
9. Auxiliary Systems
10. Experimental Facilities*
11. Radiation Protection and Waste Management
12. Conduct of Operations
13. Accident Analysis
14. Technical Specifications
15. Financial Qualifications
16. Other License Considerations*
17. Decommissioning*
18. Uranium Conversions*
19. Environmental Review

*Not applicable to the SHINE construction permit application

NRC Review Methodology

- Since construction permit only allows construction, level of detail needed in application and staff's SER different than for combined operating license or operating license
- For the purposes of issuing a construction permit, the SHINE facility may be adequately described at a functional or conceptual level in the PSAR
- SHINE has deferred providing many design and analysis details until the submission of its final safety analysis report (FSAR) with its operating license application
- Staff's review tailored to unique and novel technology described in SHINE's construction permit application using appropriate regulatory guidance

Resolving Technical Deficiencies

- For technical areas requiring additional information, the staff has several options:
  - The staff may determine that such technical issues must be resolved prior to the issuance of a construction permit
  - The staff may determine that such information may be left until the submission of the FSAR
  - The staff may require that such technical issues be resolved prior to the completion of construction, but after the issuance of the construction permit
- In all cases, staff may issue requests for additional information
- In the second and third options, staff may track regulatory commitments or identify necessary license conditions

Status of the SHINE Review

- As of September 2015, SHINE has adequately responded to all requests for additional information
- Final environmental impact statement complete and set for NUREG publishing in October 2015
- Safety evaluation report in concurrence and set for NUREG publishing in October 2015
- Mandatory hearing on construction permit application scheduled for December 15, 2015

Regulatory Basis for Construction Permit

- The following findings must be made to issue a construction permit, based on 10 CFR 50.35:
  - Facility has been described, including the principal architectural and engineering criteria for the design
  - Further technical or design information may be reasonably left for later consideration in the FSAR
  - Safety features or components requiring research and development have been identified
  - Safety questions will be resolved prior to the completion of construction and the proposed facility can be constructed without undue risk to the health and safety of the public
- Staff's conclusions also based on the considerations in 10 CFR 50.40 and 50.50

10 CFR 50.35(a)(1) Findings

- *Facility has been described, including the principal architectural and engineering criteria for the design, and major features or components have been identified for protection of public health and safety*
  - Staff evaluated preliminary design to ensure sufficiency of principal design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions
  - When necessary, staff issued requests for additional information, conducted audits and performed confirmatory calculations
- Staff finds that there is reasonable assurance that final design will 1) conform to design basis, 2) provide adequate margin for safety, 3) provide for the prevention and mitigation of accidents and 4) meets applicable regulatory requirements and acceptance criteria

10 CFR 50.35(a)(2) Findings

- *Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report*
  - The staff evaluated the sufficiency of the preliminary design of the SHINE facility based on SHINE's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety
  - Throughout PSAR and in response to RAIs, SHINE has indicated areas that require further technical or design information
  - Staff is tracking this information as regulatory commitments
- Staff finds that SHINE has provided reasonable assurance that further technical or design information, which can reasonably be left for later consideration, will be supplied in the FSAR

10 CFR 50.35(a)(3) Findings

- *Safety features or components requiring research and development have been described and a program has been identified to resolve any safety questions*
  - SHINE has identified two ongoing research and development activities related to 1) irradiation and corrosion testing and 2) precipitation studies
- Staff finds SHINE has adequately described research and development programs
- Staff has determined additional information needed on certain matters related to nuclear criticality safety and radiation protection
  - Staff recommending inclusion of conditions in construction permit
  - Conditions require periodic updates on status of design maturation in selected areas necessary to confirm facility design bases

10 CFR 50.35(a)(4)(i) Findings

- *There is reasonable assurance that such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility*
  - Latest date of construction completion proposed to be December 31, 2022
  - Based on research and development schedules, SHINE expected to resolve safety questions prior to completion of construction
  - Permit conditions must also be satisfied prior to completion of construction
- Staff finds that there is reasonable assurance that SHINE's research and development activities will be satisfactorily completed at or before the latest date for the completion of construction of the SHINE facility

10 CFR 50.35(a)(4)(ii) Findings

- *There is reasonable assurance that taking into consideration the site criteria contained in 10 CFR Part 100, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public*
  - While 10 CFR Part 100 site criteria applicable to power reactors, staff considered similar site-specific conditions in SER Chapter 2
  - Staff confirmed that radiological releases during normal and accident scenarios within 10 CFR Part 20 limits in SER Chapters 11 and 13
  - Preliminary emergency plan meets requirements of Appendix E to 10 CFR Part 50
- Staff finds that there is reasonable assurance that the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public

10 CFR 50.40 and 50.50 Considerations

- Based on the findings of 10 CFR 50.35, the staff concludes that there is sufficient information to issue a construction permit, as guided by the considerations in 10 CFR 50.40 and 50.50:
  - There is reasonable assurance: (i) that the construction of the SHINE facility will not endanger the health and safety of the public, and (ii) that construction activities can be conducted in compliance with the Commission's regulations
  - SHINE is technically and financially qualified to engage in the construction of its proposed facility
  - The issuance of a permit for the construction of the facility would not be inimical to the common defense and security or to the health and safety of the public
  - The application meets the standards and requirements of the AEA and the Commission's regulations, and that notifications, if any, to other agencies or bodies have been duly made

Discussion

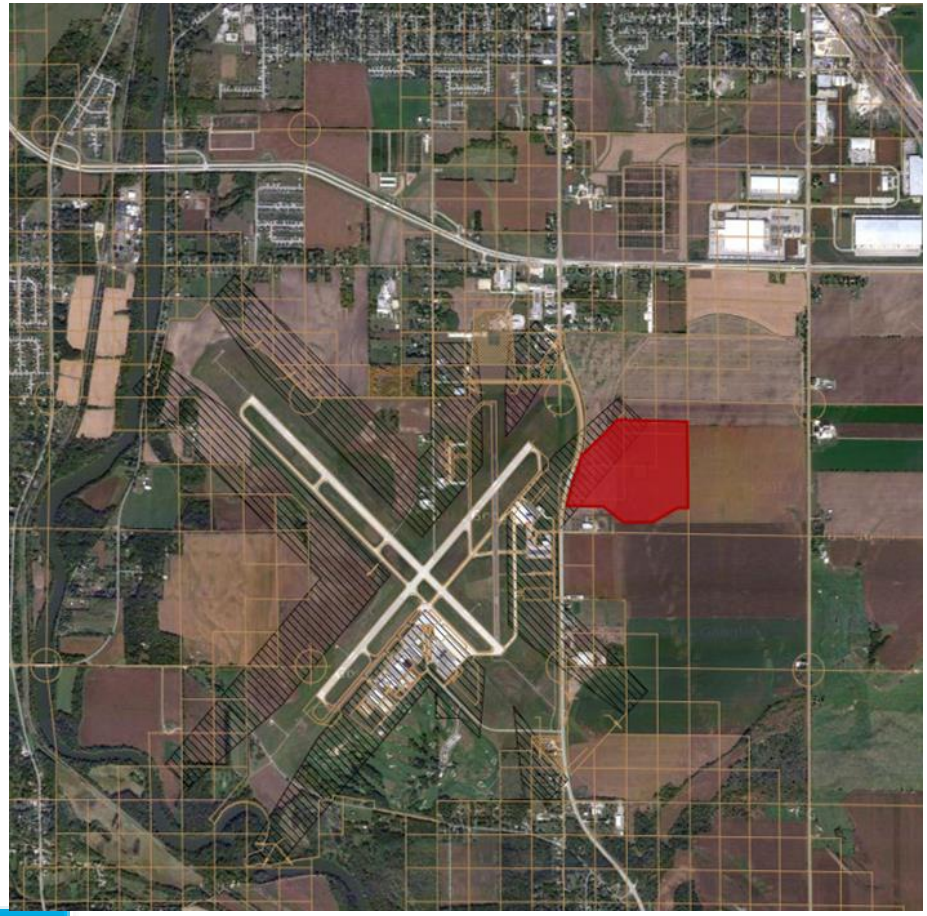
Advisory Committee on Reactor Safeguards
SHINE Construction Permit Application

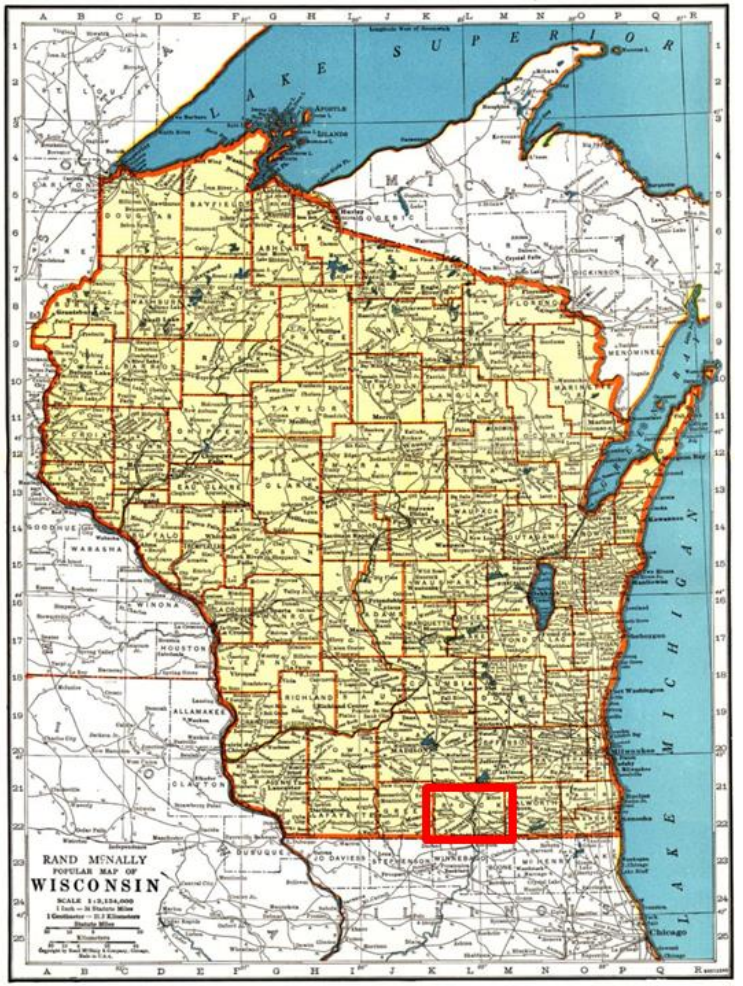
October 8, 2015

An Introduction to SHINE

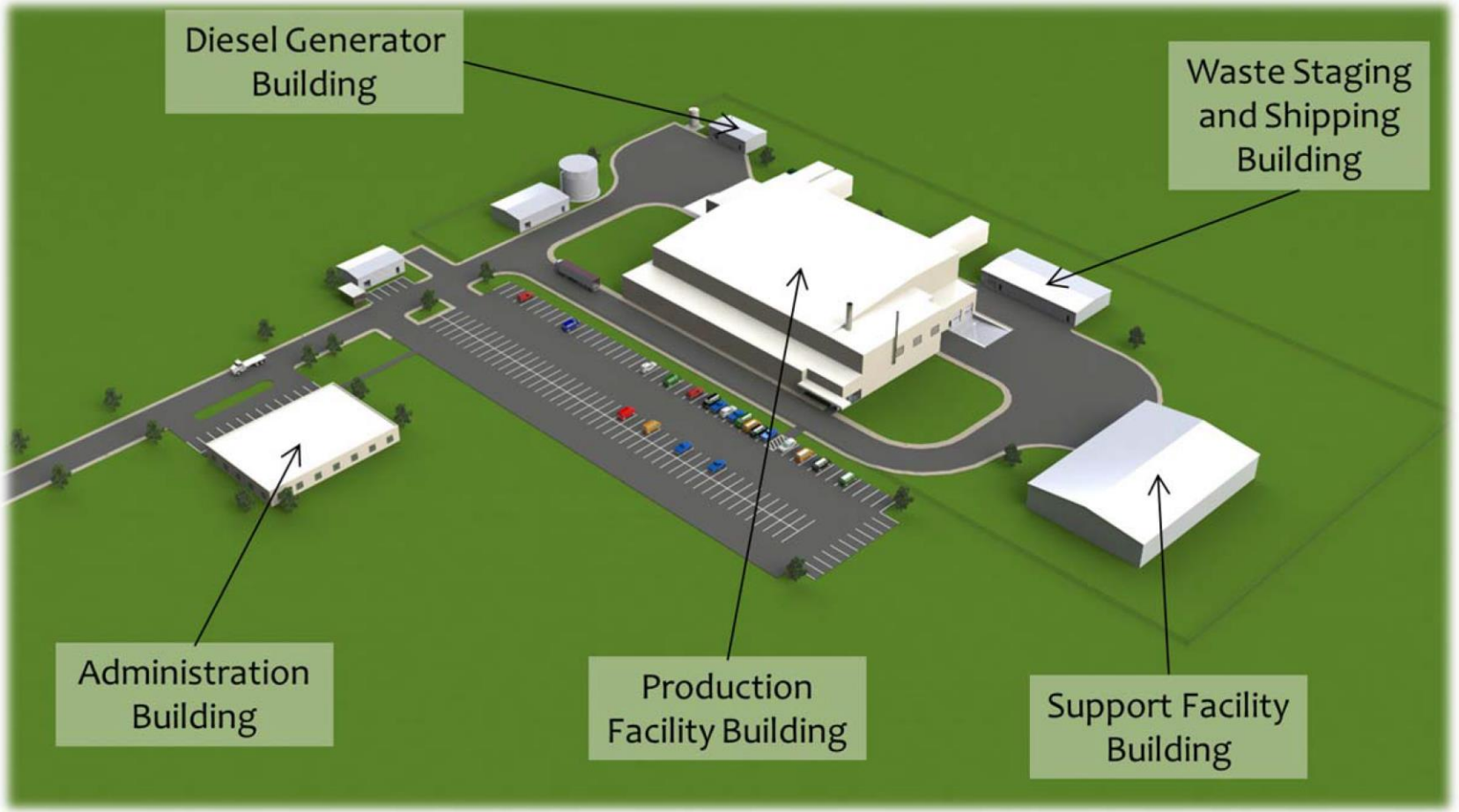
- SHINE Medical Technologies
  - Private corporation, based in Monona, Wisconsin
- SHINE facility
  - Purpose of the facility is to produce the medical isotope molybdenum-99 (Mo-99)
  - The SHINE production facility consists of an Irradiation Facility (IF), Radioisotope Production Facility (RPF), shipping and receiving area, and other areas that contain various support systems and equipment
  - The SHINE facility is located on a previously undeveloped 91 acre parcel in the southern boundaries of the City of Janesville in Rock County, Wisconsin

SHINE Facility in Southern Wisconsin

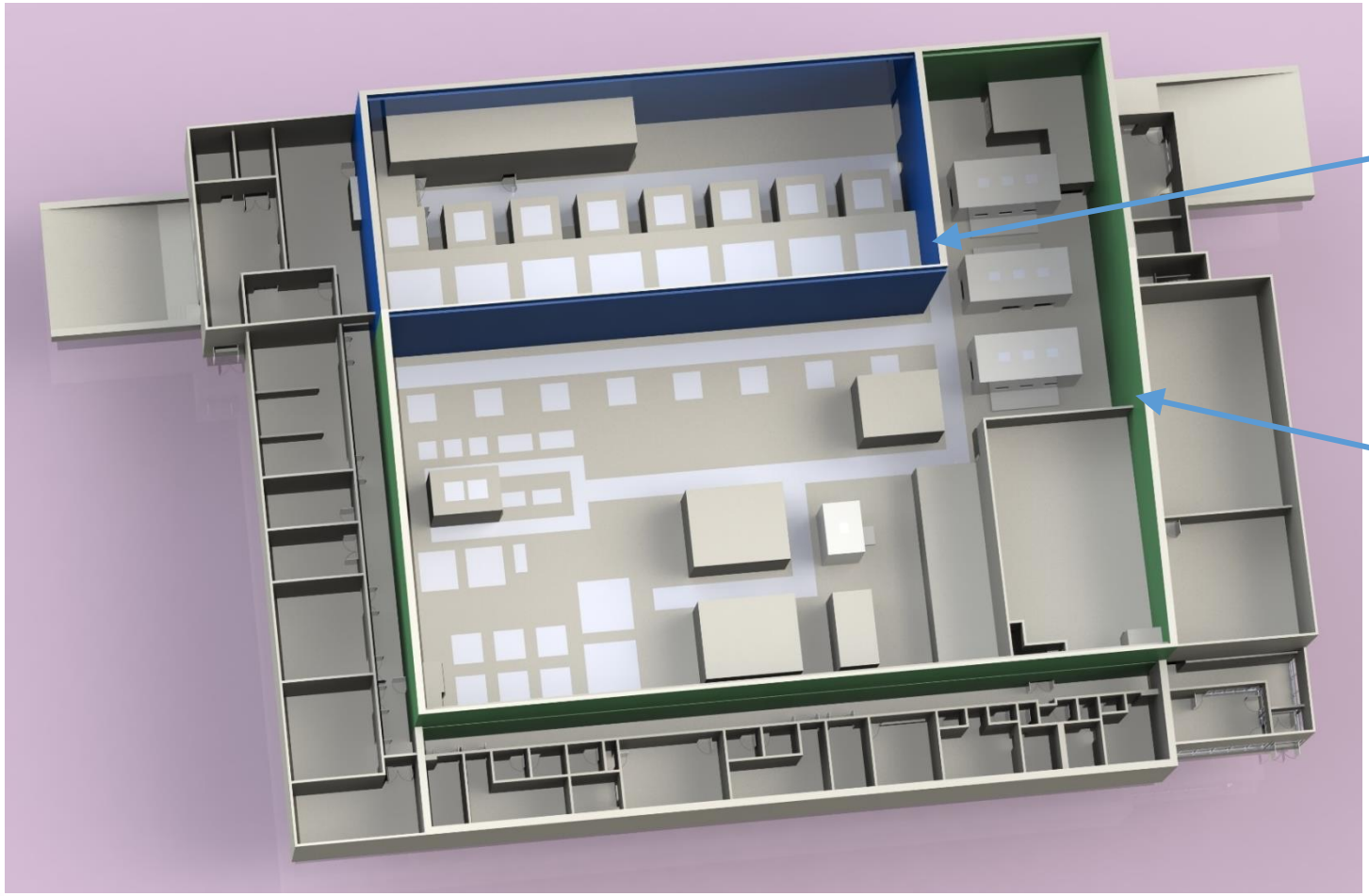




Integrated Operations at a Single Site



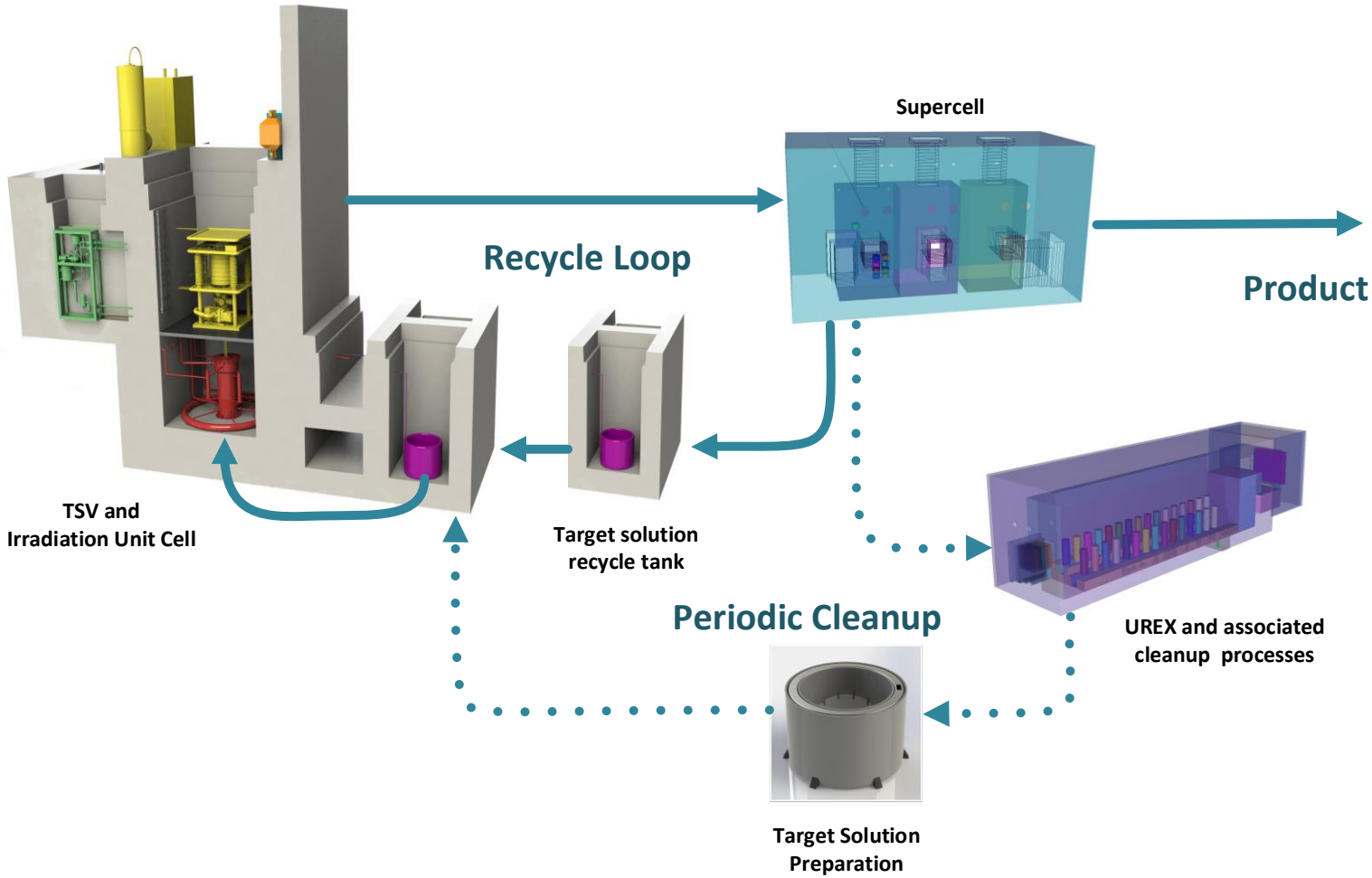
SHINE Facility Layout



Design of Systems and Components

- SHINE system designs based on defense-in-depth practices, with preference for engineered and passive controls over administrative controls.
- Single failure criterion is applied to safety systems.
  - Ensures a single failure, in conjunction with an initiating event, does not result in the loss of a system's ability to perform its intended safety function.
- Plant structures, systems, and components (SSCs) are designed to withstand the effects of the design basis earthquake (DBE) if they perform a safety-related function or if necessary to ensure they do not degrade the function and performance of any safety-related SSC.
- The SHINE QAPD describes the administrative and engineering controls for ensuring compliance with regulatory requirements.

SHINE Process Overview



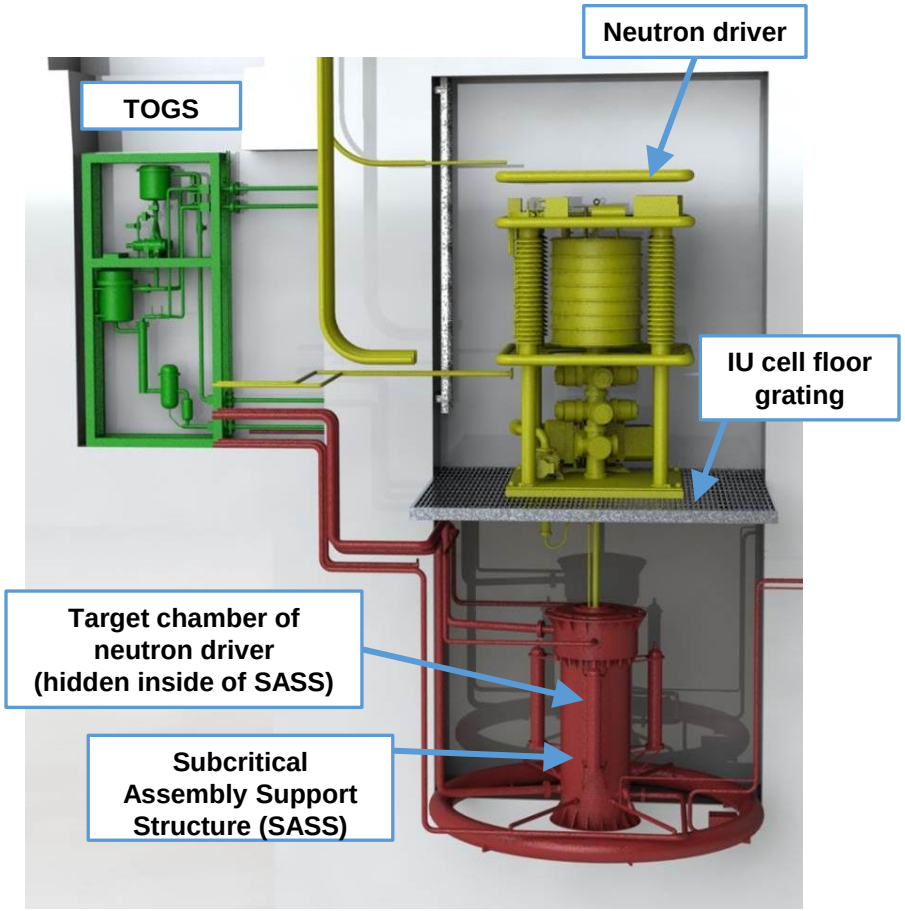
SHINE Irradiation Facility

- An irradiation unit (IU) consists of a subcritical assembly, a neutron driver, and supporting systems
  - There are eight IUs in the SHINE IF
- Supporting systems include:
  - Biological shielding
  - Light water pool
  - Target solution vessel (TSV) off-gas system (TOGS)
  - Primary closed loop cooling system (PCLS)
  - Tritium purification system (TPS)
- Primary system normally operates slightly below atmospheric
- Target solution is drained from the TSV via gravity to TSV dump tank
  - TSV dump tank is criticality-safe by geometry and passively-cooled
  - Two redundant, fail-open dump valves
- TSV is an annular vessel to be constructed of Zircaloy-4
  - No mechanical mixing of the target solution; solution undergoes natural convection in the TSV and is agitated by radiolytic bubble production

Subcritical Assembly

Neutron Driver and Supporting Systems

- One Neutron Driver per IU cell (8 total)
  - Electrostatic accelerator with a gas target
  - D-T fusion reaction generates 14 MeV neutrons that drive the fission process
  - Neutron driver performs no safety-related function; therefore, it is a nonsafety-related system
- TSV off-gas system (TOGS)
  - Contains the fission product gases
  - Removes iodine from the off-gas
  - Recombines hydrogen and oxygen to maintain hydrogen gas below the LFL
  - Maintain the system at a negative pressure to reduce potential for egress of gases
- Light water pool is in the lower portion of the IU cell
  - Provides shielding and heat removal
- Tritium purification system
  - Receives mixed deuterium/tritium from neutron drivers, separates gases, and supplies clean tritium back to neutron drivers
  - Tritium lines and processing equipment in gloveboxes and double-walled pipe



TSV Startup

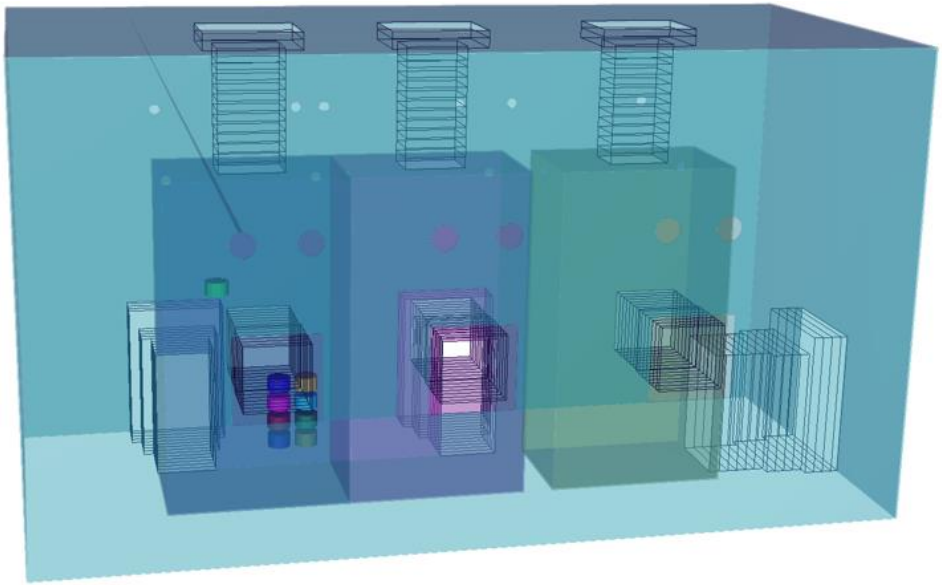
- Uranium concentration of solution and any other necessary parameters are measured prior to filling
- Operators use a 1/M startup methodology to monitor the reactivity increase in the TSV
  - TSV is filled in discrete increments
  - Final fill level is approximately 5% by volume below critical
- Automatic safety systems will be designed to protect the PSB and ensure the TSV remains subcritical
  - High flux trips, PCLS temperature trips
- Transition to irradiation mode

TSV Irradiation Mode

- After the system is transitioned to irradiation mode:
  - Further solution addition is prevented by closing two redundant (series) fill valves
  - Tritium is supplied to the target, and neutron driver output is gradually increased
  - Reactivity decreases significantly in the assembly due to the generation of heat and radiolytic gases in solution
- Normal irradiation mode operations are approximately 5.5 days
  - Temperature in the TSV expected to increase from 20°C to nominally 60°C during operation at the licensed power limit
  - Radiolytic and fission product gases are handled and contained by the TOGS
  - PCLS removes heat from TSV during operation
  - Light water pool cooling loop removes heat from the pool, neutron multiplier, and tritium chamber during operation
- Following shutdown, light water pool provides decay heat removal
  - On a loss of offsite power, pool passively removes heat
  - Temperature rise of 12°F (7°C) after 90 days without cooling

Radioisotope Production Facility

- Portion of the SHINE facility used for
  - Preparing target solution
    - Low enriched uranium metal dissolved in nitric acid
    - Uranyl nitrate converted to uranium oxide
    - Sulfuric acid used to produce uranyl sulfate target solution
  - Extracting, purifying and packaging Mo-99
    - Performed in supercells
  - Recycling and cleaning target solution
    - Uranium extraction (UREX)



Waste Handling

- Solid wastes consolidated and packaged
- Aqueous liquid wastes concentrated, processed, and solidified for shipment offsite
- Gaseous wastes treated on site prior to release
  - Noble Gas Removal System (NGRS) stores TSV off-gas for at least 40 days of radioactive decay prior to sampling for release
  - Decayed off-gas released to the Process Vessel Vent System (PVVS)
    - PVVS also receives gases from process vessels in the RPF
    - Caustic scrubbing removes acid gases and some iodine species
  - Off-gas releases are passed through charcoal and HEPA filters and monitored to ensure radioactivity levels are below regulatory limits for discharge to the environment.

Engineered Safety Features (ESFs)

- SHINE protects public health and safety during postulated accidents via a confinement system
  - Radionuclide inventory in any one confinement area is approximately 10,000 times less than a power reactor
  - Low dispersion forces due to relatively low temperature and pressure of processes
- Confinement functions provided by:
  - Biological shielding (IU cells, hot cells, trenches, tank vaults)
  - Isolation valves on piping systems
  - RCA Ventilation Zone 1 (RVZ1) and RCA Ventilation Zone 2 (RVZ2)
    - RVZ1 hot cell isolation dampers
    - RVZ1 and RVZ2 ductwork up to filters
    - RVZ1 and RVZ2 filters
    - RVZ2 isolation dampers
  - Engineered Safety Features Actuation System (ESFAS) and Radiological Integrated Control System (RICS)

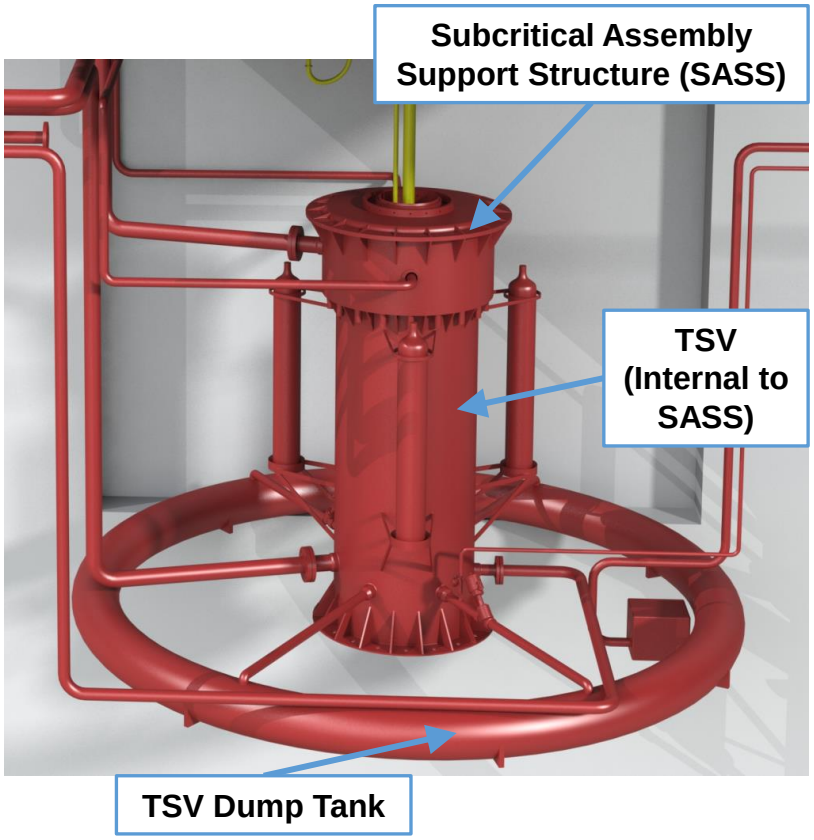
Locations of ventilation zones

Accident Initiating Events and Scenarios

- Bases for identification of Design Basis Accidents (DBAs) and their Initiating Events (IEs) are:
  - Hazard and Operability Study (HAZOPS) and Preliminary Hazard Analysis (PHA) within the Integrated Safety Analysis (ISA)
  - List of IEs and accidents provided in the Final ISG Augmenting NUREG-1537
  - Experience of the hazards analysis team in a range of disciplines
  - Current preliminary design information; analysis will be re-evaluated with detailed design
- Qualitative evaluations performed within categories of accidents to identify bounding or limiting accidents and scenarios
  - Quantitative evaluations performed for those DBAs with consequences
- MHA was postulated for both the IF and RPF
  - ISG Augmenting NUREG-1537: "… MHA may be a non-mechanistic failure assumed to establish an outer limit consequence, the scenario need not be entirely credible."
  - Most limiting MHA was in the RPF ("Facility MHA")

IF Postulated Maximum Hypothetical Accident

- The postulated MHA in the IF is a release of irradiated target solution to the IU cell as a result of a loss of TSV integrity
  - Assumed TSV and SASS have breached (non-mechanistic)
- Maximum inventories assumed in TSV (110% power, maximum fission product carryover, end of cycle, no decay)
- Pool presence ignored
- Radionuclides drawn into HVAC system
  - High radiation detected by RAMS in exhaust ductwork, initiates alarms
  - ESFAS actuates confinement isolation of IU cell
- HEPA filters and charcoal adsorbers credited

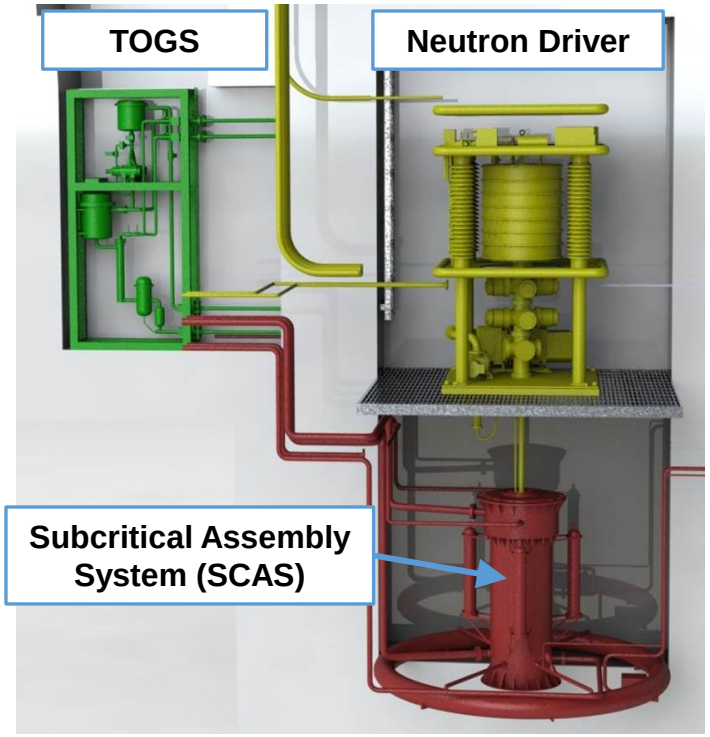


IF Postulated Maximum Hypothetical Accident

- Dose consequences
  - Worker TEDE: 3.1 rem
    - On-site doses below 5 rem regulatory limit specified in 10 CFR 20.1201
  - Public (site boundary) TEDE: 0.017 rem
    - Public doses below 0.1 rem regulatory limit specified in 10 CFR 20.1301
- Calculations contain significant conservatisms
  - TSV normally at or below ambient pressure; however, large leak assumed capable of releasing all contents without driving force
  - Pool will normally prevent direct dispersal of aerosols and volatile fission products should a breach in the TSV or TSV dump tank occur
  - Pool will dilute target solution, reducing releases
  - Noble gases assumed to immediately evolve from solution as it is released and also immediately disperse
- Mishandling or Malfunction of Target Solution event analyzed another IU cell target solution release scenario
  - Initiating event a dump tank pipe rupture during solution transfer
  - Similar sequence of events and mitigating factors
  - Worker TEDE: 1.50 rem
  - Public (site boundary) TEDE: 0.002 rem

Mishandling or Malfunction of Equipment Affecting the Primary System Boundary

- DBA analyzed failure of IF systems handling gaseous products from irradiation
- Limiting event determined to be release of inventory of TOGS into the TOGS shielded cell
  - Maximum inventories assumed in TOGS (110% power, end of cycle, no decay)
  - Release of off-gas occurs from TOGS equipment within the TOGS shielded cell
  - Zeolite bed within TOGS assumed to retain 95% of iodine in gas stream
- High radiation signal in ventilation exhaust results in alarm and ESFAS actuation
- 25% of activity enters shielded cell before evacuation, 10% released through TOGS penetrations
- 1% bypasses dampers, charcoal adsorbers in exhaust ductwork credited for 95% efficiency for halogens
- Worker TEDE: 1.9 rem
- Public (site boundary) TEDE: 0.016 rem

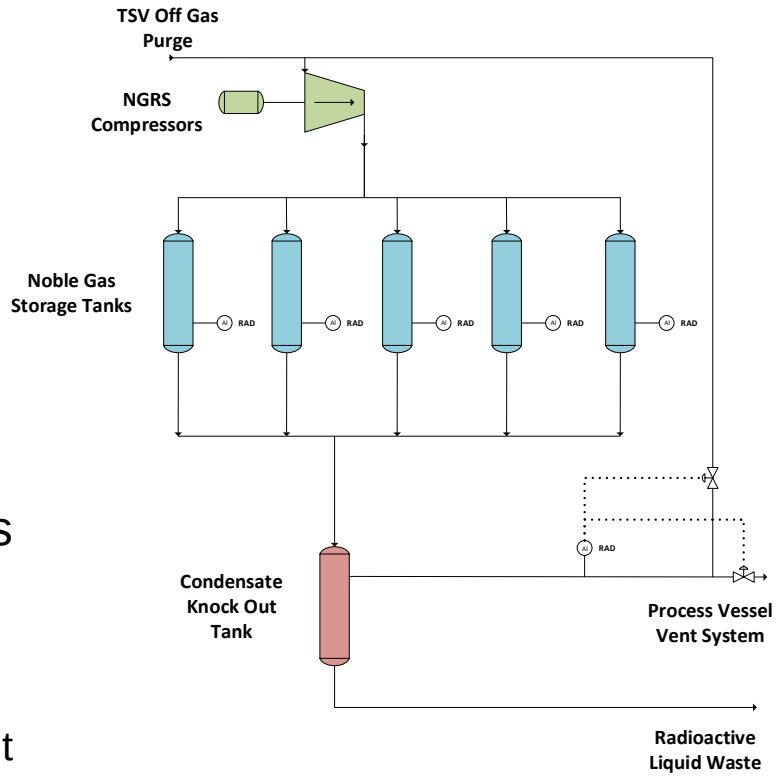


Tritium Purification System Design Basis Accident

- Unique, facility-specific events analyzed
- Mishandling or malfunction of equipment in tritium purification system was considered, including failure of piping, processing equipment malfunctions, fire, and human errors
  - Tritium supply and return lines in double-walled pipe, and lines are subatmospheric
  - TPS glovebox and double-walled piping is inerted with nitrogen
  - Automatic isolation valves isolate tritium supply on loss of system integrity
- Limiting event determined to be loss of entire tritium inventory of the eight neutron drivers
  - Release of inventory into IU cells, high radiation or other actuation signal activates confinement isolation and alarms
  - Up to 1% of released material bypasses the isolation dampers
- Confinement features would significantly reduce dose to workers, but no reduction was assumed in this analysis, providing margin
- Worker TEDE: 2.4 rem
- Public (site boundary) TEDE: < 0.001 rem

RPF Maximum Hypothetical Accident (Facility MHA)

- The most limiting event was determined to be a simultaneous release of the inventory in the five NGRS gas storage tanks
  - NGRS is assumed to be at the maximum inventory at the time of the event
  - Contents are instantly released to storage cell
  - High radiation levels detected in exhaust ductwork
  - RICS initiates alarm and cell isolation
- Redundant bubble-tight isolation dampers on the inlet and outlet of the cell close
  - 10% of the activity released into the cell assumed to bypass the isolation dampers
  - 10% of the activity leaks from the confinement area and exposes personnel



RPF Maximum Hypothetical Accident (Facility MHA)

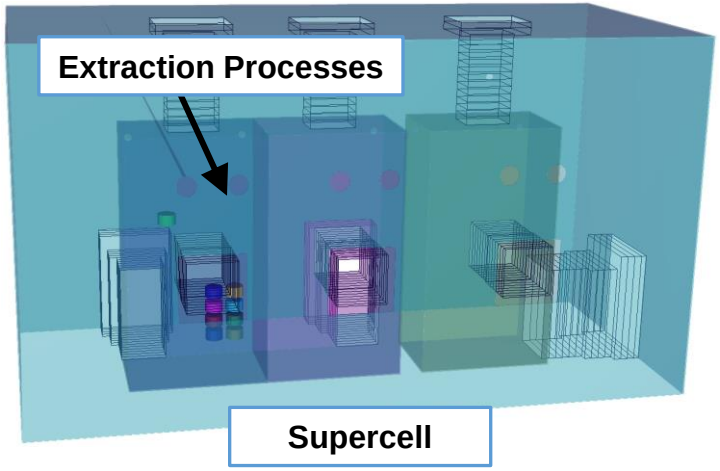
- Dose consequences
  - Worker TEDE: 3.6 rem
    - On-site doses below 5 rem regulatory limit specified in 10 CFR 20.1201
  - Public (site boundary) TEDE: 0.082 rem
    - Public doses below 0.1 rem regulatory limit specified in 10 CFR 20.1301
- The MHA consequences are conservative
  - Five tanks assumed to simultaneously, instantaneously rupture with no mechanistic cause
  - 100% of the generated noble gas is assumed to leave the target solution and be transferred to the NGRS
  - The five NGRS tanks are completely filled, which is beyond planned operations
  - Isolation dampers in the RVZ1 exhaust ductwork downstream of the final filters also automatically close, but no credit is given to these dampers in the analysis

Inadvertent Nuclear Criticality in Radioisotope Production Facility

- Preliminary evaluation of scenarios that could lead to inadvertent nuclear criticality were evaluated in ISA
  - Leaks in piping or process equipment, accumulation of material, vessel overflows, and misdirection of material are some of the potential scenarios
  - Engineered controls and administrative controls have been identified based on this evaluation to ensure that each identified scenario is highly unlikely (see PSAR Table 13b.2.5-1)
- Nuclear criticality safety evaluations (NCSEs) will be performed with detailed design
- Passive engineered controls (e.g., geometry of tanks) are used as the preferred means to ensure NCS
  - Each of the RPF process tanks, with the exception of the liquid waste processing tanks, are criticality-safe by geometry
  - Tanks are designed to be criticality safe at the most reactive uranium concentration, ignoring realistic saturation behavior
  - The absence of appreciable quantities of fissile material is measured and independently verified prior to the transfer to the waste processing tanks
  - Pipe runs are single-parameter criticality-safe by geometry
  - Criticality-safe tank vaults are connected via a non-valved gravity drain to a criticality-safe sump catch tank, which is criticality-safe by geometry
- Safety-related SSCs and activities ensure criticality is highly unlikely

Radioisotope Production Facility Fire

- Fire initiating events have potential to damage safety-related SSCs within RPF and lead to radioactive release
  - Fire events considered in ISA for normal and maintenance operations, within and outside of shielded process enclosures
- Most limiting fire scenario determined to be a fire affecting the Mo eluate hold tank within the supercell
  - A fire occurs inside of a supercell enclosure in the extraction portion
  - Hot cell fire detection is activated, alerting operations personnel
  - The hot cell ventilation is automatically isolated by the detection system interface
  - Hot cell fire suppression is not credited, but would be activated automatically or manually
  - Due to the thick radiation shielding of the cell, fire damage is limited to the hot cell interior
- RVZ1 exhaust filters release
  - HEPA filters remove 99% of particulates
  - Charcoal adsorbers remove 95% of halogens
- Dose consequences
  - Worker TEDE: 0.58 rem
  - Public (site boundary) TEDE: <0.001 rem



Summary

- The preliminary design described in the PSAR shows the SHINE facility can be constructed such that it meets the applicable regulatory requirements
- Radiological consequences to workers and the public during normal operation and postulated accidents are within the limits of 10 CFR 20.1101, 20.1201, and 20.1301
- Robust engineered and administrative controls have been identified to ensure protection of the public, the environment, and our workers
- The plant is being designed with safety as the primary criterion

Industry Views on NRC Draft Guidance on Standards for Acute Chemical Exposures

Janet R. Schlueter
Senior Director, Radiation and Materials Safety
ACRS Committee Meeting – Acute Chemical Exposure Guidance
October 8, 2015 – Rockville, MD

Central Points

- No Safety Issue Identified
- New Quantitative Exposure Standards Are Unnecessary, Impractical and Constitute Unanalyzed Backfit
- Limited Resources Should Focus on Issues of Higher Significance
- Industry 2008 Position Remains Unchanged
  - Most recent letters: 3/2014; 11/2014; 6/2015

Exposure Standards Unnecessary

Current Licensee Chemical Safety Programs Ensure Protection of Workers and Public

- Programs Focus on Prevention and Mitigation
  - Equipment Integrity and Maintenance; Personnel Protective Equipment and Barriers; and Mitigation for All Exposure Pathways

- Chemical Programs Follow OSHA Standards and Approved by NRC Through Integrated Safety Analysis Summary
  - NRC Reporting Requirements Exist and Met Without Standard
  - Very Low Number of Reportable Events Over Decades of Operation

Exposure Standards Unnecessary (cont)

- *NRC Staff Acknowledges Quantitative Standard Not Needed for Safety*
  - No Commensurate Safety Benefit
- *Imposing Standard is False Sense of Security*
  - Not Necessary to Categorize Event Consequence
  - Standard Would Not Result in New/Improved Protection Programs
  - Standards Do Not Prevent Events

Exposure Standards Impractical

- *Quantitative Standards to Address Wide Variety of Chemicals in Use Do Not Exist*
  - Organizations With Industrial Hygiene Expertise Do Not Have Standards
    - OSHA 1992 Rule on Occupational Exposure
    - OSHA Reps Confirmed During 2009 NRC Public Meeting
  - Draft ISG Method Would Yield Different Standards for Same Chemical at Different Facilities

Unanalyzed Backfit

- NEI Letters to NRC Dated March 26, 2014, November 7, 2014 and June 30, 2015 Articulate Basis for Industry Position That Imposition of New Standard Constitutes Unanalyzed Backfit

- We Await Final Agency Determination

Recap

- Existing Licensee Programs Ensure Protection and Determined Adequate by NRC
- New Standard is Unnecessary, Impractical and Constitutes Unanalyzed Backfit
- Limited NRC and Industry Resources Should Focus on Issues of Higher Significance

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

ISG – Guidance for Evaluation of Acute Chemical Exposure and Proposed Quantitative Standards

Marissa Bailey, Director
Division of Fuel Cycle Safety, Safeguards and Environmental Reviews
Office of Nuclear Materials Safety and Safeguards
U.S. Nuclear Regulatory Commission

Why is this ISG important?

- Chemical Safety
- Regulatory gap
- Safety implications

U.S.NRC
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Protecting People and the Environment

Advisory Committee on Reactor Safeguards

ISG – Guidance for Evaluation of Acute Chemical Exposure and Proposed Quantitative Standards

Marilyn Diaz
U.S. Nuclear Regulatory Commission

October 8, 2015

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Topics

- Background:
  - Overview of Fuel Cycle Facilities
  - OSHA MOU
  - Regulatory Framework
- Chemical Safety Requirements
- Content of Interim Staff Guidance
- Summary

U.S.NRC
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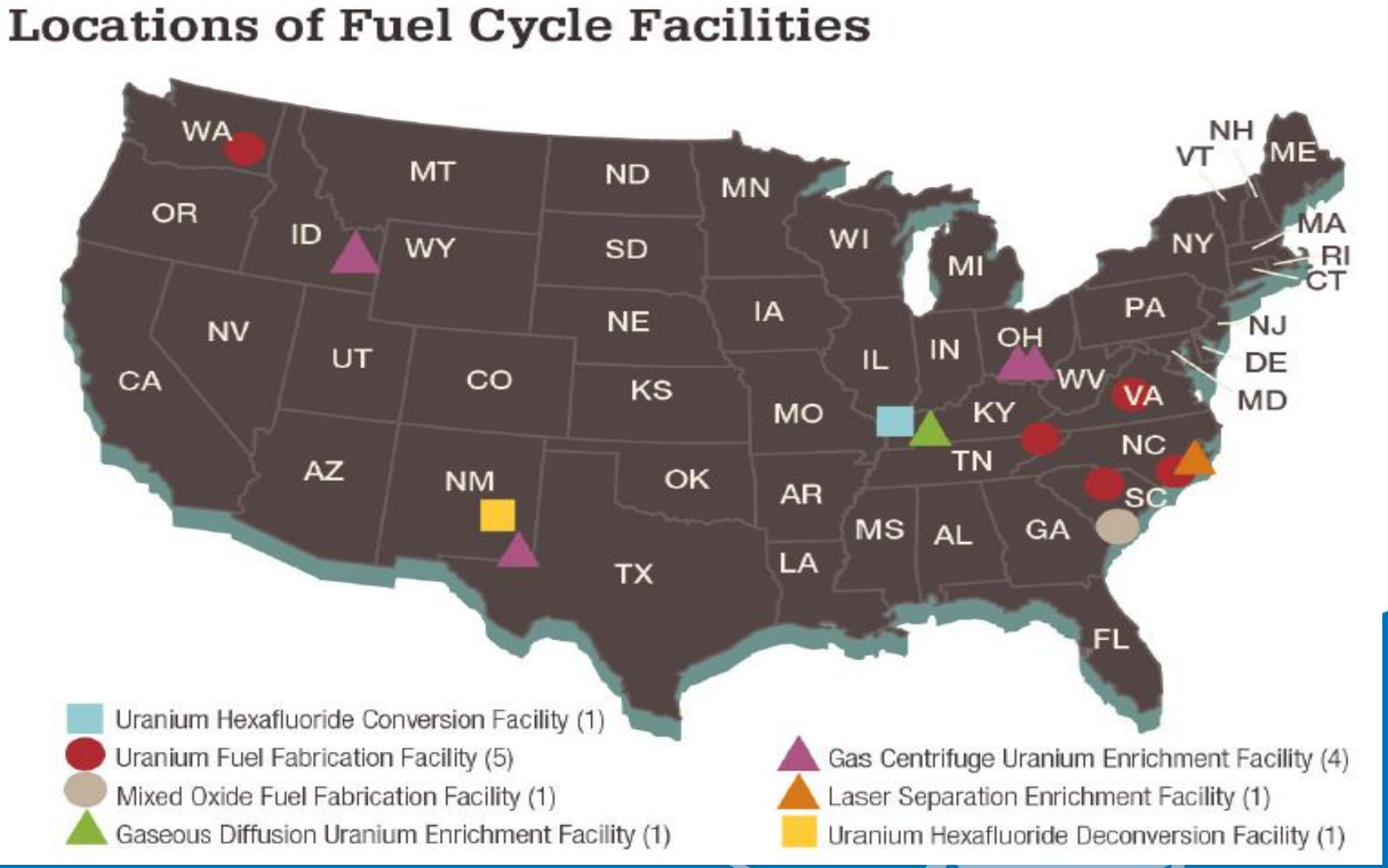
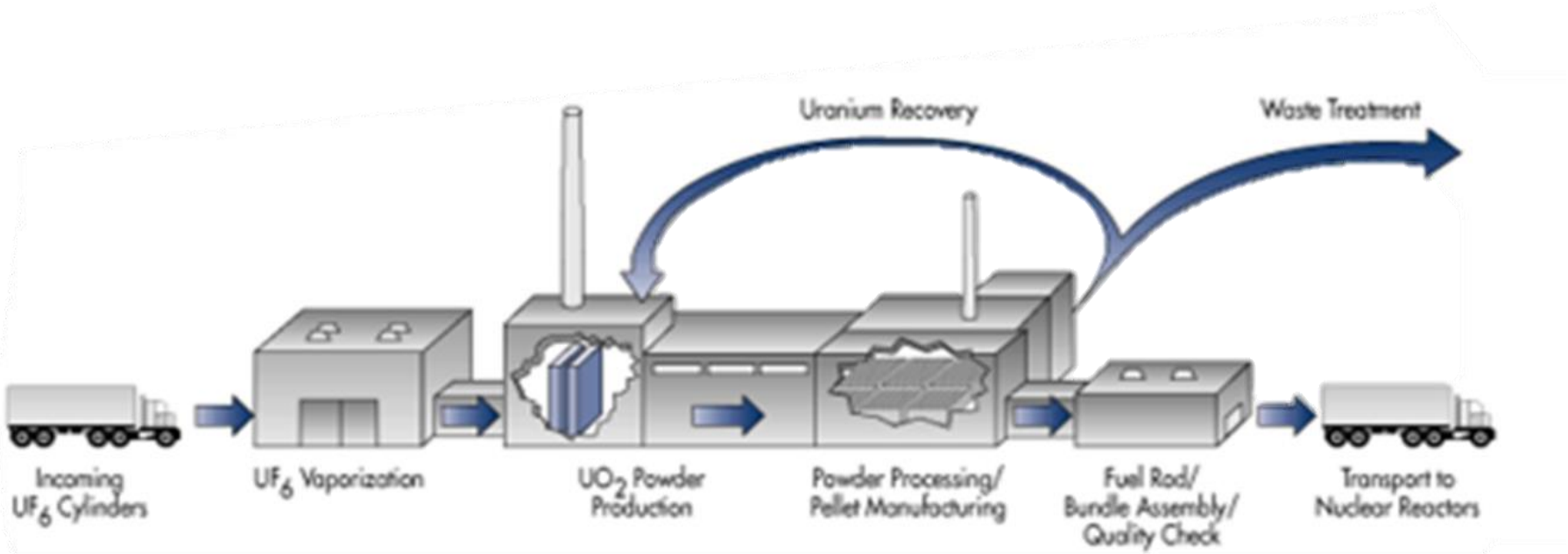
Background

Overview of Fuel Cycle Facilities



Overview of Fuel Cycle Facilities



Chemical Hazards

- Numerous chemicals used at fuel cycle facilities (FCF) for processing uranium and other heavy metals
- Some chemicals used a FCF:
  - $UF_{6,}$ hydrogen fluoride, ammonia, hydroxylamine nitrate, nitrogen oxides, nitric acid, other acids and solvents.

Memorandum of Understanding between OSHA and NRC

- NRC is responsible for:
  - Radiation risks of licensed materials
  - Chemical risks of licensed materials, and
  - Plant conditions that affect or may affect the safety of licensed materials and thus , present an increased risk to workers.
- OSH Act, Section 4 - OSHA is not responsible for working conditions of employees where another Agency exercises statutory authority.

Regulatory Framework

- 10 CFR part 70: Amended to incorporate Subpart H, the risk informed, performance-based integrated safety analysis (ISA)
  - Performance Requirements (70.61)
  - Conduct and maintain an ISA (70.62)
  - Identification of items relied on for safety (IROFS)
  - ISA summary must include quantitative standards (70.65)

Regulatory Framework (cont'd)

- 10 CFR 70.61 Performance Requirements

Severity of Consequences	Likelihood of Occurrence		
	Likelihood Category 1 Highly Unlikely (1)	Likelihood Category 2 Unlikely (2)	Likelihood Category 3 Not Unlikely (3)
Consequence Category 3 High (3)	Acceptable Risk 3	Unacceptable Risk 6	Unacceptable Risk 9
Consequence Category 2 Intermediate (2)	Acceptable Risk 2	Acceptable Risk 4	Unacceptable Risk 6
Consequence Category 1 Low (1)	Acceptable Risk 1	Acceptable Risk 2	Acceptable Risk 3

Regulatory Framework (cont'd)

- 10 CFR 70.61 Performance Requirements

Severity of Consequences	Likelihood of Occurrence		
	Likelihood Category 1 Highly Unlikely (1)	Likelihood Category 2 Unlikely (2)	Likelihood Category 3 Not Unlikely (3)
Consequence Category 3 High (3)	Acceptable Risk 3	Unacceptable Risk 6	Unacceptable Risk 9
Consequence Category 2 Intermediate (2)	Acceptable Risk 2	Acceptable Risk 4	Unacceptable Risk 6
Consequence Category 1 Low (1)	Acceptable Risk 1	Acceptable Risk 2	Acceptable Risk 3

Example: HF exposure event

AEGL-3: [50ppm]

Regulatory Framework (cont'd)

- Quantitative standards

Severity of Consequences	Likelihood of Occurrence		
	Likelihood Category 1 Highly Unlikely (1)	Likelihood Category 2 Unlikely (2)	Likelihood Category 3 Not Unlikely (3)
Consequence Category 3 High (3)	Acceptable Risk 3	Unacceptable Risk	Unacceptable Risk 9
Consequence Category 2 Intermediate (2)	Acceptable Risk 2	Acceptable Risk 4	Unacceptable Risk 6
Consequence Category 1 Low (1)	Acceptable Risk 1	Acceptable Risk 2	Acceptable Risk 3

> 50 ppm

< 50 ppm

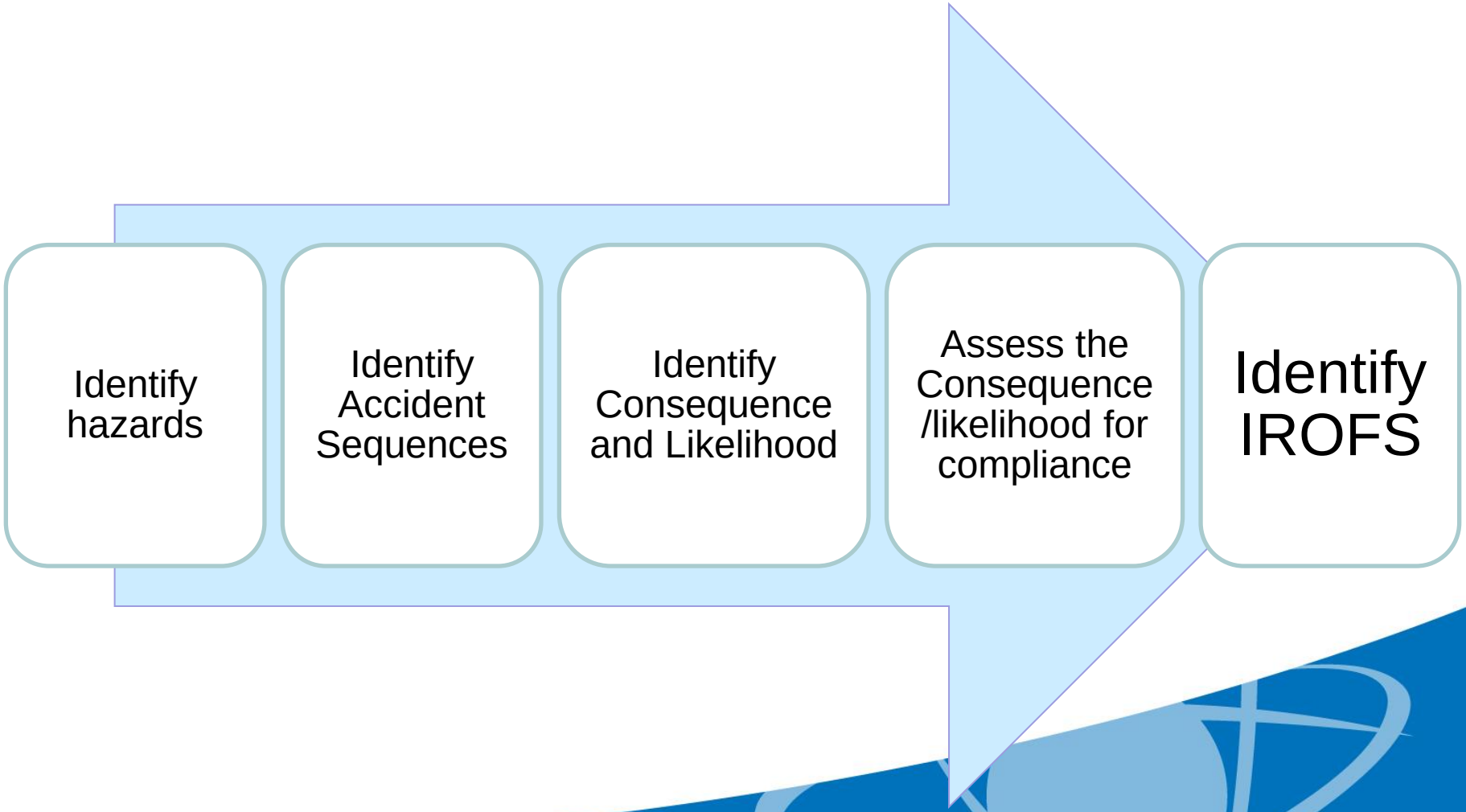
[HF] 50 ppm: High or intermediate?

Chemical Safety Requirements

- 10 CFR Part 70.61(b) and (c) requires an applicant or licensee to limit the risk of high or intermediate consequence events resulting from acute chemical exposures

- 10 CFR Part 70.65(b)(7) requires a description of the proposed quantitative standards used to assess the consequences to an individual from acute chemical exposures

ISA Process


Identify hazards
Identify Accident Sequences
Identify Consequence and Likelihood
Assess the Consequence /likelihood for compliance
Identify IROFS

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ISG – Guidance for Evaluation of Acute Chemical Exposure and Proposed Quantitative Standards

Content of ISG

- Review of Chemical Hazards and Accident Sequences
- Review of Chemical Accident Consequences
- Review of Chemical Accident Likelihood
- Review of Proposed Quantitative Standards for Acute Chemical Exposures
  - General Criteria for Reviewing Proposed Quantitative Standards
  - Information Sources for Air, Dermal and Ocular exposure pathway

Interim Staff Guidance

- Discussion
  - Are all pathways considered?
- Review of Chemical Hazards and Accident Sequences
  - Description of chemical hazards
  - Credible scenarios identified in the ISA

Interim Staff Guidance (cont'd)

- Review of Chemical Accident Consequences/ Likelihood
  - Exposure estimate
  - Consequence estimate
- Proposed Quantitative Standards for chemical consequences
  - When is a standard necessary?
  - Physical and chemical properties

ISG: Proposed Quantitative Standards

- General criteria: reasonable estimate of the consequences
- Publicly available, useful sources identified
  - AEGLs, ERPGs, TEELs and others
  - Globally Harmonized System of Classification and Labelling of Chemicals (GHS): Hazard Statements
  - NIOSH Skin Notations for dermal exposures

Table 1 – Acute Exposure Hazard Information for Common Fuel Cycle Process Chemicals[8]

Chemical	GHS Hazard Statement in GHS database[9] (Inhalation, dermal, ocular, ingestion exposure)	NIOSH skin notation[10] (Dermal exposure)	Noted by OSHA list for skin adsorption[11] (Dermal exposure)	AEGL; ERPG[12]; TEEL (Inhalation exposure)
ammonium hydroxide (NH_4OH)	H314 1B (causes severe skin burns and eye damage) H335 (may cause respiratory irritation): C≥ 5 %	No	No	Yes
ammonium fluoride (NH_4F)	H301 (toxic if swallowed) H311 (toxic in contact with skin) H331 (toxic if inhaled)	No	No	No
hydrochloric acid (HCl)	H314 1B (causes severe skin burns and eye damage): C ≥ 25% for 1 hour exposure H335 (may cause respiratory irritation): C ≥ 10 %	No	No	Yes
hydrofluoric acid (HF)	**H300 (fatal if swallowed)** **H310 (fatal in contact with skin)** H314 (causes severe skin burns and eye damage): C ≥ 7% for 3 minute exposure; 1% ≤ C < 7% for 1 hour exposure **H330 (fatal if inhaled)**	SK: **SYS (FATAL)**-DIR (COR): **may be potentially lethal or life-threatening following exposure of the skin**; corrosive following exposure of the skin	Yes	Yes
hydrogen peroxide (H_2O_2)	H302 (harmful if swallowed) H314 (causes severe skin burns and eye damage): C ≥ 70% for 3 minute exposure; 50% ≤ C < 70% for 1 hour exposure H322 (harmful of inhaled) H335 (may cause respiratory irritation) C ≥ 35%	No	No	Yes
nitric acid (HNO_3)	H314 (causes severe skin burns and eye damage): C ≥ 20% for 3 minute exposure; 5% ≤ C < 20% for 1 hour exposure	No	No	Yes
perchloroethylene (C_2CL_4, also called tetrachloroethylene)	H315 (causes skin irritation)	No	No	Yes
sodium hydroxide (NaOH)	H314 (causes severe skin burns and eye damage): C ≥ 5% for 3 minute exposure; 2% ≤ C < 5% for 1 hour exposure	SK: DIR (COR). corrosive following exposure of the skin	No	Yes
sulfuric acid (H_2SO_4)	H314 (causes severe skin burns and eye damage): C ≥ 15% for 3 minute exposure	No	No	Yes
Tributyl phosphate ($(CH_3CH_2CH_2CH_2O)_3PO$)	H302 (harmful if swallowed) H315 (causes skin irritation)	No	No	Yes
uranyl nitrate ($UO_2(NO_3)_2$)	**H300 (fatal if swallowed)** **H330 (fatal if inhaled)**	No	No	Yes

Note: Exposure to chemicals with hazard or skin notation statements in bold would generally be considered a high consequence event in the context of an ISA. Exposure to chemicals with a hazard or skin notation statement that is underlined would generally be considered an intermediate consequence event in the context of an ISA. Skin Corr 1A is for exposure less than 3 minutes. Skin Corr 1B is for exposure less than 1 hour.

Table 2 – Inhalation Exposure description and statements related to the performance requirements in 70.61

	Description in 70.61	Description in AEGL[13]	Description in ERPG[14]	Description in GHS Hazard Statements
High Consequences	Could endanger the life of a worker	**AEGL-3** is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death.	**ERPG-3** is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing or developing life-threatening health effects.	H330 Fatal if inhaled
	Could lead to irreversible or other serious, long-lasting health effects to any individual located outside the controlled area	**AEGL-2** is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.	**ERPG-2** is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hr without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual's ability to take protective action.	H331 Toxic if inhaled
Intermediate Consequences	Could lead to irreversible or other serious, long-lasting health effects to a worker	**AEGL-2** is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.	**ERPG-2** is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hr without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual's ability to take protective action.	H331 Toxic if inhaled
	Could cause mild transient health effects to any individual located outside the controlled area	**AEGL-1** is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic non-sensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.	**ERPG-1** is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hr without experiencing other than mild transient adverse health effects or perceiving a clearly defined, objectionable odor.	H332 Harmful if inhaled

Table 3 – Dermal Exposure descriptions and statements related to the performance requirements in 70.61

	Description in 10 CFR 70.61	Description in GHS Hazard Statements	Description in NIOSH Skin Notation
High Consequences	Could endanger the life of a worker	H310 Fatal in Contact with skin	SYS:(FATAL) - highly or extremely toxic, and may be potentially lethal or life-threatening following skin exposures
Intermediate Consequences	Could lead to irreversible or other serious, long-lasting health effects to a worker	H311 Toxic in contact with skin H314 Causes severe skin burns and eye damage	DIR:(IRR) indicates that a chemical is a skin irritant, DIR: (COR) which indicates that a chemical is a corrosive.

Note: The information contained in this table reflects information at the time of its preparation. Staff should review validity of classification using currently available information.

Table 4 -Ocular Exposure descriptions and statements related to the performance requirements in 70.61

	Description in 10 CFR 70.61	Description in GHS Hazard Statements
High Consequences	Could endanger the life of a worker	
Intermediate Consequences	Could lead to irreversible or other serious, long-lasting health effects to a worker	H318 Causes serious eye damage H314 Causes severe skin burns and eye damage

Note: The information contained in this table reflects information at the time of its preparation. Staff should review validity of classification using currently available information.

Summary

- The ISG will provide guidance to:
  - Ensure the ISA review considers all exposure pathways.
  - Verify that the applicant's ISA analyzes for all phases of operation (normal, maintenance, etc.)
  - Ensure "proposed quantitative standards" are identified when necessary.
  - Ensure proposed standards are consistent with available scientific information.

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QUESTIONS

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ADDITIONAL SLIDES

Safety Benefit

- Analyze all hazards to maintain safety performance
- Fundamental purpose of Subpart H was to establish and maintain safety performance
  - Performance requirements in 70.61
  - 70.62 requires a licensee or applicant to conduct and maintain a safety program and an Integrated Safety Analysis

Safety Benefit (cont'd)

- Chemical Safety Regulations
  - Hazardous chemicals produced from licensed materials (70.4)
  - OSHA compliance does not equal compliance with NRC Part 70 Subpart H regulations

FUEL CYCLE FACILITY PAST EVENTS - DERMAL AND OCULAR EXPOSURES

Date	Event Description (drawn from NMED text)
12/3/1992	Employee sprayed with an acid/uranium mixture
1/27/1998	UF_6 release, three workers received minor HF acid burns on necks and arms (NRC Event Notification (EN) 33601)
8/10/2001	UF_6 release, two workers treated for HF acid burns (EN38198)
4/4/2006	UF_6 release, “minor reddening of the skin … as an apparent result of HF exposure” (NRC Press Release (ML061170441))
2/26/2007	UF_6 release, worker received chemical burn while working with UF_6 cylinder. (NRC Inspection Report 70-1151/2007-022, ML071980047)
4/28/2008	HF spill that resulted in an operator receiving an ocular exposure requiring onsite and offsite emergency medical treatment. (EA-08-204-ML082960026, IR 70-27/2008-0287)
2/12/2009	Holes in glove resulted in second degree nitric acid burns (EN44848)
4/5/2011	KOH exposure to face (EN46730)
4/13/2011	Residual HF passed through zipper of chemical resistant suite and onto the skin of abdomen (EN46749)
4/23/2012	Exposure to dilute nitric acid on left forearm and left foot from exposure to uranium bearing acid (EN47861)

Quantitative Standards

- Are necessary to assess the consequences established in 10 CFR 70.61
- History on the rulemaking of Subpart H demonstrates:
  - Intended to cover all hazards
  - rule was not limited by pathway
  - Consistent with OSHA regulations

Process Safety Management vs NRC Subpart H (and other) Requirements			
OSHA PSM 29 CFR1910.119	EPA Chemical Accident Prevention 40 CFR 68	NRC Regulation	Relevant NRC Inspection Procedures
(c) employee participation	68.83 employee participation		
(d) process safety information	68.65 process safety information	70.62(b) safety program, process safety information	IP 88020 Operational Safety
(e) process hazard analysis	68.67 process hazard analysis	70.62(c) safety program, integrated safety analysis	IP 88020 Operational Safety
(f) operating procedures	68.69 operating procedures	Element of management measures in 1520 (11.4.3.4)	IP 88005 Management organization and Controls
(g) training	68.71 training	Element of management measures in 1520 (11.4.3.3)	IP 88020 Operational Safety
(h) contractors	68.87 contractors		
(i) pre-startup safety reviews	68.77 pre-startup reviews		
(j) mechanical integrity	68.73 mechanical integrity		
(k) hot work permits	68.85 hot work permit		
(l) management of change	68.75 management of change	Configuration management is identified as an example of a management measure (more limited in scope than overall management of change?)	IP 88070 Permanent Plant Modifications
(m) incident investigation	68.81 incident investigation	Element of management measures in 1520 (11.4.3.6)	IP 88005 Management organization and Controls
(n) emergency planning and response	68.95 emergency response program	70.22(i)(3) emergency response plan but this has a different scope	
(o) compliance audits	68.79 compliance audits	Element of management measures in 1520 (11.4.3.5)	

Regulatory Framework (cont'd)

- 10 CFR 70.61 Performance Requirements