UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of SHINE MEDICAL TECHNOLOGIES, INC. (Medical Radioisotope Production Facility)	Docket No. 50-608-CP

ORDER
(Adopting Proposed Transcript Corrections, Admitting Post-Hearing Exhibits, and Closing the Record of the Proceeding)

The Commission held an evidentiary hearing at its Rockville, Maryland headquarters on December 15, 2015. The parties have provided proposed transcript corrections. The transcript corrections identified in Appendix A to this order are adopted. Appendix B to this order contains a revised hearing transcript that incorporates all of the adopted corrections.

In addition, the parties have submitted responses to post-hearing questions. As directed, these responses were filed as new exhibits, using the previously-established numbering scheme. Neither party objects to the admission of these new exhibits. Therefore, exhibits NRC-014 and SHN-030 are admitted into the evidentiary record. The Staff also has filed a revised exhibit, NRC-002-R, and represents that SHINE has no objection to its admission. This exhibit is admitted, and the previous version of the exhibit, NRC-002, is stricken from the record.

The adoption of transcript corrections and the admission into evidence of the new exhibits completes the procedural activities that remained pending at the conclusion of the mandatory hearing. The record of this proceeding is closed, effective as of the date of this order. This order is issued pursuant to my authority under 10 C.F.R. § 2.346(a) and (j).

IT IS SO ORDERED.

For the Commission

NRC SEAL

/RA/
Annette L. Vietti-Cook
Secretary of the Commission

Dated at Rockville, Maryland,
this 14th day of January, 2016.

APPENDIX A: Changes to the Transcript for the SHINE Medical Technologies, Inc. Mandatory Hearing December 15, 2015

Page	Line	Correction
1	21	Change "JEFF BARAN" to "KRISTINE L. SVINICKI"
1	23	Change "KRISTINE L. SVINICKI" to "JEFF BARAN"
2	1	Add "AND WITNESSES" after "STAFF"
2	11	Insert “STEPHEN MARSCHKE, S. Cohen & Associates” before “Jane Marshall”
3	5	Replace “HENNESY” with “HENNESSY”
3	11	Delete “Stephen Marschke, Sanford Cohen and Associates”
5	16	Replace “189A” with “189a”
6	2	Replace “189A” with “189a”
7	22	Replace “to this common” with “to the common”
8	1	Replace “NEPA Sections 102.2(a), (c) and (e)” with “NEPA Sections 102(2)(A), (C) and (E)”
8	6	Add semicolon after "taken"
8	12	Add semicolon after "values"
9	1	Replace “of witness” with “of witnesses”
9	9	Replace “the witness” with “the witnesses”
9	10	Replace “their name” with “their names”
9	14	Replace “Hennesy” with “Hennessy”
9	13, 14	Replace “Richard Van Bynum” with “Richard Vann Bynum”
13	23	Replace “HENNESY:” with “HENNESSY:”
13	23	Replace “Hennesy” with “Hennessy”
18	2	Replace “insure” with “ensure”
19	2	Replace “insure” with “ensure”
19	17	Replace “insure” with “ensure”
19	18	Replace “insure” with “ensure”
20	14	Replace “insure” with “ensure”
20	25	Replace “radiation” with “irradiation”
23	3	Replace “all together” with “altogether”
25	11	Replace “plan” with “plans”
25	23	Replace “licensed” with “license”
26	24	Replace “tank is which is” with “tank which is”
27	3	Replace “radiation” with “irradiation”
27	8	Replace “for the proper” with “to the proper”
29	2	Replace “than pass” with “then pass”
32	18	Replace “is discrete” with “in discrete”
33	15	Replace “of accelerator” with “of the accelerator”
34	21, 22	Replace “ATSV off gas system” with “eight TSV off gas systems,”
36	16	Replace “insure” with “ensure”
39	3	Replace “insure” with “ensure”
40	17	Add comma after "phase" and add a question mark after "license"
40	23	Replace “HENNESY:” with “HENNESSY:”
40	24	Replace “Hennesy” with “Hennessy”
41	16	Replace “HENNESY:” with “HENNESSY:”
42	17	Change "presentation" to "panel"
43	24	Change "work" to "wrap"

Page	Line	Correction
44	14	Change "area" to "areas"
46	6	Change the period to a question mark after "financial"
47	23	Replace “HENNESY:” with “HENNESSY:”
48	5	Replace “HENNESY:” with “HENNESSY:”
48	25	Delete "for"
49	4	Replace "some" with "a"
49	7	Replace “HENNESY:” with “HENNESSY:”
50	3	Replace “HENNESY:” with “HENNESSY:”
50	12	Replace “HENNESY:” with “HENNESSY:”
50	8, 9	Replace "th is" with "this"
51	12	Replace “our’s” with “ours”
52	5	Replace "your's" with "yours"
52	16	Replace “insure” with “ensure”
54	14	Change "explore" to "explored"
54	17	Change "insure" to "ensure"
55	5	Change "use" to "used"
55	8	Replace “HENNESY:” with “HENNESSY:”
55	18	Replace “HENNESY:” with “HENNESSY:”
57	11	Change “Go to” to “Could I have”
57	16	Change "technetium-99m stable" to "technetium-99 metastable"
60	1	Change "NMSA" to "NNSA"
60	23	Change "5034" to "50.34"
61	6	Change "or FSAR" to ", or FSAR,"
62	4	Change "insure" to "ensure"
64	5	Change “wall’s” to “wall”
64	8	Change "think" to "thin"
66	9	Change "review inform" to "review, inform"
67	17	Change "areas except" to "areas, except"
67	18	Change "traffic" to "traffic,"
68	14	Change "320" to "20"
70	12	Change “SHINE stated” to “SHINE has stated”
70	20	Change "criterion" to "criteria in"
73	17	Delete the comma after "support" and change "organization" to "organizations"
73	21	Delete "it's"
78	14	Delete "you think"
78	16	Change "has" to "have"
80	10	Change “our’s” to “ours”
82	22	Insert em dash between "guidance" and "in"
82	23	Replace comma and space with em dash
83	3	Set off "I'll say" with commas
84	6	Delete the first "the"
86	15	Delete "is - -"
86	22	Change "action" to "actions"
87	20	Change "insure" to "ensure"
89	3	Change "concept" to "concepts"

Page	Line	Correction
90	10	Change "insure" to "ensure"
91	18	Change “facilities” to “facility”
92	14	Change "MR. LYNCH" to "MR. DEAN"
96	25	Add "that" after "Guidance" and add a comma after "used"
100	17	Change “in your” to “many of the”
100	18	Change “ask the questions we practice” to “asked are questions we practiced”
101	1	Change “need to” to “need. To”
101	3	Change “permit. That” to “permit, that”
101	12	Change “MS. YOUNG” to “COMMISSIONER SVINICKI”
102	8	Replace “Hennesy” with “Hennessy”
104	5	Replace “in a radiation” with “and irradiation”
104	6	Replace “maintain at shutdown” with “maintain it shutdown”
105	12	Replace “commensurate what” with “commensurate with”
105	15, 16	Replace “single family criterion” with “single failure criterion”
106	21	Delete "will discuss"
109	19	Change "nature" to "nature,"
109	21	Change "Part 70" to "Part 70,"
111	1	Change "Because of the" to "Because of their"
111	3	Change "reactors" to "reactors,"
112	16	Change "b" to "be"
112	19	Change “application” to “application,”
114	8	Replace "to" with "of"
115	5	Replace “MR. VAN ABEL:” with “MR. HENNESSY:”
115	8	Replace “MR. VAN ABEL:” with “MR. HENNESSY:”
116	19	Change "the" to "that"
116	25	Change "of" to "on"
117	3	Change "that we" to "would be"
117	15	Change "committing to" to "committing to to"
119	18	Change “Thanks you.” to “Thank you.”
119	3, 4	Change "And the" to "But in the"
120	14	Replace “HENNESY:” with “HENNESSY:”
120	23	Replace “HENNESY:” with “HENNESSY:”
121	3	Replace “HENNESY:” with “HENNESSY:”
121	5	Replace “HENNESY:” with “HENNESSY:”
122	2	Change “COMMISSIONER BARAN” to “CHAIRMAN BURNS”
122	5	Change “that replaced” to “that were placed”
122	23	Add "a" between "of" and "temporal"
125	18	Change “traverse” to “transverse”
126	2	Change "large" to "larger"
127	7	Change “COMMISSIONER BARAN” to “CHAIRMAN BURNS”
128	13	Add "a" after "got"
128	16	Replace “HENNESY:” with “HENNESSY:”
128	19	Replace “HENNESY:” with “HENNESSY:”
128	22	Replace “HENNESY:” with “HENNESSY:”
129	2	Replace “HENNESY:” with “HENNESSY:”

Page	Line	Correction
129	6	Replace “HENNESY:” with “HENNESSY:”
129	20	Replace “I put” with “I was put”
130	2	Replace “will able” with “will be able”
131	19	Replace “sites” with “site”
131	23	Replace “sites” with “site”
132	1	Replace “sites” with “site”
132	2	Replace “and the” with “in the”
132	3	Replace “events” with “event”
132	10	Change "analysis" to "analyses"
132	16	Change “HULL” to “VAN ABEL”
133	9	Change “be either” to “be for either”
133	13	Delete "are of course"
134	10	Delete "of"
136	9	Change "being" to "begin"
136	13	Replace “HENNESY:” with “HENNESSY:”
136	13	Replace “Hennesy” with “Hennessy”
136	20	Replace “MR. COSTEDIO:” with “MR. VAN ABEL:”
137	20	Replace “preformed” with “performed”
137	7, 8	Replace “nuclear plant operations and engineering personal experience in reactor and nuclear process safety.” with “nuclear plant operations and engineering, personnel experienced in reactor and nuclear process safety.”
138	8	Replace “a radiation” with “irradiation”
138	11	Replace “in the pool” with “of the pool”
138	11	Replace “disburses” with “disperses”
138	16	Replace “filter” with “filtered”
138	19	Replace “work” with “worker”
138	23	Replace “designated” with “designate it”
139	3	Replace “store” with “stored”
140	4	Replace “duct.” with “stack.”
140	17	Change “as the” to “ask the”
140	24	Change "Kevin Morrissey" to "Kevin Morrissey, Fuel Cycle Safety Review."
140	25	Change "Dave Lynch" to "Steve Lynch, Project Manager, Research and Test Reactors Licensing"
141	7	Change "Projection" to "Production"
142	19	Change “facilities. The” to “facilities, the”
143	1	Change “radiation facility” to “irradiation facility”
144	23, 24	Change "where gas is produced in the irradiation process or stored" to "where gases produced in the irradiation process are stored"
145	12	Change "RM." to "MR."
148	1	Add "to" after "witnesses"
151	14	Change “engineering and safety” to “engineering safety”
151	18	Change “offsite conditions.” to “upset conditions.”
152	6	Change “Chris,” to “Chris Tripp,”
152	17	Change "vessel" to "special"

Page	Line	Correction
153	4	Change “KANATAS" to "KOLB"
153	11	Replace “176” with “1.76”
153	17	Add question mark after "that" and capitalize "the" in "The one other thing"
153	17	Insert “MR. LYNCH:” before "The one other thing…"
153	19	Change "rain, snow" to "rain-snow"
153	20	Change “event?” to “event.”
153	21	Change "MR. LYNCH" to "CHAIRMAN BURNS"
153	23	Change "CHAIRMAN BURNS" to "MR. LYNCH"
153	24	Change "MR. LYNCH" to "CHAIRMAN BURNS"
153	25	Change "CHAIRMAN BURNS" to "MR. LYNCH"
154	1	Change "MR. LYNCH" to "CHAIRMAN BURNS"
154	2	Delete "CHAIRMAN BURNS:"
154	9	Replace “MR. VAN ABLE:” with “MR. VAN ABEL:”
156	1	Change “15.20” to “1520”
157	18	Add "you" after "Thank"
158	10	Change "MS. KANATAS" to "MS. KOLB"
158	17	Change "MS. KANATAS" to "MS. KOLB"
158	20	Change "MS. KANATAS" to "MS. KOLB"
159	1	Replace “license” with “licensed”
159	5	Replace “a waste control specialist” with “at Waste Control Specialists”
159	11	Change "KANATAS" to “KOLB"
159	16	Change “KANATAS” to “KOLB”
159	19	Delete "broadly"
160	11	Replace “that’s on the license and operators.” with “that’s how they license their operators.”
160	25	Replace “HENNESY:” with “HENNESSY:”
161	18	Delete "in" and the second "the"
161	19	Delete "is" and replace with "that we've"
161	19	Replace the comma with a period and capitalize "is"
161	22	Replace "of" with "or"
161	24	Replace “No, you know, have various” with “No – we have various”
162	20	Delete "just for"
162	23	Replace "are" with "seem"
162	24	Delete "And," and capitalize "are"
162	3, 4	Replace “monitor the activity in the neutron population in the TSV radiation.” with “monitor the reactivity and the neutron population in the TSV during irradiation.”
163	4	Replace “manual” with “manually”
163	11	Replace “there would” with “they would”
163	18	Replace “not only” with “nominally”
163	19	Replace “two dampers, but every place” with “two dampers at every place”
163	8, 9	Replace “many traces available” with “many choices available”
164	19	Replace “HENNESY:” with “HENNESSY:”
164	19	Replace “Hennesy” with “Hennessy”

Page	Line	Correction
164	19, 20	Replace “Manager of Engineer” with “Manager of Engineering”
165	20, 21	Replace “of the affect in the environment” with “of the affected environment”
169	8	Replace “alterative” with “alternative”
171	25	Replace “Sections 102.2(a), (c)” with “Sections 102(2)(A), (C)”
171	5, 6	Replace “both to Stevens Point and the Chippewa Falls” with “both to Stevens Point and to Chippewa Falls”
172	1	Replace “and (e)” with “and (E)”
174	14	Change “and” to “an”
174	22	Change “actions” to “action's”
176	7	Change “of the an EIS” to “of an EIS”
177	12	Change "NEC" to "NRC"
178	23	Change "visited site" to "visited the site"
183	19	Change “publically” to “publicly”
185	13	Change "residents" to "resident"
186	20	Change “medial” to “medical”
187	12	Change "adjust" to "address"
189	21	Change "provides" to “revised”
191	4	Change "15" to "51"
192	24	Add a comma after "source" and change "an aging" to "are"
193	18, 19	Add a comma after "Where" and add quotation marks before "I" and after "technology"
194	17	Change "were" to "was"
198	3	Delete "I actually came at --"
199	12	Change "and" to "an"
200	6	Replace “Trial entities” with “Tribal entities”
200	23	Replace "Christinesville" with "Kristinesville"
201	17	Replace "NCR" with "NRC"
201	19	Replace "ways" with "Waze"
202	5	Insert "a" after "Katrina"
202	8	Insert "with" between "experience" and "the"
202	9	Delete comma, change "with" to "and," delete "regular"
202	10	Begin "Commercial Power Reactors" with lower case letters
202	13	Replace "doing" with "the"
203	15	Delete "just, you know,"
203	10, 11	Delete "just like, you know,"
204	1	Change “several questions.” to “a separate question.”
204	24	Replace “didn’t new time.” with “didn’t add any time.”
205	5	Replace "comments" with "comment"
205	5	Insert "the" before "NRC"
207	6	Replace “Van Bynum” with “Vann Bynum”
207	10	Replace “Van Bynum” with “Vann Bynum”
208	21	Change "You" to "We"
209	18	Change "I" to "it"
209	20	Delete "any that,"
210	8	Add "make" after "can" and change "it that" to "what"

Page	**Line**	**Correction**
218	3	Change "bear in town" to "Barantown"
218	5	Delete period after "immediately"
218	5	Add "that" after "immediately" and change capital "T" to lowercase
218	19	Change “A conducted” to “A we conducted”
218	24	Replace “resumption” with “presumption”
219	19	Delete "working at"
220	2	Insert "not" between "may" and "be"
221	9	Change “the Commission” to “the Office of Commission”
221	24	Add "be" after "probably" and change "issue" to "issued"

APPENDIX B: Corrected Transcript
December 15, 2015

Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title:	Hearing on Construction Permit for Shine Medical Isotope Production Facility
Docket Number:	(n/a)
Location:	Rockville, Maryland
Date:	Tuesday, December 15, 2015

Work Order No.: NRC-2982 Pages 1-220

NEAL R. GROSS AND CO., INC.
Court Reporters and Transcribers
1323 Rhode Island Avenue, N.W.
Washington, D.C. 20005
(202) 234-4433

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

HEARING ON CONSTRUCTION PERMIT FOR SHINE MEDICAL ISOTOPE PRODUCTION FACILITY:

SECTION 189A OF THE ATOMIC ENERGY ACT PROCEEDING

+ + + + +

PUBLIC MEETING

+ + + + +

TUESDAY

DECEMBER 15, 2015

+ + + + +

ROCKVILLE, MARYLAND

+ + + + +

The Commission met in the Commissioners' Conference Room at the Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, at 9:00 a.m., Stephen G. Burns, Chairman, presiding.

COMMISSION MEMBERS:

STEPHEN G. BURNS, Chairman

KRISTINE L. SVINICKI

WILLIAM C. OSTENDORFF

JEFF BARAN

ALSO PRESENT:

ANNETTE L. VIETTI-COOK, SECY

NRC STAFF AND WITNESSES PRESENT:

ALEXANDER ADAMS, JR., NRR

MARY ADAMS, NMSS

MARISSA BAILEY, NMSS

GREGORY CHAPMAN, NMSS

WILLIAM DEAN, NRR

MARGARET M. DOANE, OGC

MIRELA GAVRILAS, NRR

CATHERINE KANATAS, OGC

STEVEN LYNCH, NRR

STEPHEN MARSCHKE, S. Cohen & Associates

JANE MARSHALL, NRR

KEVIN MORRISSEY, NMSS

MICHELLE MOSER, NRR

JOSEPH STAUDENMEIER, RES

CHRISTOPHER TRIPP, NMSS

CARL WEBER, NRO

DAVID WRONA, NRR

MITZI YOUNG, OGC

APPLICANT AND WITNESSES PRESENT:

STEPHEN BURDICK, Morgan Lewis & Bockius

RICHARD VANN BYNUM, SHINE Medical Technologies

JIM COSTEDIO, SHINE Medical Technologies

BILL HENNESSY, SHINE Medical Technologies

CHRISTOPHER HEYSEL, Information Systems Laboratories

ALAN HULL, Golder Associates, Inc.

CATHERINE KOLB, SHINE Medical Technologies

TIMOTHY KRAUSE, Sargent & Lundy

GREG PIEFER, SHINE Medical Technologies

KATRINA PITAS, SHINE Medical Technologies

ERIC VAN ABEL, SHINE Medical Technologies

A G E N D A

P R O C E E D I N G S

9:01 a.m.

CHAIRMAN BURNS: I call this hearing to order on a more serious event, but first let me get my script out as we do need to go through a number of things before we begin this hearing.

I want to welcome the audience and those who may be viewing this remotely on line. Welcome to the Applicant, to the Staff, members of the public. And the Commission is here today to conduct an Evidentiary Hearing on the SHINE Medical Technologies application for a construction permit for a medical radioisotope production facility in Janesville, Wisconsin.

This hearing is required under Section 189a of the Atomic Energy Act of 1954, as amended. And the Commission will also be reviewing the adequacy of the NRC Staff's Environmental Impact Analysis under the National Environmental Policy Act of 1969, which many of us refer to as NEPA.

This is the third so called mandatory or uncontested hearing that the Commission has held this year, but unlike the two previous ones, this one is for a construction permit, not for a Combined License. But the requirements for the necessity of a hearing on a construction permit is required as I noted under Section

189a.

During the hearing, SHINE and the Staff will provide testimony and witness panels that will provide an overview of the application, as well as address safety and environmental issues associated with the review, and Commission questions will follow each panel. And there will be a rotation of the Commissioners from panel to panel, and the Commissioners may allocate their total time among the panels as each Commissioner sees fit.

In order to issue a construction permit the Commission must make certain specific safety and environmental findings. On the safety side, the Commission will determine whether in accordance with 10 CFR 50.35(a), whether the Applicant has described the proposed design of the facility, including the principal architectural and engineering criteria for the design, and whether the Applicant has identified the major features or components incorporated therein for the protection of the health and safety of the public. Also, such further technical or design information as may be required to complete the safety analysis, and those which can be reasonably left for later consideration to be supplied in the Final Safety Analysis Report; whether safety features or components, if any, that require research and development have been described by the Applicant, and the Applicant has identified, and there will be conducted a research and development program reasonably designed to resolve any safety questions associated with such features or components; and whether on the basis of the foregoing there is reasonable assurance that, one, such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of the construction of the proposed facility; and, two, 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.

In making these findings, the Commission will also be guided by the considerations in 10 CFR Section 50.40 which include the Commission's opinion as to whether the issuance of the construction permit will not be inimical to the common defense and security or to the health and safety of the public.

With respect to environmental matters, the Commission will determine whether the requirements of NEPA Sections 102(2)(A), (C) and (E), and the applicable regulations in 10 CFR Part 51 have been met. The

Commission will independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken; determine after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives whether the construction permit should be issued, denied, or appropriately conditioned to protect environmental values; and determine whether the NEPA review conducted by the Staff has been adequate.

This meeting is open to the public, and we do not anticipate the need to close the meeting to discuss non-public information, but if a party believes that a response to a question may require a reference to non-public information, then I would ask the party to answer the question to the best of its ability and practicality with information that is on the public record, and file any non-public response promptly after the hearing on the non-public docket.

Before proceeding, do my fellow Commissioners have anything they'd like to add? Then we'll proceed with the swearing in of witnesses. We'll start first with SHINE. I'd ask counsel for SHINE to introduce himself.

MR. BURDICK: Good morning. This is Stephen Burdick from Morgan Lewis & Bockius, also joined by my colleague, Paul Bessette. We are counsel for SHINE.

CHAIRMAN BURNS: Okay. Counsel, would you read the names of the witnesses?

MR. BURDICK: Yes, and if the witnesses would please stand when I read their names, and then remain standing until the Chairman directs otherwise.

In alphabetical order SHINE's witnesses are Joseph M. Aldieri, Jeffrey M. Bartelme, Richard Vann Bynum, James Costedio, William Hennessy, Alan Hull, Catherine Kolb, Timothy P. Krause, Thomas Krzewinski, C. Michael Launi, James W. McIntyre, John B. McLean, William D. Newmyer, Greg Piefer, Katrina M. Pitas, Erwin T. Prater, Louis Restrepo, Eric N. Van Abel, George F. Vandegrift, Tamela B. Wheeler, Ernest Wright, and Steven L. Zander. Thank you.

CHAIRMAN BURNS: Okay, thank you.

Witnesses, I'd ask you to raise your right hand to take the oath.

Do you swear or affirm that the testimony you will provide in this proceeding is the truth, the whole truth, and nothing but the truth?

ALL WITNESSES: I do.

CHAIRMAN BURNS: Did anyone fail to take the oath? Indicate so, otherwise. No. Thank you. You may be seated.

Is there any objection to including the witness list into the record?

MS. KANATAS: No objections.

CHAIRMAN BURNS: Okay, thank you, counsel.

And then with respect to -- we'll proceed in terms of the admission of evidence on behalf of the Applicant. Are there any edits to your exhibit list, counsel?

MR. BURDICK: There are no edits.

CHAIRMAN BURNS: Okay. Would you read the range of numbers of the exhibits to be admitted?

MR. BURDICK: Yes. SHINE has submitted Exhibits SHN-001 through SHN-029.

CHAIRMAN BURNS: Okay. And I presume you propose to move those into the record?

MR. BURDICK: We move to admit those into the record.

CHAIRMAN BURNS: Okay. Is there any objection?

MS. KANATAS: No objections.

CHAIRMAN BURNS: Okay, very good. So, the list of exhibits is admitted for the Applicant, SHINE.

Okay. Turning to the Staff, counsel, would you introduce yourself, please.

MS. KANATAS: My name is Catherine Kanatas, and along with my counsel, Mitzi Young, we represent the Staff.

CHAIRMAN BURNS: Okay, great. Would you read the names of the proposed Staff witnesses?

MS. KANATAS: Yes, and if they can --

CHAIRMAN BURNS: And I'll ask them to stand. Thank you.

MS. KANATAS: Thank you. Alexander Adams, John Adams, Mary Adams, Stephen Alexander, David Back, Marissa Bailey, Daniel Barrs, Thomas Boyle, Gregory Chapman, William Dean, James Downs, Thomas Essig, Kevin Folk, Mirela Gavrilas, Mary Gitnick, James Hammelman, Shawn Harwell, Christopher Heysel, Gregory Hofer, Robert Hoffman, Anthony Huffert, Steven Lynch, Stephen Marschke, Jane Marshall, Nancy Martinez, James McIlvaine, Diane Mlynarczyk, Kevin Morrisey, Michelle Moser, Thomas Pham, Paul Prescott, William Rautzen, Jeffrey Rikhoff, Michael Salay, Alexander Sapountzis, Raymond Skarda, Soly Soto-Lugo, Joseph Staudenmeier, Christopher Tripp, Glenn Tuttle, Carl Weber, Abraham Weitzberg, and David Wrona.

CHAIRMAN BURNS: Okay, thank you.

So, for the Staff witnesses, I'll ask you to raise your right hand.

Do you swear or affirm that the testimony you will provide in this proceeding is the truth, the whole truth, and nothing but the truth?

ALL WITNESSES: I do.

CHAIRMAN BURNS: Did any -- please inform me if any of you decline to take the oath. Okay, you may be seated.

Is there any objection to including the witness list?

MR. BURDICK: No objection.

CHAIRMAN BURNS: Okay. So, proceed to the admission of the evidence on behalf of the NRC Staff. Are there any edits, counsel, to your exhibit list?

MS. KANATAS: There are no edits.

CHAIRMAN BURNS: Would you read the range of numbers on the list of exhibits to be admitted?

MS. KANATAS: Staff exhibits run from NRC-001 through NRC-013.

CHAIRMAN BURNS: Okay. And I presume you would move to admit those exhibits into evidence.

MS. KANATAS: We would like to move to admit them into the record.

CHAIRMAN BURNS: Are there any objections?

MR. BURDICK: No objection.

CHAIRMAN BURNS: Okay. And seeing no objection, the exhibits are admitted. So, thank you for those -- we got through the preliminaries.

I think at this point we're ready to have the Overview Panel for SHINE. And for this portion of the proceeding we'll have the Overview Panel from SHINE, and I believe then we have the questions on the Overview Panel, and then we'll have the Staff Panel. So, thank you, counsel.

And, again, this is an Overview Panel for opportunity for the Applicant to provide us overview of the application and the proposed project. I would remind the witnesses that you remain under oath. You may assume that the Commission is familiar with the pre-hearing filings on behalf of the Applicant, as well of the Staff. And I would then ask the panelists to introduce themselves. I'll start here.

MR. PIEFER: Yes, sir. My name is Greg Piefer. I'm the founder and CEO of SHINE Medical.

MR. HENNESSY: My name is Bill Hennessy. I'm the Manager of Engineering for SHINE.

MR. COSTEDIO: My name is Jim Costedio. I'm the Licensing Manager for SHINE.

MR. VAN ABEL: My name is Eric Van Abel. I'm the Engineering Supervisor for SHINE.

CHAIRMAN BURNS: Okay. Thank you, gentlemen. And you may proceed with your presentation.

MR. PIEFER: So, once again, my name is Greg Piefer, and I want to thank the Commission, Commissioners, Mr. Chairman for your consideration of this very important matter. To start it off, I'd like to give you guys a little bit of background on SHINE and our mission as a company.

SHINE Medical Technologies is dedicated to being the world leader in the clean, affordable production of medical tracers and cancer treatment elements commonly known as medical isotopes by the medical community.

We recognize fully that in order to run this business successfully our highest priority needs to be on safety and reliability of the processes used to produce these isotopes. At the end of the day, these products will serve the needs of approximately 100,000 patients per day around the globe making this a very, very significant endeavor in terms of health care of patients. Of course, we can't operate the plant at all if we're not focused on safety in our house, and so those are the highest sort of values within the company.

Also interesting is that we come with this technology to the market at a very interesting time when there is a tremendous amount of transition happening in the existing supply chain for these medical isotopes. Currently, the only producer in the Western Hemisphere of any significant volume will be leaving the market permanently in 2018, and the products have a 66-hour half-life, the most commonly used product has a 66-hour half-life, and that creates substantial challenges for U.S. patients here if we need to bring all of our medical isotopes from overseas. Next slide, please.

Just a little bit more background on the primary medical isotope that the world uses. Molybdenum-99 decays into a daughter, technetium-99m, and is used in about 85 percent of the nuclear medicine scans performed globally.

Technetium-99m is extremely versatile. Its chemistry allows it to attach itself to a wide variety of drugs where it acts as a tracer, and essentially allows doctors to see what that drug is doing. It has a 6-hour half-life and so it is very difficult to distribute as technetium, but because it's a daughter of molybdenum-99 which has a 66-hour half-life, you can distribute it around the globe fairly easily.

Collectively, these procedures make up about 40 million doses on an annual basis, so very, very high volume, and very important to patients all around the world, the U.S. being approximately half of those doses.

The pie chart included on Slide 3 shows a breakdown of the procedures primarily that use technetium-99m. I'm just going to call your attention to two of the slices. The largest slice is labeled myocardial profusion. Myocardial profusion is just a way of saying looking at blood flow through the heart muscle and, in fact, is commonly known as a stress test. If a doctor wants to know where to put a stent, if a patient is having chest pain they'll do this. If they want to see if the heart has been damaged by a heart attack, they'll do this test, so very, very useful when you look at the number one killer of human beings in the United States, cardiac disease. And the number two use is for something called a bone scan which is used to stage cancer. And that is the number two killer of people in this country. So, very important products, very widely used today, and it's very important that the supply chain remain robust for many, many years to come. Next slide, please.

However, it is not clear that the supply chain will remain resilient on the current track without new production. In fact, it looks like it will not be able to meet the needs, the growing needs of the globe in terms of medical isotope production.

I mention the Canadian reactor is exiting the market permanently in March of 2018, and they actually plan to decommission that reactor, at which time the Western Hemisphere will not have a source barring new entrants coming in. And this is not going to create just a problem over here, but it's going to create a global problem. In fact, the Nuclear Energy Agency as part of the Organization of Economic Cooperation and Development has been performing studies on exactly this situation for the last several years, and we've included a small bit of data from the most recent study which shows current demand growth in the green line, and current production capacity in the orangish line. As you see, it kind of dips down when Canada leaves.

I'll note that this demand graph does include something called outage reserve capacity and so, you know, there's a little buffer on what's actually required, but that's important. That's what the market needs in order to operate reliably and ensure that patients can get the products they need and manage the occasional outage because the supply chain is on the order of 50 to 60 years old in most cases, the research reactors producing this isotope.

So it's a very, very, I think, stressful situation for the medical community right now not knowing where their answers are going to lie in the long term, and that problem creates an opportunity for new technology to come in and sort of change the way we've been making medical isotopes in this country, and really do it in a better way. And that's what we believe we've done here. You're going to hear a lot more about how we plan to do that as the day goes on.

But when we developed this technology, we've been working on it since about 2006, we had some core values as a company when we founded the company that really are embodied by the technological approach you're going to hear about. And, obviously, as I mentioned in the beginning, we believe at the very highest level that it is impossible to run this company without protecting the health and safety of our workers, the public, and the environment, so these have been factors in our consideration from day one when we were looking at what technologies to choose and what approach to go forward on.

On top of that, we need to ensure based on the short half-life of these products that we can get the product out regularly, on time every time. Again, with 66 hours, you know, there's really no forgiveness for substantial delays. It just means that patients aren't going to get the products they need if you can't deliver. And that's unfortunate if a patient presents with chest pains and a doctor is concerned they may have had a heart attack and has to tell them to come back, you know, maybe in a week and hope you make it, or has to give them an alternative isotope that will leave them radioactive for weeks. Stay away from small children for quite some time. It's just not good for the patients, so we need to get this out every single time.

We also needed to ensure cost-effectiveness. We had to ensure an approach that would allow us to make medical isotopes that can be bought. You know, it's a time when reimbursement is generally across the board decreasing in the United States, and it's important that a cost-effective technology be developed so that this doesn't become prohibitive in terms of cost for patient access.

And, finally, something that's been very strong in our minds since the beginning is that it's not necessary to use highly enriched uranium to make medical isotopes; however, it is commonly used around the globe today. So, we designed our process to eliminate the need for highly enriched uranium and, in fact, use only low enriched uranium as part of our process.

The risk posed to the U.S. public by the proliferation of highly enriched uranium is extremely high. If there were to be an event, the consequences would be disastrous, and we fully support the U.S. Government's initiatives to remove highly enriched uranium from the supply chain and, in fact, stop shipping it around the world to ensure that we have appropriate medical tracers.

So, these are all things that drove our mission and drove our values, or drove our technology rather. So, I'm going to just give you a high level view of the technology and how it reflects those values.

Fundamentally, the biggest protection that we have is that these systems have been designed to be small, and I'm talking about small in terms of thermal power equivalent. When you look at a SHINE production unit or irradiation unit, you'll hear more about this throughout the day, the thermal power of one of these systems is on the order of 100 kilowatts when its producing at full tilt. If you were to compare this to a reactor like the NRU which is also producing medical isotopes today, that reactor's thermal power equivalent is 135 megawatts, so there's about a factor of 1,000 difference in thermal power from a SHINE-based system to a reactor-based system. And that has tremendous safety benefits for us, including low source term and very low decay heat. If we shut one of our systems within hours, just a few hours we're down to about a kilowatt of decay heat, so we're talking about something that's less than a hair dryer. So you don't have a lot of the concerns you would have with loss of power in much larger facilities.

In addition to the safety benefits just from the lower source term and lower decay heat, of course, we're producing less radionuclides overall that a much larger reactor would do, and that allows us to use commercial disposal for much, if not all, of our disposal path. It's a great economic benefit and certainty benefit in terms of final disposition of waste products.

Secondly, we developed a low enriched uranium target that is not only novel in terms of being aqueous, the target is in a liquid form, but it's also the first target that I'm aware of that is reusable. And the reusability of our target actually gives us a substantial economic advantage.

Currently in the supply chain, metal targets are used, solid targets are placed next to a reactor core. They're irradiated. Much of the uranium does not fission, they're dissolved and the medical isotopes are extracted out, and the rest of the uranium is essentially thrown away. Well, in fact, since it's highly enriched uranium in most of these cases, it's thrown into tanks and very carefully monitored. But the reusable target for us is a major, major improvement.

And, finally, the system is driven by a low energy electrostatic accelerator. I say low energy, that's about 300 kilovolts, 300 kilo electron volts beam energy. And if you were to compare that to a cyclotron that would be found in a pharmacy today that makes isotopes such as fluorine-18, those are on the order of 10 MeV, Mega Electron Volts, so it's much lower, much simpler accelerator that we're using to drive this target. And that also allows us to operate below criticality.

Some liquid reactors have been operated in the past and they operate at criticality with control rods. We've chosen for a number of reasons to eliminate criticality altogether and use this accelerator system to drive the liquid target. And that gives us, again, substantially less waste by eliminating the need for a reactor as the primary neutron source. It is also proven, demonstrated, and fairly cost-effective technology that actually people can come and see if they'd like. It's in our lab.

So, I guess that concludes my presentation. I'm going to turn the rest of the overview over to Jim Costedio.

MR. COSTEDIO: Good morning. Next slide, please.

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. If you look at the map, the area outlined in red on the southern boundary is Rock County. Next slide, please.

The SHINE facility layout consists of an irradiation facility or the IF, and a radioisotope production facility, or the RPF. The area outlined in blue is the irradiation facility which houses the irradiation units, and the area outlined in red is the radioisotope production facility which houses the hot cells. The facility is relatively small compared to the size of the parcel. It's a 91-acre parcel, and the facility is about 55,000 square feet centered approximately in the middle of the parcel. Next slide, please.

The SHINE IF consists of eight subcritical irradiation units which are comparable in thermal power level and safety considerations to existing non-power reactors licensed under 10 CFR Part 50. However, due to the subcriticality, the irradiation units did not meet the existing definition of utilization facility in 10 CFR 50.2. To align the licensing process with the potential hazards, the NRC issued a direct final rule modifying 10 CFR 50.2 definition of utilization facility to include the SHINE irradiation units. An irradiation unit consists of a subcritical assembly, a neutron driver and supporting systems. Next slide, please.

The radioisotope production facility is a portion of the SHINE facility used for preparing target solution, extracting, purifying, and packaging moly-99, and the recycling and cleaning of target solution. Based on the batch size of greater than 100 grams, the RPF meets the definition of a production facility as defined in 10 CFR 50.2. Next slide, please.

SHINE submitted a construction permit application in two parts pursuant to an exemption from 10 CFR 2.101. Part one of the application was submitted on March 26, 2013 which included PSAR Chapter 2 on site characteristics, PSAR Chapter 19 for the environmental review, and general and financial information. Part two of the application was submitted May 31st, 2013 which provided the remaining PSAR chapters. And then a discussion of preliminary plans for coping with emergencies in accordance with 10 CFR 50.34(a)(10) was provided September 25th, 2013. The SHINE facility will be licensed under 10 CFR Part 50, Domestic Licensing of Production and Utilization Facilities. Next slide, please.

SHINE used for regulatory guidance and acceptance criteria, SHINE used NUREG-1537 guidelines for preparing and reviewing applications for licensing of non-power reactors, and the Interim Staff Guidance augmenting NUREG-1537 Parts 1 and 2. The ISG incorporated relevant guidance from NUREG-1520, a Standard Review Plan for the review of a license application for a fuel cycle facility. SHINE also used additional guidance such as regulatory guides and ANSI Standards in developing the application.

That ends my presentation. I'll now turn it over to Eric Van Abel to discuss the SHINE technology.

MR. VAN ABEL: Next slide, please.

Good morning. I want to give a brief overview of the process and technology that SHINE plans on using. In this slide, as Jim showed there, there's two main areas of the production facility building. There's an irradiation facility, an IF, and a radioisotope production facility, an RPF. I'm going to go through the processes in these two areas in the next few slides. Next slide, please.

Here's a general schematic of the overall SHINE process overview. Just to orient you relative to the last figure, the TSV and Irradiation Unit Cell in the left there is part of the irradiation facility, and the other components on this diagram are all part of the RPF.

So, we begin our process in the bottom there at the target solution preparation step. In that process we dissolve uranium in sulfuric acid and produce what we call target solution. That target solution is then moved to a hold tank which is number 2 on the figure there. There's one of these hold tanks for each of our eight irradiation units so there's eight hold tanks. Those hold tanks are staging areas prior to the irradiation cycle, so in that hold tank we'll measure the uranium concentration, the pH to insure that the parameters are correct to begin the irradiation cycle. And then once we're ready to begin we'll start pumping that solution over to the TSV in discrete batches. We'll fill up the TSV to the proper level and then once the TSV is at the proper level we begin the irradiation process by energizing the neutron driver which is our accelerator that Greg mentioned.

That accelerator runs for approximately five and a half days. We irradiate the solution, produce medical isotopes of interest in the solution, and then we -- once we're done with the irradiation process we drain that solution to a dump tank located right in the irradiation unit cell.

The solution is held there for a short period to decay, and then once we're ready to process it we transfer it over to the super cell, which is number 4 on the figure there. The super cell is just a larger hot cell that has several processes inside a single hot cell. And the first part of that process is the extraction process. And that's where we actually separate out the moly-99 from the other isotopes in the solution.

And then most of the time the uranium solution just goes right on to the recycle tank which is number 5 in the figure. And there it's just recycled back into the process and it goes in a loop. It goes to another hold tank, to another irradiation cycle.

Occasionally, we also send it to the UREX process which is item 6 in the figure there. And that's where we periodically clean up the solution, we remove the uranium from the other fission products using solvent extraction technology UREX, and we recover the uranium and recycle that back into the process. So, we just send that back to the target solution preparation steps and recreate target solution again. Next slide, please.

In the irradiation facility, SHINE has a system that couples fusion and fission technology, so we have an accelerator that's fusion-based, deuterium-tritium fusion-based accelerator coupled to a fission-based subcritical assembly. The little diagram on the right there shows a schematic of that process. In the accelerator we accelerate deuterium ions into a tritium gas target. That results in the production of fusion neutrons, 14 MeV fusion neutrons. Those neutrons then pass through a component we call the neutron multiplier. In that multiplier the yield of neutrons is increased and then the neutrons are transferred into the target solution. The target solution is where the uranium is actually located.

In the target solution there's subcritical multiplication so the fission occurs, it causes more fission but in a subcritical process. And then that fission yields the radioisotopes of interest directly in the solution for ready extraction from the solution.

There are additional supporting systems including a light water pool system. The entire system is located in a pool similar to a research reactor. The target solution vessel off gas system, as I'll mention in a few slides here, manages the gas products from the fission process. The primary closed loop cooling systems cools the TSV during the irradiation process, and there's a tritium purification system that supplies clean gases to the accelerator for the irradiation.

It's important to note that this process is done at essentially atmospheric pressure. It's a low temperature, low pressure process. These aren't highly pressurized, high temperature systems like a power reactor would be. The target solution at the end of the irradiation cycle is simply drained to a dump tank, as I mentioned, right in the irradiation unit so that's a passively cooled, safe-by-geometry tank to store the solution. And that's drained through redundant fail-open dump valves.

The TSV itself is just an annular, a simple annular vessel constructed of Zircaloy, a widely used alloy in the nuclear industry. And there's no pumping of the solution while irradiating it. It's just naturally convected inside of the vessel. Next slide, please.

This slide shows just a rendering of the subcritical assembly. The outer vessel in the center there is the subcritical assembly support structure, the SASS. This is a secondary vessel that surrounds the TSV. The TSV is internal to that along with the neutron multiplier. SASS is just there in case there's a leak in the TSV, that solution would be contained inside of that. The dump tank is located directly below it there, and there are dump and overflow lines from the TSV to the dump tank to connect it. Next slide, please.

So we were just looking at the components in red on this figure. Directly above that is the accelerator. The accelerator sits on a grating above the pool and the accelerator is in yellow in this picture. It's an electrostatic accelerator, a simple accelerator technology. As Greg pointed out before, it generates fusion neutrons from DT fusion that drive the fission process. When we shut down the accelerator, the fission process terminates because the subcritical assembly is never at critical.

The tritium purification system is not shown in this figure, but it's also in the irradiation facility. And that system separates gases from the accelerator, so the accelerator as it's operating, it's mixing deuterium and tritium together. The tritium purification system separates those back apart and resupplies the purified tritium back to the accelerator for continued operation. And the tritium lines for that system and the processing equipment are in glove boxes and double-walled pipe. Next slide, please.

The TSV off-gas system is shown in green on the figure here. That system is directly adjacent to the irradiation unit cells. That system contains the fission product gases that are generated in the TSV during irradiation. It removes iodine from the gas stream, and also its major function is to recombine hydrogen and oxygen. So as we irradiate the solution, radiolysis of the water generates hydrogen and oxygen, and this system sweeps sweep gas air over the target solution vessel to dilute the hydrogen and send it to a recombiner, and then recombine the water and return that water back to the TSV, so it's just a closed loop.

The subcritical assembly, as I mentioned before, is immersed in a light water pool. That pool provides significant radiation shielding and decay heat removal. Next slide.

For the irradiation process, when we're ready to begin the irradiation we measure the relevant parameters of the target solution, such as uranium concentration, pH, any other chemical parameters that we need to determine, and then we begin moving the solution in discrete batches over into the target solution vessel. We measure the count rate at each step there and from that we can do the 1/M process that's used in reactors all over the world to predict the critical state of the assembly. And the difference with us is that we increase volume, we predict where the critical state is, and we never go there. We stop 5 percent by volume below critical. And that's our highest reactivity point for the system.

And during that process there are automatic safety systems that are monitoring and will initiate a shutdown on high neutron flux or primary coolant temperature should the operators not stop the system before that. And that would prevent a criticality. Next slide, please.

Once we begin the irradiation process we isolate that batch of uranium solution in the TSV so it's a fixed target, fixed batch of solution. We close the fill valves, the redundant fill valves and isolate the fill pump from the system. We energize the accelerator, and then we begin slowly supplying tritium to the accelerator and that causes the output of the accelerator to gradually increase, and that increase in the neutron output of the accelerator results in increased fission power in the TSV. That fission power results in increased temperature and void fraction in the TSV which the system has very strong inherent negative feedback coefficients so the increase in temperature and void fraction causes reactivity to drop significantly in the system. And we don't do anything to compensate for the reactivity drop. We let the system drive further subcritical.

We do this for approximately five and a half days, and then following shutdown we drain the solution into that dump tank where it's passively cooled. Normally, we're maintaining the temperature of that pool but should we lose offsite power or active cooling for any reason of the pool, there's sufficient heat capacity in the pool for a temperature rise of only 12 degrees after 90 days without cooling, so it's a large body of water. There's very little decay heat because this is such a small system. Next slide, please.

In the radioisotope production facility once we're ready we transfer that solution over to the RPF and there we extract the moly-99. We have a purification process that it then goes to. This is the LEU modified Cintichem process where it's a laboratory scale glassware process that's done in the hot cell just to purify the product. And then we package it and get it ready for shipment to customers.

In the RPF there's also a noble gas removal system, the NGRS. This system collects those off gases from the TSV off gas systems, the eight TSV off gas systems, stores them, holds them for decay for 40 days prior to sampling, and then a filtered monitored discharge to our process vessel vent system.

Also in the RPF is the processes for recycling and cleaning the target solution, the UREX process. That's, as I mentioned before, a solvent extraction process that separates the fission products and plutonium from the uranium. The uranium is recovered for reuse in the process. Next slide, please.

In the SHINE facility we used engineered safety features to protect public health and safety, and these are principally confinement. It's important to note that our inventory in any one of these confinement areas is approximately 10,000 times less than the radionuclide inventory in a power reactor, so they're much lower inventory which reduces the risk. And also these are low temperature, low pressure processes so there's not a lot of stored energy to encourage dispersal, so there's lower dispersion forces which, of course, reduces releases.

The confinement functions themselves are provided by the biological shielding. There's -- over most of the processes there's thick reinforced concrete biological shielding, usually several feet thick concrete. Isolation valves on the piping systems, ventilation systems play an important role in the confinement features. As shown in the figure on the right there, that shows you some of our cascaded ventilation zones. From Zone 1 to Zone 4 there's a pressure gradient with Zone 1 being at the lowest pressure, so any potential contamination is reduced outside of those areas in Zone 1 where radiological materials are normally stored. And in any accident scenario, those areas in red on the figure there are the areas where isolation would principally occur and contain that material should an accident occur. And also, of course, instrumentation and control systems that actuate the confinement features. Next slide, please.

So as described in SHINE's PSAR, we have a preliminary design that shows that we can construct this facility to meet the applicable regulatory requirements. We've identified robust engineered and administrative controls to ensure that we can protect public health and safety, the environment, and our workers, and that we are certainly designing this plant with safety as our primary criterion. And that concludes my presentation.

CHAIRMAN BURNS: Does that conclude the presentations?

MR. PIEFER: It does.

CHAIRMAN BURNS: Okay, thank you. Starting, we'll have Commissioner questions now. We'll start -- I'll start off this round of questioning.

Just to make sure I understand the design facility laid out, each of these individual -- the eight TSVs, these are essentially independent. Correct?

MR. VAN ABEL: Yes. Yes, they can be operated independently run. We can run anywhere from zero to eight of them.

CHAIRMAN BURNS: Okay. So, there's no real interconnection between them.

MR. VAN ABEL: There are some shared systems, like the ventilation system is common to them. There's a common chilled water system that's supplying chilled water to the heat exchangers.

CHAIRMAN BURNS: Okay.

MR. VAN ABEL: But the individual primary cooling systems are unique for each one.

CHAIRMAN BURNS: Okay, thank you.

A couple of questions. Could you give me an idea of what level of public engagement you had in terms of the site selection process for the facility, and the type of feedback you got from that? I guess, Mr. Piefer, that might be for you.

MR. PIEFER: Yes. I actually would like to call Katrina Pitas to the witness stand.

CHAIRMAN BURNS: Okay.

MR. PIEFER: She's got that pretty thoroughly. Are you ready?

MS. PITAS: I think so.

MR. PIEFER: Okay.

CHAIRMAN BURNS: Well, come -- Ms. Pitas, come up to the podium here. And what I'd ask you to do, and just for other witnesses, when you come up identify yourself, your position. And I remind you you're -- and I presume you took the oath. Yes, I saw you take the oath, and you remain under oath.

MS. PITAS: Thank you.

CHAIRMAN BURNS: So, thanks.

MS. PITAS: So, my name is Katrina Pitas. I'm the Vice President of Business Development for SHINE.

Our site selection process involved 11 criteria which I'd be happy to go through, but in terms of public involvement, the individual community governments that we were working with during the later stages of our site selection process were very -- we had a very good relationship with all three of the sites that we considered, the specific sites that we considered. And then once we chose Janesville, that relationship has continued to grow, and we believe we have a very good relationship with that community. And I'd be happy to go into some of the actions we've taken to ensure a good relationship with the community, if you'd like.

CHAIRMAN BURNS: Well, I just -- yes, briefly.

MS. PITAS: Sure. So, once we chose Janesville, we set up twice yearly public meetings that were open to the entire community. They were just informational sessions where Greg would give a presentation on our progress, the type of facility, and what the company was aiming to do in the community. And then we also have recently started giving twice yearly updates to the city council which are open sessions, so that makes a total of four times a year we meet directly with the community. It's open to anyone to ask whatever questions they have, voice concerns. And the result of that has been truly -- a relationship based on mutual respect and trust. So, it's been very positive.

CHAIRMAN BURNS: Thank you very much.

The other question I have goes to the nature of what the application is for, which is a construction permit. As I noted earlier, more recently the Commission has been -- has held hearings on Combined Licenses which is by intention a more comprehensive review, maybe not more comprehensive but it's a broader scope of review because it is actually the construction permit and the ultimate operating license combined.

With a construction permit there are important design parameters that have to be met, requirements that have to be met. But as with the current generation of operating plants in the U.S., going through the construction permit process allows some completion of certain design features, updating all that.

Could you give me sort of a feel of, if a construction permit is issued, what are, in effect, the things you would see that need to be worked on from a design perspective before we come to the next phase, which would be the operating license? What are the things that are still, in a sense, open? And I don't mean open in a negative way, but it's the idea that the Applicant may have some design issues that it needs to address and to resolve prior to a final determination on operating license.

MR. HENNESSY: I'll take this one. This is Bill Hennessy, the Engineering Manager.

The state of our design right now is a

preliminary design where we've outlined the principal design features and the technology that we're going to use. So, the next phase of design will be to go into detailed design where we'll actually work through the details, the many, many details that are needed to get to the construction stage. So, there aren't any real, other than the research and development which we've outlined separately, there aren't any real issues that we need to do other than just the hard work of engineering that's required to move on.

CHAIRMAN BURNS: Okay. So, you're not -- there aren't what I'll call big gaps, any particularly big gaps in terms of sort of filling in. It's primarily the engineering work, getting the design from paper to the actual facility and all that.

MR. HENNESSY: Yes, that's correct.

CHAIRMAN BURNS: Okay, thank you. Thank you very much. Commissioner Svinicki.

COMMISSIONER SVINICKI: Good morning and welcome to all of the SHINE witnesses, the Applicant witnesses that are here today and others who have participated in this very complex undertaking.

As a former resident of Dane County, it was a long time ago, I'm familiar with the general geographic and demographic area that you're talking about. This is a significant new facility and capability for that kind of a more agricultural and rural area. I appreciate that you have done a lot of community education and awareness of this activity. I might suggest to you that if the construction permit is issued and large-scale construction activities start taking place, I think you might have to cover some of the same territory because that's when the community really becomes engaged and very interested when they start noticing all of that activity. And then they will -- a number of them I'm sure will begin their inquiry into exactly what you're doing there. So, it's good that you've got the structure in place to begin to educate and communicate with people about what it is that you are undertaking.

I note also, this is an overview panel so I'm going to ask some questions that may or may not have a direct relevance to the findings that the Commission will make in order to make a decision on authorizing the construction permit per se.

You provided in your overview presentation some NEA statistics on the projected growth in the use of the product that would come out of the SHINE facility. I don't believe, though, that those projections give any indication of the great swaths of the globe where people are medically under-served and so it doesn't really capture upon the demonstration of a new technology that doesn't use HEU the potential long term maybe to have more penetration of these types of diagnostic techniques where arguably in medically under-served areas of the globe they could do even greater good than they do in areas that have access to a lot of alternatives, or perhaps more invasive procedures.

So, it is interesting that there is a large public good that comes out of constructing a facility like this. Of course, that cannot have a direct bearing on a safety determination. The facility, you know, either is or isn't going to be safely operated, so we have to set that aside. But in my preparation for the mandatory hearing today on the construction permit I couldn't help but think that if any of the SHINE witnesses are fans of Monty Python, it's the opportunity to say "And now for something completely different." So, the Chairman has made reference to the fact that we've been looking a lot at power reactor mandatory hearings, so this was a chance to wrap our minds around something that is very different.

It's commendable for the NRC Staff, and I'll make this point in their overview presentation. They've used what I call an adaptive process, meaning there was no part of the Code of Federal Regulations that SHINE or the NRC Staff could turn to and say oh, for this type of medical isotope production, here is the regulatory framework. So, as you look forward there are elements of your design that are not complete, there is a research and development program and plans that you have to close on technical uncertainties that the NRC Staff has, of course, reviewed. And that is part of their finding is to see that you have plans and programs in place to complete and answer questions about areas of technical uncertainty.

But would SHINE assess -- as the Applicant, do you assess that this adaptive process, a kind of going to things, guidance, regulations that we have in place, deciding which portions of those standing procedures and regulations were or were not relevant to the technology you were proposing, and then applying that and going through a Request for Additional Information process? Would you say that you found that process workable to get through this construction permit stage? And what would you offer in terms of your confidence in continuing to pursue that kind of adaptive process at the operating license stage? And embedded in that, could you address what percent of design do you think you are complete, if you had to put a number on it?

MR. PIEFER: So, I think the answer is yes, and I'm going to turn it over to Jim to do a little bit more comments on the process.

MR. COSTEDIO: I think the process is very workable. All the way through we've met several times with the Staff, we've had public meetings to work through some of the issues, you know, you talked about that the code doesn't specifically in all cases clearly, I mean, address us, but we were able to work through that during the public meetings with the Staff.

COMMISSIONER SVINICKI: Do you see it basically carrying forward into the -- if the construction permit is issued, do you see this same process basically carrying forward in the same form to the operating license phase?

MR. COSTEDIO: Absolutely.

COMMISSIONER SVINICKI: Okay. And would you say then that in terms of uncertainties for you going forward, you do have certain proof of concept and technical issues that you have plans in place to close on. There's also regulatory uncertainty that exists at some level. Would you say regulatory uncertainty or technical and proof of concept uncertainty, which of those would dominate the uncertainty going forward for you, or perhaps it's financial?

MR. COSTEDIO: I would think the regulatory uncertainty.

MR. PIEFER: Yes, of those two, I would agree. I think the -- we've done enough technology demonstrations at this point, including a recent demo where General Electric made injectable drugs out of our process, and they looked beautiful. So, we feel pretty confident in the technology at this point. There's a few things outstanding in terms of longevity of the plant, et cetera, that are being worked on as we go forward; corrosion studies, for example, that we're going to be interested in finding out the data there. But, you know, timeline and financing, you know, you mentioned financing uncertainty. Those two are tied hand and hand, and so that's another thing, we're in a hurry. We've got to do it right, but obviously given the exit of the reactors we'd like to move as quickly as possible. And up until now, you know, we've been able to move this project forward in a largely serial fashion, which is eliminate risks, perceived risks from investors, and then move forward and get the next slug of money.

COMMISSIONER SVINICKI: Can I ask on that point, the draft construction permit, or the construction permit if issued includes a date by which construction would complete. Do you have a notional time frame by which you anticipate beginning construction? In a non-proprietary basis, is that something you could share in this open meeting?

MR. PIEFER: Yes, I think so. I mean, what does the schedule currently say?

MR. COSTEDIO: Spring of 2017.

MR. PIEFER: Spring of 2017.

MR. COSTEDIO: And we would follow with the OL application about three months later.

COMMISSIONER SVINICKI: Okay. And then the last question I had was, I'm not familiar, though, with the airport facility that would be your nearest facility. Is that a cargo hub, or is it -- what size of aircraft -- how active is that facility? Would you have dedicated flights out of there?

MR. HENNESSY: We might have dedicated flights out of there. That's certainly one thing we're considering, using a carrier that would provide service from that area.

COMMISSIONER SVINICKI: Is the airport facility currently adequately sized for your projected needs, or are there upgrades to the airport itself?

MR. HENNESSY: It would be sized for our needs, yes.

COMMISSIONER SVINICKI: Okay.

MR. PIEFER: It's not used for much other than recreational flying.

COMMISSIONER SVINICKI: I was surprised, frankly, again it was a long time ago, but having lived in an adjacent county, I was surprised that there even was an air facility there. I didn't recall that. Okay, thank you for that. Thank you, Mr. Chairman.

CHAIRMAN BURNS: Thank you, Commissioner. Commissioner Ostendorff.

COMMISSIONER OSTENDORFF: Thank you, Chairman. Thank you all for your presentations this morning.

I appreciate that my colleagues have already highlighted that this is a very different type of hearing than we've had under our Part 52 hearings, so having that philosophical mind set change by your comments was very helpful there, Chairman and Commissioner Svinicki.

I guess this is a question. I think that Commissioner Svinicki may have asked this, I may have missed the answer, but a question that came up about the overall characterization of design completion. What can you say about that?

MR. HENNESSY: I'll take that question. We debate this amongst ourselves quite a bit, as you can imagine. The characterization of design complete is variable depending on the systems you're looking at. Some systems are pretty far along like our tritium purification system, and others are still back at conceptual. Where those systems we know we can fill in quickly with, design what we need to, like HVAC. So, overall, I would say the percent design complete is around 15 percent, which I believe is appropriate for being able to say that we've completed preliminary design.

COMMISSIONER OSTENDORFF: Okay. So, let me just stay with you there for a minute on the design piece. I appreciate there's first-of-a-kind engineering issues here, there's some things that have not been attempted before. What are the top two or three areas, sub-components, is it the TSV, is it the hot super cell? I'm curious as to where do you see the most difficult challenges ahead on the design completion?

MR. HENNESSY: We have prototypes built in our lab in Monona, and we're continuing to evolve the TSV design, and the TOGS design, and doing testing on components. And I think that's going on pretty well. I think Eric can comment on that some more.

COMMISSIONER OSTENDORFF: As you answer this question, can you please maybe give a little more detail on what you have in the form of prototype, mockups, or simulations?

MR. HENNESSY: Sure. I'll turn that over to Eric.

MR. VAN ABEL: Yes. We have -- each of these components in that overall process diagram, each of those components has been demonstrated individually either by SHINE, by Phoenix Nuclear Laboratories who's the accelerator provider, or by the National Laboratories. You know, the TSV off-gas system, the one that recombines the hydrogen, that system we have a full-scale prototype in our facility in Monona where we've demonstrated full-scale hydrogen recombination testing flow rates, droplet pickup, various things of engineering interest. We have a tritium purification system prototype in our Monona facility constructed by Savannah River National Lab. We have an accelerator in the Monona facility that we share with Phoenix Nuclear Labs that's demonstrated the full production scale accelerator technology. The TSV, we have a mockup TSV. We can't, obviously, put uranium solution in it, but we have a mockup TSV demonstrating -- that's connected to the TOGS system to demonstrate that that system combined performance. And then Argonne National Laboratory is doing experiments on the extraction and purification of our solution, so they've irradiated what they call a mini-SHINE experiment, which is essentially a system very similar to ours from a chemical standpoint of uranyl sulfate solution irradiated by an accelerator. They process it through our same extraction technologies, our same purification technologies that we plan to use. And as Greg mentioned before, they've shipped product to one of our expected customers and demonstrated that it met the purity specifications that we plan to meet.

COMMISSIONER OSTENDORFF: If you had to draw a comparison between your preliminary design for the SHINE facility and some existing facilities, irrespective of location, are there a couple of facilities that you think you've borrowed from -- I'm not talking about from an intellectual property standpoint, but just as far as known processes or procedures? I'm trying to figure out what's the analogy, if there are any analogies, as to what other existing facilities might be somewhat comparable in some aspects to yours?

MR. VAN ABEL: Yes. So, for the TSV, this is a subcritical assembly, it doesn't go critical, but it shares a lot of the physics and thermal-hydraulic characteristics of aqueous homogenous reactors, AHRs.

Those have been built and tested at several facilities. The SUPO reactor at Los Alamos National Lab is one we use a lot for validation. SILENE reactor, the homogenous reactor experiment done at Oak Ridge, HRE reactor. All these facilities we are using their operational history, transient analysis from them to validate our codes to ensure that our codes adequately predict the TSV behavior. Working with Los Alamos National Lab on that, so we borrowed, essentially, how they ran their facilities and operated those AHRs really to feed the design of the TSV.

The accelerator, as we mentioned, we have a full-scale prototype of that accelerator already. And the LEU modified Cintichem process that we use for purification, that's based -- that originated at the Cintichem facility, which is an NRC -- previously NRC-licensed facility that produced moly-99 for commercial sale. There they used a typical solid fuel reactor to irradiate solid targets, but then they dissolved them, and processed them, and purified them similar to our technology, so we've looked at that Cintichem facility and use that technology in our facility, as well, for the processing side.

COMMISSIONER OSTENDORFF: Thank you. That was very helpful. Thank you, Chairman.

CHAIRMAN BURNS: Thank you, Commissioner. Commissioner Baran.

COMMISSIONER BARAN: Welcome. Thanks for being here, and for your presentations.

Following up on this distinction between the construction permit application and the operating license application, I'm interested in hearing a little bit about how you decided what level of information to include in the construction permit application. When drafting the application, how did you weigh the benefits of having more issues reviewed by the Staff early in the process against having more flexibility during construction, if you were to receive a construction permit?

MR. COSTEDIO: Well, we provided the principal design criteria, and the design basis of the structure, systems, and components. From that we were able to do our accident analysis, and the results of the accident analysis shows we're within regulatory limits, within the Part 20 limits. Our definition of safety-related implements those requirements on 10 CFR 20 and Part 70.61 for the performance requirements. So, you know, we believe that we've provided the necessary information to obtain the construction permit.

COMMISSIONER BARAN: In the final ACRS

letter to the Commission, the ACRS raised seven topics to be further addressed in the application for an operating license. Pre-hearing Question 4, explored this issue, and your response indicated that these topics are not included as commitments in Appendix A of the Safety Evaluation Report. How will SHINE ensure that the ACRS topics will be addressed at the operating license stage?

MR. COSTEDIO: All of those topics are included -- we issue what we call Issue Management Reports, which are contained in our Corrective Action Program. And every one of them is being tracked to be included in the operating license application.

COMMISSIONER BARAN: Okay, thank you.

Although the SHINE facility is not a reactor, part of the licensing basis for the construction permit utilizes design principles from the general design criteria for nuclear power plants. Can you clarify the process you used to determine which general design criteria are applicable to the SHINE facility?

MR. HENNESSY: We reviewed all of the general design criteria as outlined in our PSAR when we were looking at the preliminary design, and the PSAR also contains a description of how each of those GDC would apply to SHINE, or how it's integrated into our design, so we actually reviewed all of them.

COMMISSIONER BARAN: Okay. So, you went through them all systematically and assessed whether each one would apply in concept at least to this facility.

MR. HENNESSY: Yes.

COMMISSIONER BARAN: Okay, thank you. Thank you, Mr. Chairman.

CHAIRMAN BURNS: Thank you, Commissioner.

I want to thank the Applicant's panel for their presentations. We'll now proceed with the Overview Panel from the NRC Staff. I'll ask the witnesses please come forward, yes.

Okay. Again, this will be the Overview Panel, or an overview from the Staff Panel with respect to the application. I'm going to remind the witnesses you're under oath, and did you all take the oath?

WITNESSES: Yes, sir.

CHAIRMAN BURNS: Okay. And, again, assume that the Commission is familiar, generally familiar with the pre-hearing filings from the Staff and the Applicant. And I will ask the panelists to introduce themselves. Ms. Gavrilas.

MS. GAVRILAS: Mirela Gavrilas, Division of

Policy and Rulemaking in NRR.

MS. MARSHALL: Jane Marshall. I'm the Deputy Director for the Division of License Renewal in NRR.

MR. DEAN: Bill Dean, Director of Office of Nuclear Reactor Regulation.

MS. BAILEY: Marissa Bailey. I'm the Director for the Division of Fuel Cycle Safety Safeguards and Environmental Review in NMSS.

CHAIRMAN BURNS: Okay, thank you. And let the Staff proceed.

MR. DEAN: Okay. Good morning, Chairman, Commissioners. We're pleased to be here with you this morning to provide testimony associated with the application for a construction permit submitted by SHINE Medical Technologies for a medical radioisotope irradiation and production facility.

What you'll hear from this panel is an overview of the Staff's review methodology, as well as highlighting some of the technical and environmental review aspects of it. Essentially, we'll be setting the stage for the panels that you'll have later today on both the technical and environmental aspects of the review. Could I have the next slide, please.

So, I'm not going to spend much time on this slide. I think the SHINE representatives did a very good job in terms of setting the stage for the importance of moly-99 production, benefits of the technetium-99 metastable as an important radioisotope for medical diagnostic procedures. I think they also set the stage in terms of how much this radioisotope is used in both the United States and globally, so I think they set a pretty good stage for why it's important that we pursue domestic supply, particularly with the Canadian facility scheduled to shut down in 2018, as well as the challenges that have existed at some of the foreign facilities with interruptions in supply because of extensive shutdowns for maintenance activities and so on. So, I think we have a pretty good case for why it's important domestically that we have a moly-99 production facility. Next slide, please.

So, national policy objectives which support domestic production capabilities really have three major components to them. One is to assure that we have a reliable source of moly-99 production. Secondly, that it's not utilizing highly enriched uranium in producing the moly-99, as well as no market subsidies. Those are three aspects of the national objectives associated with moly-99 production domestically.

We have -- DOE's National Security

Administration has engaged in cost-sharing agreements with various organizations, and SHINE Medical Technologies is one of those in terms of helping to develop moly-99 production capability. As the SHINE representatives noted, they plan on utilizing a uranium fission process utilizing low enriched uranium in an aqueous homogeneous reactor, and then chemically separating the moly-99 in a radioisotope production facility.

I think the important thing here is that from a Staff perspective, our review is consistent with the national policy, and conforms with the Atomic Energy Act, and all the applicable regulations. Next slide, please.

We've been preparing for the SHINE review, and actually review of any medical radioisotope facility for some time. Back in 2009, we formed an interoffice working group that contributed substantial technical and regulatory diversity and expertise in terms of developing approaches that we would consider if and when we got a production facility application.

Back in 2012, we created a Interim Staff Guidance document that was specifically focused on aqueous homogeneous reactors to support and supplement the SRP or the Standard Review Plan for research and test reactors. And this is the products that the SHINE facilities have utilized in terms of developing their construction application.

We've had a number of public meetings with engaged stakeholders. This includes, obviously, the SHINE management and staff, public individuals, as well as federal, state, and local governments. These meetings have been focused on the technical, the regulatory, and the environmental review aspects of the SHINE facility. We also have coordinated our review with federal, state, and local governments. So, for example, NNSA from DOE has been involved, the Environmental Protection Agency, the National Fish and Wildlife Foundation, and the Advisory Council on Historical Preservation. And at the state and local levels, the State of Wisconsin Department of Health Services, and the Janesville City Council has been significantly involved with us in terms of some of the review aspects. Next slide, please.

So, at this point I'd like to turn it over to Mirela who will discuss the Staff's review of the SHINE construction permit.

MS. GAVRILAS: Thank you, Bill.

In 2013, SHINE submitted a two-part application for a construction permit under 10 CFR Part

50. If granted, the permit will allow SHINE to construct a medical radioisotope production facility in Janesville, Wisconsin. SHINE's application only seeks authorization to construct the proposed SHINE facility; therefore, the 10 CFR Part 50 regulations require less detail than for an operating license or a Combined License application.

The necessary elements of a construction permit application are provided in Section 50.34 and include a preliminary design of the facility, a preliminary analysis of structures, systems, and components, probable subjects of technical specifications, a preliminary emergency plan, a quality assurance program, and ongoing research and development.

SHINE will submit the Final Safety Analysis Report, or FSAR, with their operating license. The FSAR will include SHINE's final design, plans for operation, emergency plan, technical specification, and physical security plan. Next slide, please.

The Staff's evaluation of SHINE's construction permit application consisted of two concurrent reviews. One, of SHINE's Preliminary Safety Analysis Report, or PSAR, and the other of SHINE's environmental report. I will discuss the Staff's safety review, and Jane Marshall will discuss the Staff's environmental review.

The Staff's safety review assessed the sufficiency of the preliminary design. This includes the principal design criteria and the design basis of SHINE's proposed medical radioisotope facility. The SHINE facility consists of an irradiation facility, or IF, and a Radioisotope Production Facility, or RPF. Next slide, please.

From the Staff's perspective, SHINE's irradiation facility and radioisotope production facility rely on novel and unique technology. Therefore, the Staff tailored its activities and coordinated with offices throughout the Agency to ensure an informed and efficient review.

SHINE's irradiation facility consists of eight subcritical operating assemblies or irradiation units. Each irradiation unit is a 10 CFR Part 50 utilization facility. While not reactors, irradiation units are similar to research reactors.

SHINE's proposed radioisotope production facility consists of three super cells for the separation of molybdenum-99 from irradiated target solution. The RFP is a 10 CFR Part 50 production facility. However, the RFP has physical and chemical processes similar to existing fuel cycle facilities. For both the irradiation facility and the radioisotope production facility, the Staff used the Commission's regulations and existing guidance to determine acceptance criteria that demonstrate compliance with regulatory requirements.

The Staff's safety evaluation for both the irradiation facility and the radioisotope production facility was informed primarily by NUREG-1537 which is the Standard Review Plan for research and test reactors. The Staff augmented NUREG-1537 with Interim Staff Guidance or ISG for evaluating aqueous homogenous systems and production facilities. The Staff also assessed the preliminary design to have reasonable assurance that SHINE's final design will conform to the design basis. Next slide, please.

An important part of the Staff's review was to determine what additional technical and design information beyond SHINE's initial PSAR was necessary to support the evaluation of the construction permit application. The Staff issued Requests for Additional Information and SHINE supplemented its application.

After reviewing the application as supplemented, the Staff found that SHINE provided all the information necessary for the Staff to complete its safety review for the purposes of issuing a construction permit. However, the Staff identified certain areas where additional information is required before construction is complete. The Staff is, thus, recommending construction permit conditions.

The conditions require SHINE to provide periodic updates on the design of certain features related to criticality safety and radiation protection. These updates are consistent with 10 CFR 50.35. They are intended to confirm that SHINE's final design will conform to the PSAR design basis. For example, SHINE has proposed a criticality alarm system in the radioisotope production facility. A shielding wall will surround the criticality alarm system. The Staff believes that before construction is complete, SHINE must establish the appropriate shielding wall thickness because if the shielding is too thick, the alarm system will not perform as required. If the shielding is too thin, radiation protection will become a concern.

In instances where additional information may reasonably be left for later consideration, SHINE has made commitments to provide such information in the FSAR. These commitments are listed in Appendix A of the Safety Evaluation Report, or SER. The Staff will verify that necessary information has been provided during the review of SHINE's operating license application.

The Staff's SER also initially proposed conditions related to the Preliminary Amendment Request process. However, as noted in our answers to pre-hearing questions, the Staff has determined that this process is better suited for construction based on a final facility design. As such, the Staff no longer recommends these conditions. The Staff finds that the existing regulations in 10 CFR 50 are sufficient to accommodate changes to the SHINE facility as the design matures. Next slide, please.

I will now turn over the presentation to Jane Marshall for an overview of the SHINE environmental review.

MS. MARSHALL: Thank you, Mirela.

The environmental review for the SHINE construction permit application was performed in accordance with the National Environmental Policy Act of 1969, commonly referred to as NEPA. NEPA established a national policy for considering environmental impacts and requires federal agencies to follow a systematic approach in evaluating potential impacts, and to assess alternatives to the proposed action. The NEPA process also involves public participation and public disclosure.

10 CFR Part 51 contains NRC's environmental regulations which implement NEPA. These regulations describe when the Staff should prepare an Environmental Impact Statement or EIS. The NRC's regulations did not require the preparation of an EIS for SHINE's application; however, the Staff determined that an EIS would be appropriate because SHINE is a first-of-a-kind application for medical radioisotope production facility with a unique application of technologies and an EIS would allow several opportunities for public involvement in the environmental review process.

Ultimately, the purpose of the environmental review is to identify the environmental impacts of constructing, operating, and decommissioning the proposed SHINE facility, as well as alternatives to the SHINE facility, and in combination with the safety review, inform the Staff's recommendation to the Commission whether or not to issue the construction permit. Next slide, please.

The Staff began the environmental review with a scoping process to gather input from the public, other government agencies, and tribes on the necessary scope for the EIS. The Staff conducted an Environmental Site Audit to view the environmental features at the proposed site and the alternative sites, and met with

SHINE's technical specialists that developed the environmental report. The Staff also developed Requests for Additional Information to clarify aspects of SHINE's environmental report and to seek additional information not included in SHINE's environmental report.

The Staff developed a Draft EIS based on the Staff's independent review, information in the environmental report, answers to the Staff's Request for Additional Information, and input received during the scoping process and Environmental Site Audit. The Draft EIS was published for comment in May of 2015. The Staff responded to all comments received in the Final EIS which was published in October 2015. The Staff also updated the Final EIS based on in-scope comments and newly available information. Next slide, please.

The proposed site is currently an agricultural field which has been previously disturbed from decades of agricultural activities, and is currently zoned for light industrial use. The proposed site does not contain any surface water features, threatened or endangered or candidate species, or historical or cultural resources. The Staff determined that the impacts to all resource areas, except for traffic, would be small. The impacts to traffic would be small to moderate because of the noticeable increase in average daily traffic flow. Next slide, please.

I will now turn the presentation over to Marissa Bailey to discuss the Staff's regulatory findings supporting its recommendation that SHINE be issued a construction permit.

MS. BAILEY: Thank you, Jane. And I'm on Slide 13, and as Jane mentioned, I'll be discussing the Staff's findings to support issuance of a construction permit.

Section 103 of the Atomic Energy Act authorizes the Commission to issue licenses to utilization and production facilities subject to the Commission's regulations. The principal regulatory requirements for utilization and production facilities are in 10 CFR Part 50.

After completing the environmental and safety reviews, the Staff has determined that SHINE's application met the applicable requirements of 10 CFR Parts 20, 50, and 51. Also, because processes and hazards are similar to fuel cycle facilities, the Staff determined the performance requirements in 10 CFR 70.61 can be used to demonstrate adequate safety for the radioisotope production facility. Slide 14, please.

The Staff's review supports the four

findings in 10 CFR 50.35 for issuance of a construction permit. The first finding is that the Applicant has described the proposed design of the facility. The Staff used 10 CFR 50.34(a) and our guidance to evaluate the sufficiency of the preliminary design making sure that SHINE's proposed design basis and criteria are consistent with policy regulations and guidance.

SHINE committed to design the facility to meet the operational safety requirements in 10 CFR Part 20, and the accident consequence and likelihood criteria in the Interim Staff Guidance augmenting NUREG-1537. SHINE designated safety-related structures, systems, and components that will be provided for the protection of the health and safety of the public.

The second finding is that the Applicant has identified technical or design information that can be reasonably left for the Final Safety Analysis Report. The Preliminary Safety Analysis Report identified such information. This includes the security and safety emergency plans, facility operating procedures, and certain design information that SHINE committed to provide in the Final Safety Analysis Report.

The third finding is that the Applicant has identified safety features that required further research and development, and SHINE has done that. SHINE has ongoing research and development activities related to irradiation and corrosion testing, and precipitation studies. These tests are being performed by Oak Ridge and Argonne National Laboratories respectively.

The fourth finding is, one, for those safety questions and SHINE's research programs, Staff has reasonable assurance that SHINE will be able to complete the research programs before the latest date of construction. And, two, taking into consideration the site criteria contained in 10 CFR Part 100, the proposed facility can be constructed and operated without undue risk to the public. And with respect to that fourth finding, SHINE has stated that the latest date of their construction would be December 31, 2022. Based on the schedule SHINE has given us, we're expecting that the research programs will be completed before this date. Also, the additional permit conditions related to criticality safety and radiation safety must be satisfied before the completion of construction.

The site criteria in Part 100 applied to power reactors and testing facilities, and not to SHINE's, but the Staff considered similar site-specific conditions and external events. The Staff's review confirmed that the radiological releases during normal and abnormal conditions will be within the 10 CFR Part 20 dose limits. Thus, we find that the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

Additionally, the Staff concludes that for the purpose of issuing a construction permit, it conducted a thorough and complete environmental review sufficient to meet the requirements of NEPA and adequate to inform the Commission's action on the construction permit request. Slide 15, please.

Based on these findings, the Staff concludes that there is sufficient information for the Commission to issue the subject construction permit to SHINE as guided by the following considerations in 10 CFR 50.40 and 50.50. First, there is reasonable assurance that the construction of the SHINE facility will not endanger the health and safety of the public, and that construction activities can be conducted in compliance with the Commission's regulations.

Second, SHINE is technically and financially qualified to engage in the construction of its proposed facility. Third, the issuance of a construction permit for the facility would not be inimical to the common defense and security, or to the health and safety of the public. Fourth, after weighing the environmental, economic, technical and other benefits of the facility against environmental and other costs and considering reasonable available alternatives, the issuance of this construction permit is in accordance with Subpart A of 10 CFR Part 51, and all applicable requirements have been satisfied. And fifth, the application meets the standards and requirements of the Atomic Energy Act and the Commission's regulations, and that notifications to other agencies or bodies have been duly made. Slide 16, please.

The Staff will discuss novel aspects of its review of the SHINE construction permit application. Safety Panel 1 will discuss the unique licensing considerations. Safety Panel 2 will follow with details of the Staff's accident analysis. And, finally, the Environmental Panel will provide a summary of the process for developing the Environmental Impact Statement.

This concludes the Staff's remarks in the Overview Panel. We're prepared to respond to any questions you may have at this time. Thank you.

CHAIRMAN BURNS: Okay. I want to thank the

Staff Panel. We'll begin this round of questioning with Commissioner Svinicki.

COMMISSIONER SVINICKI: Well, good morning, and thank you to the NRC Staff witnesses, and all the NRC Staff that contributed to the review which is the topic of our evaluation and consideration here today.

I should have been born in Missouri, I guess, because I'm the kind of person that I don't really judge things by what people tell me they're capable of, or what they say they plan to do, but what they actually perform, how they actually perform, and what they actually do. You know, the Chairman was talking in his opening remarks about some of the significant licensing work that the NRC Staff has undertaken this year. We've had a number of mandatory hearings, and there are many tens of thousands of NRC Staff hours that go into that review, not just licensing staff, but legal, and a lot of other support organizations support that work.

I think if we look at, in particular, Watts Bar 2 operating license and in the Staff's work in support of the findings they've made for issuance of this construction permit, an interesting thing has happened. And, again, I -- you know, these days with the news such as it is, I'll turn over every rock and look for some good news, so you can fault me for that, if you want. But there are many questions being asked about the NRC's potential readiness to look at novel reactor technologies. And I think if we looked at the kind of work and adaptation and agility that had to be demonstrated in the Watts Bar 2 history which had a very unique history in terms of the run-up, the many decades run-up to the issuance of that operating license. And then if we complement that with the Staff's work here in looking at the SHINE construction permit application, but ultimately, also, you're looking forward towards the operating phase and making the safety and environmental determinations that you will need to make there.

I think it demonstrates to those skeptical, or maybe those who feel that the NRC's approach and regulations and guidance indicates a very linear and rigid approach to licensing new and novel things. I think both of those licensing activities demonstrated significant ability to take a regulatory framework, existing guidance, maybe complemented by some new Interim Staff Guidance and take that and kind of wrap it around the thing that's in front of you and say what are the relevant and appropriate parts, and how do we do that? And, often, you haven't taken years and years worth of trying to develop the little bits that you need to augment support.

Mr. Dean did mention that the Staff has been preparing itself for a medical isotope application, but the truth of the matter is, it could have taken a lot of different forms. There's -- it could have been vastly different, so what the Staff needed to have in place is something that they could innovate and adapt, and tailor to the thing in front of it. And I think, at least to this stage of the process, and there are quite a few issues, might get a little tricker in the operating license phase because you've got to come to finality on some complex issues. But that being said, the reason I asked the Applicant in the Overview Panel about getting some calibration on their view of regulatory uncertainty is that when you're inside NRC, you often walk around -- we walk around with greater familiarity, perhaps, with the regulatory system, but maybe as a result, a greater confidence in the ability to on our feet do adaptation and innovation, and tailor that particular regulatory framework to whatever is presented to us for review and approval. And I think that we've done that here.

So, having asked the Applicant how did this adaptive process work from their standpoint, I think I got a fairly positive response on that. How would the

Staff answer that same question? Do you think that this taking the existing regulatory framework guidance and then adapting it, determining relevance of various provisions within the framework, do you think that that worked well to this stage, and is your confidence high that that will continue through the remainder of the review? Again, where you will be required to meet the higher bar of coming to closure and finality on some open issues that right now you can, in essence, to use a bad word, punt those off to the operating license stage.

MR. DEAN: So, thank you for the remarks, Commissioner. And I would agree with you, I think the Staff has shown a high degree of flexibility and agility in terms of how they have managed this review activity.

I think one of the important things for us, and maybe Mirela can add something to this, is having a sense of commitment on the part of the Applicant, so that it was worthwhile to invest what we needed to do in order to be at the stage that we're at to be able to conduct the review. I think having some predictability and confidence in that certainly helps us move forward in a way that would allow us to apply all the resources that we did. For example, to develop the ISG on the aqueous homogenous reactor, I think was an important development given the fact that we had confidence that there would be something coming forward from SHINE. Mirela, do you have anything to add?

MS. GAVRILAS: Yes. I can add to that, and I certainly agree what Bill said, that having the interactions with SHINE throughout the process through public meeting was very helpful. But getting back to your original statement, indeed, the Staff does have some confidence in the regulatory framework, and that starts with we know that Part 50 is applicable to irradiation facilities and to production facilities. We know that the irradiation facilities, while they're indeed novel to us, they look like our research reactors, and we have experience with a spectrum of research reactors that exhibit a lot of variability. We have experience with -- I think just before this meeting I was told 12 homogeneous aqueous research reactors, so even there we have the experience necessary.

On the side of the production facility, we have experience with Cintichem. Granted, that was under Part 70, but we have the West Valley facility that was actually licensed under Part 50. So, what the Staff did is, we took the guidance that we had for these -- for research and test reactor, the NUREG-1537 which is our Standard Review Plan, augmented it with ISG that captured liquid homogeneous reactors, and the production facilities and came up with a framework that was suitable for SHINE.

COMMISSIONER SVINICKI: To build on that, and this is my final question. Maybe this will be a little tricky, so bear with me. Would the Staff assert that the decisions that you've made to this point on which portions and provisions within those portions of our regulations are relevant to your review of this technology on the safety side? Are those determinations final, or subject to change? I guess what I'm asking is, as you move towards closure in areas that you or the ACRS have suggested bear additional work, criticality comes to mind, other things where we have to adapt the framework to the highly novel aspects of what we're looking at and make a final safety determination. Do you think you might determine that some section of the CFR that you previously just weren't even engaging with the Applicant on, you might suddenly go, you know, we didn't really look there earlier, but based on the path that this technical issue is taking, we now think that some new provision of the regulation, you're going to have to demonstrate that you meet some requirement there. Do you think that that's likely or unlikely?

MS. GAVRILAS: I can try to answer that, and maybe I'll need help on that. So, for the construction permit we feel we're done, so basically there's nothing that is needed. Looking forward to the operating license, that's going to be our first priority, to look at the regulations and see what, if anything, will need to be adapted, be it by rulemaking, by order, licensing conditions. We're going to think what's best for the framework to be able to accommodate the operating license review. And we already know that there are some things that impact moly production facilities. For example, the work on material characterization under 74, the rulemaking there is going to be relevant to moly producers. There's security work under Part 73 that's going to be relevant to them. We know that we'll need to look closely at operator licensing because operators might be needed not just for the utilization facility, but also for the production facility, so we'll need to scrutinize the regulation. So, we know we have some work to do going forward.

As far as your question for the technology, we haven't necessarily seen something in the regulation that might need to be changed. It's more the administrative procedural, not the technology itself that is worrying us right now going forward.

COMMISSIONER SVINICKI: I need to ask a follow-up based on that answer. Thank you for that answer.

If we look at the broad purposes of why an agency such as ours reviews and issues a construction permit, there is an element of wanting to identify issues so that irreversible or very difficult to reverse decisions are not made in the construction of the facility; that, you know, you want some sense of, if constructed in accordance with the construction permit that we would issue, there would be high confidence that if other issues are resolved you could operate that facility at some point without needing to chip out a 4-foot thick concrete wall and make fundamental changes. So, what is the Staff's level of confidence in terms of the identification of relevant regulations that you just described in your previous answer? Do you think that that lends additional uncertainty going forward to the probability of successful issuance of an operating license in terms of physical rework of what it is that they're going to construct? I know the potential always exists. I'm not asking you if it's zero. I'm asking you, you know, do you have like at least a reasonable sense of confidence that you've identified issues that have the potential for causing substantial rework?

MS. GAVRILAS: So, perhaps what would help is an example on where we set the bar for what's sufficient for construction permit, as opposed to what the expectation is for an operating license. And the bar was, we heard SHINE speak earlier about hydrogen control. So, hydrogen control is a perfect example, because the physics. In other words, what the concentrations are where deflagration becomes a concern are known. The production rate of hydrogen is known. Our models, we have well established uncertainties in those models. We can bound them.

Furthermore, what's also known is mitigation technology for that. For example, passive autocatalytic recombiners, I think SHINE mentioned those, igniters. There's technology to mitigate the broad range of hydrogen production, so we know that. So, the Staff has confidence that going forward that aspect given where the state-of-the-art is in terms of both knowledge and technology, and SHINE's responses to us on what they intend to use, we have confidence that the outstanding technical issues have a reasonable chance of being addressed.

COMMISSIONER SVINICKI: Okay. So based on that, is it fair to characterize that the Staff at this stage has not recommended anything in terms of going forward with the construction permit that it would identify as fundamentally unlicensable or unlikely to be able to be operated or licensed at the operating license stage?

MS. GAVRILAS: That's fair.

COMMISSIONER SVINICKI: Okay, thank you. Thank you, Mr. Chairman.

CHAIRMAN BURNS: Thank you, Commissioner. Commissioner Ostendorff.

COMMISSIONER OSTENDORFF: Thank you, Chairman. Thank you all for your briefs today, and for the work of you and your teams. It's important work.

I want to maybe, Mirela, pick up a little bit with where Commissioner Svinicki was probing with you. From your Slide 8 where you said the Staff used existing guidance -- in the discussions with Commissioner Svinicki and the exchange during her Q & A -- I just want to make sure I understand one thing. I think it is that you did not -- you and your team did not experience any challenges working within our existing regulations with our existing guidance as far as being able to, I'll say, on the fly adapt where judgment would lead one to say this is a reasonable way of handling a particular design issue.

MS. GAVRILAS: No, the challenges as I -- in my earlier answer, the challenge is where the bar for construction permit needs to be set relative to what our expectations are in the final design. That was where the Staff needed to exercise its technical judgment. We haven't had areas where we needed to -- where we had significant gaps that we needed to address, if I understood your question correctly. If I didn't --

COMMISSIONER OSTENDORFF: Let me rephrase it because I'm not sure -- I may not have asked it as clearly as I should have.

Were there flaws or gaps in the existing NRC regulations or guidance that prevented your team from doing their work on the construction permit?

MS. GAVRILAS: There was one issue that we had to address, specifically the fact that the irradiation facility was not covered under Part 50 because they're subcritical and the definition for irradiation facility --

COMMISSIONER OSTENDORFF: I understand. The Commission got involved in that here.

MS. GAVRILAS: Yes, that's the only flaw that we found.

COMMISSIONER OSTENDORFF: Okay. And you felt like -- working within the existing guidance documents that there was sufficient flexibility for the Staff to be able to exercise reasonable judgment as to how to apply certain sections?

MS. GAVRILAS: Yes. And that might be aided by the fact that the existing guidance that we relied upon was primarily NUREG-1537, which is designed for research reactors which do exhibit a fair amount of --

COMMISSIONER OSTENDORFF: Okay.

MS. GAVRILAS: -- differences.

COMMISSIONER OSTENDORFF: Okay. I think this is still a question for you, but others may want to chime in here. The first session with the SHINE panel, I asked a question that was addressed I think by Eric about the use of prototypes by SHINE organization, the reference to other existing reactors, and I think Eric mentioned one from the Los Alamos National Laboratory. Can you talk at a high level about how our Staff perhaps used experience of these prototypes or other existing technologies to consider the construction permit?

MS. GAVRILAS: I'm going to ask Steve Lynch who was the Project Manager on SHINE to talk about specifics.

CHAIRMAN BURNS: Okay. And, Mr. Lynch, identify yourself for the record, and confirm that you took the oath.

MR. LYNCH: Yes. My name is Steve Lynch. I am the Project Manager for SHINE on the NRC Staff. And yes, I did take the oath.

CHAIRMAN BURNS: Okay, proceed.

MR. LYNCH: Yes. As far as facilities most we considered on the irradiation facility side were existing research reactors and past experience with aqueous homogeneous reactors. On the production facility side we did look back to our licensing experience with the Cintichem facility. We actually did have on staff former employees from Cintichem that helped inform the development of our guidance and the beginning of our review.

COMMISSIONER OSTENDORFF: Can you talk about, Steve, I think Eric had mentioned SHINE's own prototype efforts. Can you talk about how you might have looked at those, or considered those in your review?

MR. LYNCH: We have not looked extensively at the prototypes. We have considered some of the papers that have come out from the National Labs describing their results. We will look more carefully at that at the operating license stage.

COMMISSIONER OSTENDORFF: Okay, thank you.

Jane, I don't want you to go without a question here.

MS. MARSHALL: Thank you, sir.

COMMISSIONER OSTENDORFF: I'll ask an

environmental review question. And, you know, I think Mirela has mentioned -- my question is what is this like, the environmental review, is this like a research test reactor, or is it like in Marissa's bailiwick the fuel cycle facility? What does the environmental review look like? Is it a hybrid of these, or something else?

MS. MARSHALL: It's a hybrid. I guess we're lucky in a sense. All of the environmental regulations are in Part 51, so we didn't have to look beyond that. And as part of the environmental review, we looked at the connected actions so we didn't just look at construction, we looked at operation, decommissioning, traffic flow. So, in that sense it was much like any other environmental impact statement that we would prepare.

COMMISSIONER OSTENDORFF: Okay. Anybody else on that? All right, thank you. Thank you all.

CHAIRMAN BURNS: Thank you, Commissioner. Commissioner Baran.

COMMISSIONER BARAN: Thanks. Well, let me start by thanking you and the rest of the Staff who worked on this application for all the hard work that went not only into preparing for today's hearing, but also all the efforts in reviewing this unique application.

I wanted to follow-up on a couple of things I asked about -- asked SHINE about on the first panel. Going back to the ACRS letter and the seven topics that they identified that should be further addressed in an application for an operating license. We talked to SHINE about that. They said those are going to be addressed in their Corrective Action Program. Can you talk a little bit about how the Staff intends to ensure that those issues are addressed in the operating license application?

MS. GAVRILAS: Some of the items that came out of the ACRS discussions are actually captured in our SER. They are among the items that we listed in Appendix A. Perhaps it's not the complete list, but we'll make sure that when operating review -- operating license review time comes we will look at the entirety of the items that were mentioned by the ACRS in their letter.

There were also commitments that SHINE made explicitly to the ACRS, and those we also captured in the SER in the same Appendix A on the two items that the ACRS had engaged them on, that the Staff had not previously had discussions with them. So, we fully intend to follow-up on all the items raised by the ACRS.

COMMISSIONER BARAN: Okay. And just to clarify then for the answers to the pre-hearing question related to this, some but not all of these items the ACRS identified were captured as commitments on Appendix A, in Appendix A.

MS. GAVRILAS: I believe that is the case. We'll check during the lunch break and we'll get back to you at the end of the day, if we need to make a correction on that.

COMMISSIONER BARAN: Okay, great. Thanks.

And as we've noted at various points, some of the regulations, like the general design criteria, don't apply to SHINE because it's not a reactor. But the Staff considered these regulations when doing its review, and the Applicant considered them in its design. Can you describe that process in a little bit more detail? Would the Staff ask RAIs on concepts from the general design criteria, or were these used as a reference for the technical reviewers? What role did they play?

MS. GAVRILAS: So, there's the expectation in 50.34 of providing principal design criteria as unambiguous, so we want that. What SHINE did in their application, they actually came and had crosswalk tables of all the 55 GDCs, how they apply or not apply, or adapt to the features of their facility. So, the Staff scrutinized that and found it acceptable. And I will give an example for containment, GDC-16 deals with containment. They have a confinement, but they adapted the notion of controlled leakage that's intended in GDC-16. So, in addition to the GDCs, they also have the GDCs, as you mentioned, are designed for light water power reactor.

They also have a production facility that has unique features. There they proposed safety systems and components that actually lend themselves to additional criteria. I'll give an example, the concentration of uranium in the solution. That will become part of the design basis. That is part of their design basis, and it's a design criteria for them.

COMMISSIONER BARAN: Thanks, that's helpful.

Bill, I have one question I think is probably for you. And that has to do with how we're going to oversee and inspect the SHINE facility during construction if a construction permit is issued. Our current construction inspectors have inspected against the more detailed information provided in an operating license. How would we ensure that the inspectors are prepared to inspect against a construction permit?

MR. DEAN: So, I'll start and there may be some others who can augment, maybe some of our battalion of witnesses might want to chime in here.

So, we'll be leveraging, obviously, the construction inspection experience that we have in Region II to support the construction activities. Clearly, we'll need to develop a construction inspection program much like we did for the Vogtle and VC Summer units. So, we have a model there, obviously, it's going to be scaled down, but I would expect that what we would have would be a replica of a much smaller scale as to what we've done with the construction of the AP-1000s.

MS. GAVRILAS: Yes, and we had -- we've done significant work in that direction. And, actually, our Office of New Reactors worked with Region II and, of course, with the rest of us, and there is inspection procedures. And the lead on that was Carl Weber, one of our witnesses, and he can talk about the substance of that procedure.

CHAIRMAN BURNS: Okay. Identify yourself, and confirm you've been put under oath.

MR. WEBER: My name is Carl Weber. I work for the Office of New Reactors in the Construction Inspection Branch. And I helped to develop the overall inspection program for basically radioactive isotope production. We didn't do a specific program just for

SHINE, we made it fairly generic. And what we did was we went back and looked at similar -- programs with similarities. For example, we looked at the Watts Bar program where they were inspecting to a construction permit. We also looked at the mixed oxide facility, and we looked at the Louisiana Energy Services programs. We got a group of people together who had experience in this area, had a working group. We got all their experience, and we developed the program specifically for the radioactive isotope production.

CHAIRMAN BURNS: Okay. And confirm you were put under oath before.

MR. WEBER: Pardon me?

CHAIRMAN BURNS: You did take the oath before?

MR. WEBER: Oh, yes. I'm sorry.

CHAIRMAN BURNS: Okay, thanks.

COMMISSIONER BARAN: Thank you very much.

CHAIRMAN BURNS: I appreciate the exploration of the differences in terms of construction permit versus operating license that my colleagues have done so far. A couple of questions I had actually, you know, potentially looking forward. In effect, what we actually have is eight production facilities. Correct?

MR. DEAN: Well, there will be eight

individual licenses.

CHAIRMAN BURNS: Eight individual. Will there be eight individual licenses --

MS. GAVRILAS: Utilization facility.

CHAIRMAN BURNS: -- or is this -- would the intention to be combined into one operating license?

MS. GAVRILAS: It's eight utilization facilities, the irradiation facilities. And we're looking at that. So, for example, just recently we were scanning 50.56 and we saw one construction permit, one operating license, and then we gave some thought to 50.52, that you can have activities from -- that you would license by themselves. You could have them all under one license. But that's all our thinking, it's preliminary. It will depend on what SHINE applies for, and then we'll need to be more rigorous in our considerations.

CHAIRMAN BURNS: Okay. And a couple of other questions. And, again, because we're adapting this type of facility to the Part 50 framework, but two others -- so, in this term have you looked down the road as well, we're looking at license -- because I heard someone mention licensed operators. So, we think that's something that would be required or of value as part of this facility licensing?

MS. GAVRILAS: SHINE has, I believe, said that they will have operators for the irradiation -- for the radioisotope production part of their facility, so that we need to look into more detail what provisions are in 50.55 for licensing operators, if there's any need for it. So, again, this is exploratory. They're just things that as we're reviewing the construction permit application are coming to mind and we're jotting them down that we need to explore them further for the operating license.

CHAIRMAN BURNS: Okay. And I'll just put one more on the plate there, because I saw in the -- I was looking at the draft construction permit and it speaks to the financial protection and indemnity requirements which are under Price-Anderson Act. And, again, it's a Part 50 facility, so I mean looking at the regulations, confirm under Part 140, Part 50 facility has those -- so, again, is that -- now, again, I take it the Staff is looking at those requirements under Price-Anderson to the extent that they would apply. Obviously, this is not a large, you know, 1,300 megawatt or 1,000 megawatt operating plant, so there are different provisions, but I'm presuming that's also something you need to resolve in the longer term for the operating license.

MS. GAVRILAS: I've noted your comment.

CHAIRMAN BURNS: okay.

MS. GAVRILAS: We haven't so far.

CHAIRMAN BURNS: Okay. Because it is mentioned in the draft construction permit which is what highlighted it to me.

MS. GAVRILAS: Okay, then I'm probably unaware of our discussions.

CHAIRMAN BURNS: Okay. One of the things, also, in terms of one of the findings highlighted, one of the findings was that the Applicant is technically and financially qualified for purposes of the construction permit. Can you give me a description of what the Staff did with respect to looking at financial qualifications for the construction permit?

MS. GAVRILAS: At a very high level, we basically scrutinized the funds that they have from private investors. We also know that they are funded by the Department of Energy, and we found that to be sufficient for the purpose of construction permit.

CHAIRMAN BURNS: Okay, thanks.

There is a distinction, I think, made on one of the slides between conditions in -- I think it's on Slide 9. The slide says, "In some cases permit conditions are necessary. In other circumstances" -- then the next bullet says, "Regulatory commitments track items for resolution in the Final Safety Analysis Report or FSAR."

Can the Staff give me a distinction, what elevates itself to a condition versus a commitment that somehow is tracked and how do you track those commitments?

MS. BAILEY: The conditions in the construction permit are really associated with the criticality, radiological safety primarily for the radioisotope production facility. Criticality safety, that part of the facility is controlled primarily through geometry and the configuration of design. As SHINE mentioned earlier, the design is preliminary. It's still under development, as well as the analysis that goes with it. So, the permit conditions basically allow the Staff to confirm as the design and the evaluations of the design progress that it's being done in accordance with the design criteria that's described in the Preliminary Safety Analysis Report.

What the conditions really do is it gives us the assurance that SHINE will be able to provide the necessary design and technical information in the Final Safety Analysis Report for us to complete our safety evaluation. So part of that goes to Commissioner Svinicki's question about mitigating or avoiding a rework of the facility once construction is well underway or completed.

CHAIRMAN BURNS: Okay. My final question relates to the -- stated by the Staff, the Staff used NUREG-1537 which has guidelines for preparation and review of applications related to non-power reactors. And it has some Interim Staff Guidance, there's some Interim Staff Guidance that was used, which states it was prepared for evolving technologies that were not fully developed and demonstrated at the time of publication. What has been your experience with using this Interim Staff Guidance? What do you think you've learned from using it? Is it doing what you hoped it would do?

MS. GAVRILAS: It is doing what we hoped it would do. It met our purposes just fine for the construction permit, and we anticipate that it will continue to do so for the operating license. We found one fundamental problem with the guidance as we developed it, and that had to do, we thought that the irradiation facility was going to be able to be reviewed as part of the production facility. That was not the case for SHINE, for example. But other than that, the Interim Staff Guidance works, and we anticipated incorporating it into NUREG-1537 at the next revision of the document.

CHAIRMAN BURNS: Okay. And the reason I want to make sure I understand; the two parts of the facility could not be -- I'm trying -- you said they could not be reviewed?

MS. GAVRILAS: Yes, we initially --

CHAIRMAN BURNS: Explain that.

MS. GAVRILAS: I'm going to have to ask for help if this is not enough. But we initially thought that the irradiation facility and the production facility can be treated as one entity. And then when we saw the SHINE application and we started giving more thought, we realized that they're actually distinct and they deserve to be -- they need to be examined separately.

CHAIRMAN BURNS: But examined separately in what sense, that the regulatory footprint is different? Again, I think of a large power reactor that has a number -- it has a reactor, it has a number of other buildings that may support it. So, help me along here.

MR. DEAN: Can I -- let me just --

MS. GAVRILAS: Yes.

MR. DEAN: At a high level, I think if you looked at the irradiation facility, that's more like a research and test reactor. Right? Whereas, the radioisotope production facility really has a lot more commonality with a fuel cycle facility.

CHAIRMAN BURNS: Okay.

MR. DEAN: Chemical processes, so I think that kind of was -- as we looked at the SHINE application, we realized we probably need to treat them sort of independently because of that. I don't know if, Marissa, you have anything you want to add in that regard?

MS. BAILEY: I think that's pretty close. I think it's really in terms of what are the applicable acceptance criteria for each type of the facility. So, for example, for the radioisotope production facility because it resembles a fuel cycle facility in terms of processes and hazards, we determined that even though it's licensed under Part 50, we could use the performance objectives in Part 70 to make a determination of acceptability for safety.

CHAIRMAN BURNS: Okay. But, ultimately, this is all licensed ---

MS. BAILEY: Under Part 50.

CHAIRMAN BURNS: Under Part 50, and it's all licensed -- there's not another licensing action going on. I understand that the criteria are different. We've sort of banged this into Part 50 for the subcritical assemblies in those units, and you have this other part which is more like something we -- that NMSS would typically license. But the whole thing is put together, ultimately, under this license.

MS. GAVRILAS: That's right.

MS. BAILEY: Yes.

CHAIRMAN BURNS: Okay. All right, thank you. Commissioner Svinicki.

COMMISSIONER SVINICKI: Just a follow-up. In response to the Chairman's question on Price-Anderson indemnification and the Staff's answer, that engendered a very energetic sidebar between counsel for the Staff. Catherine or Mitzi, was there anything counsel for the Staff wanted to respond on that, or is that just you were excited because when the Chairman opens the CFR during the meeting, you know something is going to happen. Right? Did you want to provide any augmentation to the Staff's answer on that? You could say no, it's fine. You don't have to. I'm not saying explain yourselves. I'm just saying, did you want to supplement their answer?

MS. YOUNG: Mitzi Young, counsel for the NRC Staff. First of all, let me defend myself. We've been animated through the whole hearing. Every time you ask a question we're excited because many of the questions you asked are questions we practiced with them in part, so this has been exciting from a number of respects. But in terms of Price-Anderson, that is part of the review. I believe 140 talks about a certain power level for reactors, and I think what SHINE did in their application, and Steven Lynch is obviously more conversant on this than myself. They looked at comparable power thermal output to identify what level of Price-Anderson protection they would need. To the extent that they're not receiving Special Nuclear Material to get a construction permit, that assurance is not needed now, but it would be part of the operating license review.

Steve, was there anything you wanted to add?

MR. LYNCH: That's it.

MS. YOUNG: Thank you.

CHAIRMAN BURNS: All right, thanks very much, Mitzi.

COMMISSIONER SVINICKI: Thank you.

CHAIRMAN BURNS: Thanks, Commissioner.

With that, we'll take a brief break and then resume with Safety Panel 1. So, try to be back in your seats in about five or six minutes.

(Whereupon, the proceedings went off the record at 11:05 a.m., and went back on the record at 11:15 a.m.)

CHAIRMAN BURNS: We'll call the hearing back to order. In this next session we'll have Safety Panel 1 and we'll hear first from the Applicant, SHINE. We'll immediately follow that with the staff's presentation for Safety Panel 1 and then follow with Commissioner questions. And in general the topics will cover the chapter 1 of the Safety Evaluation Report with respect to the facility, and chapter 4, irradiation unit and radioisotope production facility description to address the licensing considerations for the subcritical utilization facilities and production facility.

So with that, we'll go to our first panel from SHINE. Mr. Hennessy and Mr. Van Abel are here, but, Ms. Kolb, I'll ask you to introduce yourself.

MS. KOLB: My name is Catherine Kolb. I'm a supervisor in engineering for SHINE Medical Technologies.

CHAIRMAN BURNS: Okay. Thanks very much. And again, assume that the Commission is generally familiar with the prehearing filings, and I remind you you're under oath. And please proceed.

MR. VAN ABEL: All right. Good morning again. In this presentation I'd like to give a brief continuing discussion on the facility.

If we'd go to the next slide, slide 2. Here again is the overall facility process overview. We went through this in some detail in the overview discussion. I'm going to add a little additional detail on the design requirements for these SSCs in this presentation, but of course if we have any other questions on the overall facility design, happy to answer those as well.

Next slide, please. For the SHINE facility certain SSCs are designated as safety-related in our facility because they are relied upon to perform safety functions either during normal operations or during design-basis events. And those SSCs that are required to perform safety functions are required to perform those in the environmental conditions of normal operation and any accidents in which they are required to function. For those SSCs that have safety significance, we design them, fabricate them and test them commensurate with the criteria set forth in ANSI/ANS-15.8, which are the quality assurance requirements for research reactors. SHINE implements that ANSI/ANS-15.8 standard through our Quality Assurance Program description, or QAPD.

Next slide, please. On this slide we have the safety-related definition that SHINE applies to design. This is a comprehensive definition that we've modified from 10 CFR 50.2 and we've also included the requirements from 10 CFR 70.61, the performance requirements there as they're applicable to the radioisotope production facility.

The SSCs that are safety-related are those that are relied upon to meet any of the six criteria listed here. The first three are modifications of 10 CFR 50.2 and include the integrity of the primary system boundary, the capability to shut down our target solution vessel and irradiation process and maintain it shutdown, and the capability to prevent accident dose consequences that would exceed 10 CFR 20.

And the last three are familiar to the fuel cycle facility folks. These are to ensure that our nuclear processes remain subcritical including the use of an approved margin of subcriticality, to ensure that chemical exposures from accidents are acceptable for both the worker and the public, and that an intake of 30 milligrams or greater of soluble uranium does not occur for personnel outside the owner-controlled area, the OCA.

Next slide, please. For our SSCs we require them to be designed to withstand external events. Our outer building structure is designed to resist external events such as tornadoes, aircraft impacts and other external events. And also the SSCs within the building are required to withstand our design-basis earthquake if they perform a safety-related function or they're necessary to ensure they do not degrade the performance of a safety-related SSC.

We also apply a graded quality level to the design of our SSCs. We have three quality levels as described here. Quality Level 1 is applied to our safety-related components SSCs, and that is the full measure of our QAPD is applied to those SSCs. Also, we apply Quality Level 2 to SSCs that could affect the safety function of safety-related SSCs specifically to support or protect the safety function of those SSCs. And we apply graded quality to those components that's commensurate with their importance to safety. And Quality Level 3 is applied to those SSCs that don't meet the definition of Quality Level 1 or 2.

Next slide, please. We also apply single failure criterion to our systems. For safety systems we ensure that there is sufficient redundancy and independence such that a single failure of an active component does not result in the loss of capability to perform the safety function. And for accident analysis we ensure that a single failure in conjunction with the initiating event does not result in the loss of the safety system's ability to perform the safety function. So throughout our design process we use a robust defense-in-depth approach to design, and we have a strong preference in the design for passive and engineered controls over administrative controls. And that concludes my presentation.

CHAIRMAN BURNS: Okay. Thank you. And I'll ask the staff witnesses to come forward, take their seats at the table.

And I remind you that you're under oath and start with the introduction of the witnesses. Start with you, Mr. Lynch.

MR. LYNCH: My name is Steve Lynch. I'm the project manager for SHINE Medical Technologies on the NRC staff.

MR. ADAMS: My name is Al Adams. I'm the Chief of Research and Test Reactor Licensing in NRR.

MS. ADAMS: Mary Adams. I'm an engineer in the Division of Fuel Cycle Safety Safeguards and Environmental Review in NMSS.

CHAIRMAN BURNS: Okay. Thank you. Please proceed.

MR. ADAMS: Good morning. This panel will discuss the unique licensing considerations of the SHINE utilization and production facilities. I will discuss the general licensing considerations and a review performed by the Advisory Committee on Reactor Safeguards, the ACRS. Steve Lynch will discuss the licensing of the irradiation units and Mary Adams will discuss the licensing of the production facility.

Next slide, please. SHINE seeks to construct non-power utilization facilities and a production facility. Therefore, an initial consideration was whether to license SHINE's proposed facilities under Section 103 or Section 104 of the Atomic Energy Act. While the hazards associated with SHINE's facility are similar to non-power research reactors which are licensed under Section 104 of the Atomic Energy Act, SHINE's facility is intended to be used for commercial purposes, not for conducting research and development or medical therapy. Therefore, while the licensing process would be similar to a research reactor, SHINE's facility would be licensed under Section 103 of the Atomic Energy Act.

Section 103 imposes additional procedures on construction permit applications including an independent review of the application by the ACRS and a mandatory hearing, which we are having today.

Because SHINE's facility is a subcritical system which produces fission power, it introduces aspects of a review typically done for non-power reactors. For these areas the staff developed and used the Interim Staff Guidance for NUREG-1537, which is a standard review plan for non-power reactors.

Next slide, please. The staff presented the results of its safety review at three ACRS Subcommittee meetings and before the full ACRS. During its review the ACRS identified two safety concerns that could impact the operation of the SHINE facility if not sufficiently addressed. These concerns were the capability to lay up the facility and the facility's ability to withstand potential aircraft impact.

SHINE and the staff provided additional information to the ACRS in these areas. The ACRS determined that sufficient information was provided such that it could recommend the issuance of a construction permit. This recommendation is reflected in the ACRS letter dated October 15th, 2015, which is in the staff's SER.

The ACRS letter also noticed several issues that must be addressed at the operating license stage including criticality control and margin. The staff agrees that each item that the ACRS identified must be addressed at the operating license stage. And Mirela was correct during her testimony that written comments were not provided, or written commitments were not provided by SHINE in all these areas, however, the staff is aware of them and we determined that they're not needed for the issuance of the construction permit, but will be addressed at the operating license stage.

Next slide, please. Steve Lynch will now discuss specific licensing considerations related to the SHINE irradiation facility.

MR. LYNCH: Thanks, Al. SHINE's proposed irradiation units presented unique licensing considerations under 10 CFR Part 50, which has traditionally been applied to the construction and operation of nuclear reactors. However, unlike nuclear reactors, SHINE's irradiation units are not designed to go critical during operation. Therefore, SHINE's irradiation units represent a new application of technology.

Given their subcritical nature, the staff considered whether it should review SHINE's irradiation units under 10 CFR Part 70, which can be applied to certain facilities that possess and use special nuclear material. However, these facilities, generally referred to as fuel cycle facilities, have the common objective of avoiding criticality by a significant margin under both normal operating and accident conditions. In contrast, SHINE's minimal margin of subcriticality is less than what has been previously approved for other 10 CFR Part 70 licensees and more closely resembles the operating state of a nuclear reactor.

Because of this the staff determined that it would be most appropriate to use the 10 CFR Part 50 regulations for utilization facilities to perform its technical review of the irradiation units. Therefore, the NRC issued a direct final rule that revised the definition of utilization facility in 10 CFR 50.2 to add SHINE's subcritical operating assemblies. If licensed, SHINE's irradiation units would be the first utilization facilities to operate in a minimally subcritical range.

Next slide, please. Classifying SHINE's irradiation units as utilization facilities allowed the staff to conduct its review following the regulations designed for technologies with similar radiological, health and safety considerations. In particular, the accelerator and neutron multiplier of each irradiation unit achieve a fission rate with a thermal power level comparable to that of other non-power reactors licensed under 10 CFR Part 50. Because of their thermal power levels the irradiation units share similar safety considerations with other non-power reactors, including provisions for the removal of fission heat during operation, passive decay heat generation after shutdown, fission gas release and accident scenarios.

Given these safety considerations and the functional similarities of the irradiation units to non-power reactors, the staff relied on the guidance provided in NUREG-1537 as supplemented by Interim Staff Guidance for aqueous homogeneous reactors to conduct its review. Specific design areas of the staff's review included SHINE's reactivity control mechanisms, light water pool and biological shielding.

Next slide, please. Mary Adams will now discuss licensing considerations related to the SHINE radioisotope production facility.

MS. ADAMS: Thanks, Steve. SHINE's radioisotope production facility is distinct from the irradiation facility. The RPF contains hot cells that will process irradiated materials containing SNM in batches of greater than 100 grams. Therefore, the RPF is a production facility as defined in 10 CFR 50.2.

The RPF also consists of several physical and chemical processes that are similar to those performed at fuel cycle facilities. These processes include the UREX and liquid waste evaporation and solidification processes. With the exception of target solution preparation with fresh LEU, all of the processes will be performed on irradiated special nuclear material. Therefore, the staff used the guidance in NUREG-1537 as supplemented by Interim Staff Guidance to guide its review of the radioisotope production facility.

The acceptance criteria in the Interim Staff Guidance are drawn from NUREG-1520, the standard review plan for fuel cycle facilities. The ISG contains baseline design criteria and accident analysis guidance which include the criteria in 10 CFR 70.64. As noted in the guidance, an application meeting these baseline design criteria would be found acceptable by the staff. SHINE's construction permit application proposed these acceptable baseline design criteria for the RPF. After reviewing the application, the staff finds that SHINE's application met these baseline design criteria.

Next slide, please. In doing its review the staff identified certain items that must be addressed prior to the completion of construction, therefore, the staff is recommending certain permit conditions. In particular, the staff has proposed four criticality safety permit conditions which are confirmatory and require SHINE to submit periodic reports to the NRC.

These reports must address the technical basis of the criticality accident alarm system, the basis for determining that criticality events are not credible for the RPF processes, criticality safety analyses for processes using fissile material and the reactivity contributions from all fissile isotopes. The staff is also recommending a permit condition related to radiation protection to ensure shielding and occupancy times within the RPF are consistent with as low as is reasonable achievable practices and dose requirements of 10 CFR Part 20.

This concludes the staff's remarks for Safety Panel 1. We will respond to any questions you may have at this time.

CHAIRMAN BURNS: Okay. Thank you very much. And what I would ask the staff -- now, Mary, you're probably okay, but Mr. Lynch and Mr. Adams, if you could maybe slide over this way, then we have a good -- we can see all the witnesses at once as we begin our questions. And we'll begin our questions for this panel with Commissioner Ostendorff.

COMMISSIONER OSTENDORFF: Thank you, Chairman, and thank you all for your briefs. I do have a question for the Applicant, and I'm going to your slide 6. And under the single failure criterion being applied to safety systems, I just wanted to ask a high-level design philosophy question, if I could.

Can you talk a little bit about how your single failure does not result in a loss of the ability to perform its function? Can you talk about how you apply that concept to reliability of electrical power as it affects instrumentation control or alarms?

MR. VAN ABEL: Yes, for instrumentation control and electrical power we have very minimal requirements for those for safety-related purposes. And those that we do have are primarily for hydrogen mitigation after shutdown and some instrumentation control systems that monitor the system after shutdown. And those are provided by an uninterruptible power supply system that will be designed based on single failure criterion to look at failure of components such as a breaker supplying power to ensure that there's redundant reliable means to supply that power to the equipment requiring it.

COMMISSIONER OSTENDORFF: With respect to your criticality alarm system, does that have redundant power supplies? Or that may not have been designed yet; I don't know, but where does that fall with respect to this philosophy of redundancy?

MR. HENNESSY: It would be. It's not designed yet, but it's a safety-related system, so --

COMMISSIONER OSTENDORFF: Okay.

MR. HENNESSY: -- these same design principles would apply.

COMMISSIONER OSTENDORFF: Okay. Thank you.

Let me shift back to the staff now. Mary, I wanted to ask you a question on your slide, I think 7 -- excuse me, 8. There's a reference to criticality events not being credible. Can I just ask you to elaborate on that just a little bit about what's the basis for that statement?

MS. ADAMS: 10 CFR 70.61, which formed the basis of the Interim Staff Guidance, states as an acceptance criterion that all processes need to be subcritical under normal and credible abnormal operating conditions. And so, what exactly does "credible abnormal" mean? And we ask our applicants to very carefully define what they mean by credible and not credible with respect to criticality safety.

COMMISSIONER OSTENDORFF: So with respect to the design aspects of what's been presented to the NRC staff how is that achieved?

MS. ADAMS: I want to call on --

COMMISSIONER OSTENDORFF: Or as a condition of not having a credible criticality event.

MS. ADAMS: I'd like to call on Dr. Chris Tripp to answer that question.

CHAIRMAN BURNS: Okay. And please identify yourself for the record and confirm that you took the oath earlier.

DR. TRIPP: Okay. I'm Christopher Tripp. I'm the criticality safety reviewer in FCSS for the RPF, and, yes, I did take the oath.

CHAIRMAN BURNS: Okay. Please proceed.

DR. TRIPP: Okay. With regard to credibility, when SHINE originally provided their PSAR section on criticality safety, they said that they were going to design it so that criticality would be not credible and then any controls so identified would be identified as SSCs. This was meant to meet the performance requirements.

Some of those criteria that were mentioned were from the performance requirements of Part 70. And the usual approach on the Part 70 side has been that we required criticality and other high-consequence events to be highly unlikely and then those items would be identified as items relied on for safety under the Part 70 framework. So there seemed to be some confusion as to what the exact -- how that would be applied to the RPF.

And in the fuel cycle area we have had a lot of discussions in the existing fuel facilities concerning the basis for deciding events are credible or not credible, and when you have to make that demonstration and what you're allowed to take credit for. So this has been an ongoing issue with the industry. Therefore, we proposed these conditions to give us additional confidence that they understood what they were committing to to be able to apply that acceptably in the design.

COMMISSIONER OSTENDORFF: Okay. Well, are you expecting this condition to lead to articulation of specific engineered features as far as volume control on solution or can you be a little more specific as to how this might play out in the facility's actual design?

DR. TRIPP: Yes. So the first step in applying the criteria -- the main criteria for criticality is they be subcritical under normal and credible abnormal conditions. So the first step of that is identifying what are the credible criticality hazards and then designing the different safety barriers against that. So it's at that first step of deciding what is credible and what hazards have to be protected against that we would want to make sure that they had an acceptable way of doing that.

COMMISSIONER OSTENDORFF: So what are some examples? I'm trying to get to a more practical engineered feature discussion here. What are some examples of how the licensee might satisfy that condition?

DR. TRIPP: Well, there are three criteria for what they consider credible: One is an external event with frequency of 10 to the minus 6th based on the fuel cycle guidance that was incorporated into the ISG. The other is basically a string of independent events that together collectively make up a set of unlikely events that would have to occur that we wouldn't think are credible. And the third is that they'd be physically impossible.

COMMISSIONER OSTENDORFF: So is there an example of the physically impossible that you can offer for us?

DR. TRIPP: Well, we don't have specific examples that apply directly to SHINE because we haven't reviewed specific design features at this point. We've only reviewed the design criteria. But in the other fuel cycle arrangement -- for example, most of the processing, the solution processing, which is similar to what they have in other parts of the fuel facility, are in safe geometry containers, safe geometry columns and so forth. And one of the things you have to guard against is backflow. So a lot of the time they're protected against with say a siphon break or an overflow or something of that nature so that -- liquid doesn't flow against gravity. That would be considered incredible. But it's only based on having that passive feature in the design.

COMMISSIONER OSTENDORFF: Okay. That example was very helpful. Thank you. Thank you, Chairman.

CHAIRMAN BURNS: Thank you. Commissioner Baran?

COMMISSIONER BARAN: Thanks. I want to ask about slide 4 of SHINE's presentation which relates to the definition of structures, systems and components. The proposed definition, SSC definition states in bullet 3 that SSCs assure the capability to prevent or mitigate the consequences of accidents which could result in potential exposures comparable to Part 20. The definition also states in bullet 6 that SSCs assure that an intake of 30 milligrams or greater of uranium in soluble form by any individual located outside the owner control area does not occur.

The NRC's occupational dose requirements in Part 20 state that the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. Can SHINE discuss the basis for setting the SSC definition at no more than 30 milligrams? How does that line up with -- how is that reconciled with the Part 20 requirements?

MR. HENNESSY: The definition in Part 6, or the term in Part 6 was derived from the 10 CFR 70.61 performance requirements, and that's what it reflects back as.

As far as the 10 CFR 20 requirements, our concern, they would still be applicable and we would still apply that under No. 3. So we'll have to look at your --

COMMISSIONER BARAN: Okay.

MR. HENNESSY: -- comment and think about that.

COMMISSIONER BARAN: Do you know if there's a time frame that applies to the 30-milligram level?

MR. HENNESSY: I'm not aware of one.

COMMISSIONER BARAN: Okay.

MR. HENNESSY: Eric, do you have any idea?

MR. VAN ABEL: It's for an accident evaluation for --

COMMISSIONER BARAN: Okay.

MR. VAN ABEL: -- normal operations.

COMMISSIONER BARAN: So that's basically total intake --

MR. VAN ABEL: Yes. Right.

COMMISSIONER BARAN: -- over whatever period of time?

MR. VAN ABEL: That's correct.

COMMISSIONER BARAN: Okay. And then the Part 20 standards have a limit of 10 milligrams per week. Maybe I'll ask the staff to comment on this. How did you all conclude that the proposed definition element of an intake of 30 milligrams of uranium in soluble form is an acceptable limit for the definition?

MS. ADAMS: I'd like to call on Greg Chapman, the health physicist who reviewed the RPF.

MR. CHAPMAN: Greg Chapman, NMSS, health physicist. I did take the oath.

CHAIRMAN BURNS: Great.

MR. CHAPMAN: With regards to the 10

milligram or 30-milligrams, 30 milligrams is typically the criteria that were replaced with the public for Part 70-type review. And we typically look at it as an acute exposure over 24 hours. So 10 milligrams for accident exposure as well as 30 milligrams, I would apply the same criteria, 24 hours.

COMMISSIONER BARAN: Okay. And so under this definition the potential intake from a member of the public of 30 milligrams looks to be about 3 times higher than the limit you would have over the course of a week for someone working at the facility, is that right?

MR. CHAPMAN: That's correct.

COMMISSIONER BARAN: Okay. And can you tell us a little bit more about how when you evaluated that that that seemed like an acceptable result?

MR. CHAPMAN: I'd have to get back with you on that. I can't recall at the moment.

COMMISSIONER BARAN: I don't know if this is a matter of a temporal issue here or there's something else at play, but maybe you could get back to us on that.

Al or Steve, in prehearing question 15 we asked whether the application specified how many irradiation units a single operator could control, and both the staff and SHINE stated that that would be addressed during the operating license application. Can you talk a little bit about how the number of operators relates to the size of the control room and whether that's an issue that needs to be resolved now at the construction permit stage?

MR. LYNCH: So that is something that we haven't looked extensively at the construction permit stage. Some of the considerations: More than just the size of the control room, we're looking at the layout of the control room, especially if there will be operators looking at the production facility versus the irradiation facility, and we need to get a better understanding of how the controls will be laid out and to make a determination on the number of operators that are needed.

COMMISSIONER BARAN: Okay. So in terms of getting at the issue that Commissioner Svinicki raised about not wanting a situation where someone has a construction permit, they build something out, we look at it later and say, no, no, that's not going to work and people have to kind of redo things, from the staff's point of view is the number of operators, total number of operators that would be working in the control room -- is that going to be relevant to the layout, the construction of that control room in a way that makes it something that we should address now at the construction permit stage, or, no, it's just an operating license issue?

MR. LYNCH: So based on the information SHINE has provided in their PSAR and discussions we had with the ACRS on this issue, the staff hasn't noted anything that would prevent the facility from being able to operate.

COMMISSIONER BARAN: Okay. I want to also ask about, follow up on prehearing question 11 related to the probabilities used for aircraft accidents and external design-basis accidents. I'm interested in how the staff selected the size of the aircrafts for this hazard analysis. Did the staff look only at the types of aircraft that could land or take off from the nearest airport that the facility intends to be using quite a bit, or did you also assess larger aircraft that could potentially pass through the air space near the proposed facility?

MR. LYNCH: I think the best person to respond to this question would be Steve Marschke.

CHAIRMAN BURNS: Again, Mr. Marschke, just state your name for the record and your position and confirm that you were put under oath.

MR. MARSCHKE: My name is Steve Marschke.

I work with Sanford Cohen & Associates, and we're consulting staff on the chapter 2 review. And, yes, I did take the oath.

When we looked at the aircraft accident probability analysis, we looked at really what SHINE has done. And they looked at all the accidents which are -- or all the aircraft which land and take off at that airport, the Southern Wisconsin Regional Airport. And they have the statistics from the FAA which identifies the types of aircraft, military aircraft. And most of them are air carriers and commuter aircraft and those types of aircraft. They've been grouped into those categories. They also looked at air corridors, which transverse the area. And so, we kind of just -- we reviewed what the SHINE facility has done.

COMMISSIONER BARAN: In terms of those air corridors -- so this is a relatively small regional airport. I assume the planes as you described are relatively small that will be taking off and landing from there. Are the air corridors that SHINE examined and that you all looked at -- are those corridors that involve much larger aircraft? When we talk about planes going to like O'Hare Airport in Chicago or --

MR. MARSCHKE: The air corridor is -- the probabilities associated with the traffic in the air corridors were very low. And so, the air corridors themselves fell below the probability cutoffs. And it's really the aircraft which are utilizing the regional airport which challenge the probability cutoffs.

COMMISSIONER BARAN: Okay. So any larger aircraft beyond what would land or take off at the regional airport didn't kind of pass the probabilities level to be examined. Is that correct?

MR. MARSCHKE: That's correct.

COMMISSIONER BARAN: Okay. Thank you. And just one more question. Prehearing question 35 focused on the assessment of accidental explosions at the SHINE facility. SHINE's response to the question stated that they analyzed the potential impact of natural gas pipelines on the facility. Can the staff or SHINE, whoever makes sense; maybe the staff, Al or Steve -- can you clarify which natural gas pipelines are in the area of the proposed facility and how the staff determined that they were not hazards?

MR. LYNCH: I think we're going to ask to get some help here as well.

COMMISSIONER BARAN: You're back.

MR. MARSCHKE: I'm back.

(Laughter)

MR. MARSCHKE: Can't get enough.

CHAIRMAN BURNS: Still under oath.

MR. MARSCHKE: Yes. Well, my answer is going to be I'm going to have to get back to you on that, because in preparing for today's meeting I wasn't really looking at the pipelines. I wasn't anticipating -- I was anticipating the aircraft questions, but not the pipeline questions, and so I haven't briefed myself. Maybe after lunch I can look at my notes and get back in touch.

COMMISSIONER BARAN: Is this something that the staff has looked at?

MR. MARSCHKE: No, we have looked at it, but I just haven't looked at it recently and I don't want to misinform the Commissioners.

COMMISSIONER BARAN: Okay.

CHAIRMAN BURNS: What we can do, we can either hold to the end of the day if the staff wishes to provide a supplemental answer, or we'll proceed with putting it for perhaps a question following up.

COMMISSIONER BARAN: That makes sense. Thank you, Mr. Chairman.

CHAIRMAN BURNS: Thanks, Commissioner.

COMMISSIONER BARAN: That's all my questions. Thank you.

CHAIRMAN BURNS: A couple things: Just I guess to -- given some of my colleagues' questions regarding the facility and all, can -- probably the Applicant's the best idea. In looking at some of the slides -- it's actually from the first -- the overview presentation, can you give me an idea of the footprint, the area or size of the facility itself? Because I've got a picture, but it could be a doll house or a large enrichment facility. So just give me an idea of the footprint.

MR. HENNESSY: The main building size is around 55,000 square feet --

CHAIRMAN BURNS: Okay.

MR. HENNESSY: -- which is a little over an acre in size. The whole site is 91 acres, so --

CHAIRMAN BURNS: Yes.

MR. HENNESSY: -- we're a dot in the middle of a large area.

CHAIRMAN BURNS: Okay. And so location-wise within that 91 acres are you sort of in the middle of it? Is that the intention?

MR. HENNESSY: Yes.

CHAIRMAN BURNS: So you have a large -- in fact what we'd call in a reactor facility the owner-controlled area in that case?

MR. HENNESSY: That's correct.

CHAIRMAN BURNS: Okay. What is this -- and I'm looking and I just don't recall -- what is the seismic design-basis for the facility? Either the Applicant or the staff can respond to that.

MS. KOLB: The staff can -- or I mean SHINE can respond to that. I'd like to ask Alan Hull to take that.

CHAIRMAN BURNS: Okay.

MR. HULL: Good morning. My name is Alan Hull. I work for Golder Associates. I'm a seismic hazard specialist.

CHAIRMAN BURNS: And you were put under oath earlier?

MR. HULL: I was put under oath, yes, and I took it.

CHAIRMAN BURNS: Please proceed.

MR. HULL: So for the design-basis earthquake you notice there were three stages. I can comment only on the analysis that was done to come up with the ground shaking, and the structural engineer for SHINE will be able to talk about how that flowed on into the actual design of the facilities.

From our analysis we found that this part of the United States is one of the lowest seismic hazards in the area. In fact, there were only about 58 earthquakes within 200 miles in the last 200 or so years. So when we looked at where the seismic design should come from, we analyzed all those facilities as we might have done for a power reactor.

CHAIRMAN BURNS: Yes.

MR. HULL: And by looking at the United States geological survey seismic hazard model for the United States we determined that a magnitude 5.8 earthquake is the likely design-basis or maximum earthquake for this facility. The standard is about 0.2 g.

CHAIRMAN BURNS: Okay.

MR. HULL: That's 20 percent of the force of gravity. We looked at that seismic hazard model for the United States and found that has a return period of about 20,000 years.

CHAIRMAN BURNS: Okay. And my recollection from a long time ago dealing with some other facilities is that 0.2 g -- the shaking force is more or less equivalent to what I think a number of the other reactors are designed for.

MR. HULL: That's my understanding. And my understanding also -- and again, a structural engineer from Sargent & Lundy could provide more detail.

My understanding is that that value of 0.2 g is being used for the structural design of the Quality 1 facilities.

CHAIRMAN BURNS: Okay. All right. Thanks very much.

The other thing is I'd ask the Applicant; and the staff can certainly add, is what analysis of flooding hazards were done with respect to the site? And again, I know nothing of the site, so it may be a silly question and it may not be. But, please.

MS. KOLB: We did do flooding hazards analysis. We looked at the probable maximum precipitation events and the probable maximum flood. The Rock River is about two miles from the site, but the difference in elevation from the site elevation to the Rock River, even in the probable maximum flood situation, is still about 50 feet below the elevation of the site. So that was determined to not pose a hazard to the facility.

For the probable maximum precipitation based on the area of the site, it comes up to about the elevation of the site in the probable maximum precipitation event, which we did analyze, but it does not flood the structure. And if you'd like more detail, we have a geotechnical engineer from Golder that could answer, provide more detail.

CHAIRMAN BURNS: I think that's good for now. Thank you.

The final question I'll have here is with respect to any analyses that were done with respect to control or mitigation of release of tritium from the facility since it does use tritium, and that's been an issue, and it may be again. Because of the design it may not be as much of an issue for you all, but it has been an issue at some nuclear power plant sites.

MR. VAN ABEL: Yes. Yes, as I mentioned before, we have a tritium purification system and the accelerators themselves use a tritium gas target. There are number of features there to control and prevent the release of tritium to the environment. One of the primary ones is that second confinement barrier, the double-walled pipe around the tritium piping. And the tritium processing equipment is in glove boxes, and those glove boxes are continuous scrubbing of the atmosphere to remove tritium from the atmosphere, the glove box and maintain that concentration extremely low. And any discharges from the glove box are monitored and ensured that they're below acceptable limits.

CHAIRMAN BURNS: Okay. Thank you very

much. Thank you. Commissioner Svinicki?

COMMISSIONER SVINICKI: Thank you all for your presentations. I just have one question. It can be for either the staff or the Applicant and which subject matter expert I guess gets to a microphone more quickly, because it's kind of a background question.

10 CFR Part 50, Appendix B QA Program requirements are applicable to power reactors, so they are not in the strictest sense applicable to the SHINE construction permit application. SHINE's slide 3 states that the application was prepared in accordance with the criteria set forward in ANSI/ANS-15.8 QA for research reactors.

Could someone though who is familiar -- I'm more familiar with Appendix B and the component elements of that. What is it that is missing or sacrificed in terms of not using Appendix B versus using the ANSI/ANS standard? Both to my knowledge provide for a graduated approach to QA requirements, so is there any QA expert of the staff or the Applicant who could tell me kind of what is sacrificed between the two? I assume that the Part B -- Appendix B, I'm sorry, QA Program is more rigorous somehow.

Well, I mean, maybe -- and the other question would be; and maybe this will be a follow-up or something to be answered at the end of the day, if possible. Are all the requisite elements that are required in an Appendix B program for coverage of QA -- are those same elements addressed in the ANSI/ANS standard?

MR. ADAMS: I think I can --

COMMISSIONER SVINICKI: Okay. Thank you.

MR. ADAMS: -- take a try at that. So indeed the research reactors follow ANS 15.8, which is endorsed by Regulatory Guide 2.5, Quality Assurance Requirements for Research and Test Reactors. This standard was developed by the ANS 15 Committee, Research and Test Reactor Committee, and it was developed because Appendix B did not apply to research reactors as written.

The coverage areas are the same. In fact, the ANS standard goes a little bit further because it includes additional quality assurance area of experiments, which you don't see in power reactors. Also, the ANS standard was written with the realization that the definition of SSCs in the regulations was written for power plants and may not be strictly applicable to research reactors.

Are you sacrificing something? The staff does not believe so given the difference between power reactors and research and test reactors. Based on the Quality Assurance Program from SHINE, the answers to RAIs and the scope of the standard, and also the Interim Staff Guidance to NUREG-1537 we believe that using ANS 15.8 is applicable for meeting the requirements in 50.34(a)(7) for a Quality Assurance Program.

COMMISSIONER SVINICKI: Okay. Thank you. That's a very complete answer. I don't require any supplement to that. Thank you, Mr. Chairman.

CHAIRMAN BURNS: Okay. Well, thank you to our morning panels for their presentations. We will now adjourn until 1:30 p.m. and we'll take up Safety Panel 2.

(Whereupon, the above-entitled matter went off the record at 11:59 a.m. to reconvene at 1:30 p.m.)

CHAIRMAN BURNS: Okay, we'll call the afternoon session of the hearing on the SHINE application to order for a Construction Permit.

I'll ask the -- well, actually, what we'll do, we'll hear both from the Applicant and then we'll hear from the staff. The staff can stay where they are for the time being.

But, we'll proceed with this afternoon's panel. I'll remind the witnesses that they are under oath and ask you to introduce yourselves again as we begin the afternoon session. And then, you can proceed.

MR. COSTEDIO: I'm Jim Costedio. I'm the SHINE Licensing Manager.

MR. HENNESSY: Bill Hennessy, the Manager of Engineering for SHINE.

MS. KOLB: Catherine Kolb, I'm an Engineering Supervisor.

MR. VAN ABEL: Eric Van Abel, Engineering Supervisor.

CHAIRMAN BURNS: Okay, please proceed.

MR. VAN ABEL: Good afternoon.

For Safety Panel 2, I'd like to discuss the Accident Analysis as presented in SHINE's PSAR.

The basis for identification of accidents for our PSAR was a Hazards and Operability Study. We performed the HAZOPS, a Preliminary Hazards Analysis, a PHA. Both of those are rolled up into an Integrated Safety Analysis.

We also used the events from NUREG-1537 and the ISG augmenting NUREG-1537.

We used the experience of our hazards analysis team which included folks experienced in nuclear plant operations and engineering, personnel experienced in reactor and nuclear process safety.

Personnel familiar with process hazards analysis and safety analysis modeling and methods, personnel experienced with risk analysis and SHINE system engineers familiar with the details of SHINE's processes.

And, this analysis was all done based on our preliminary design information and we do expect to update it with detail design and submit an updated safety analysis with our Operating License Application.

We performed qualitative evaluations within categories of accidents and then performed quantitative evaluation on the limiting accidents within those categories.

We also postulated a Maximum Hypothetical Accident which is typical of the research reactor community. And that MHA was postulated for both the IF and the RPF. And, I'll discuss both of those on the next couple of slides.

Next slide, please?

In the IF, the MHA that we postulated was a rupture of the target solution vessel and its secondary vessel, the SASS, that surrounds it. So, both of those vessels rupture, the target solution is undergoing irradiation and spills into the IU cell.

We ignore the pool. This is all under

water, if you remember, and if we ignore that presence of the pool so the material just spills and disperses into the air.

The high radiation is detected in the IU cell and that initiates isolation of the cell and evacuation alarms for personnel.

The exhaust is filtered through HEPA filters and charcoal absorbers and the calculated dose consequences from that event are 3.1 rem TEDE to the worker and 17 millirem at the fence for the public.

Next slide, please?

In the RPF, the MHA that we postulated was found to have consequences more limiting than the IF MHA, therefore, we designate it the facility MHA. And, that event was the rupture of the noble gas storage tanks in the noble gas removal system.

Those tanks store the off gas from those eight irradiation units after the irradiation cycle. It's stored there for decay and we postulated all five of those tanks shown in blue on the figure on the right there, rupture simultaneously and instantaneously.

The radiation in the room then initiates confinement of that cell and high radiation alarms to initiate evacuation.

Some material bypasses the isolation

dampers and exposes and gets into the ductwork and eventually to the public and some material leaks through penetrations and exposes the workers.

Next slide, please?

The dose consequences for this event were calculated to be 3.6 rem TEDE to the worker and 82 millirem at the fence for the public.

These consequences were calculated in a conservative manner. There's several significant conservatisms including a simultaneous instantaneous rupture of these five tanks. These will be seismically designed, safety-related tanks with proper isolation between the tanks, so we would not expect multiple tanks to rupture.

The tanks, also important to notice, that there's additional isolation dampers in the exhaust ductwork that would trap a large fraction of these radionuclides later on before they get out to the exhaust stack. But, those isolation dampers were not credited in the analysis.

So, the dose consequences would be significantly lower than those calculated here. However, the consequences are within the limits of 10 CFR 20.1101, 1201 and 1301.

And, the figure on the right there shows the dose from the SHINE accident on the left most bar. The center bar is the 10 CFR 20 limit and the bar on the right is the 10 CFR 50.34 dose guidelines for power reactors for comparison.

And, that concludes my presentation.

CHAIRMAN BURNS: Thank you.

Now, we'll ask the staff witnesses to come forward.

And, I'll remind the witnesses that they're under oath and I assume you all took the oath earlier today, correct? Yes, and I want to remind you you're under oath and why don't we begin with introductions of the witnesses?

MR. MORRISSEY: I'm Kevin Morrissey, Fuel Cycle Safety Review.

MR. LYNCH: Steve Lynch, Project Manager, Research and Test Reactors Licensing.

MR. STAUDENMEIER: Joe Staudenmeier, Senior Reactor Systems Engineer, Office of Research.

CHAIRMAN BURNS: Okay, thanks. Please proceed.

MR. LYNCH: So, this panel will discuss the unique accident analyses considerations for the SHINE Utilization and Production Facilities.

I'll provide an introduction to the staff's review methodologies. Joe Staudenmeier and Kevin Morrissey will then discuss the specific details of the staff's review and findings.

Next slide, please?

Based on the anticipated hazards at the SHINE facility, two methodologies were applied to postulated accident scenarios. Postulated accidents at the SHINE facility were evaluated against the radiological exposure limits in 10 CFR Part 20.

Therefore, the SHINE workers are limited to a total effective dose equivalent of five rem per year while individual members of the public are limited to 100 millirem per year. This is consistent with the exposure limits at existing research reactors.

The limiting radiological accident at the SHINE facility is referred to as the Maximum Hypothetical Accident, or MHA.

The MHA assumes a failure that results in radiological releases and consequences exceeding those of any postulated credible accident. The radiological consequences resulting from the MHA are acceptable if the resulting doses to workers and the public are less than 10 CFR Part 20 exposure limits.

In addition to radiological exposure considerations, the radioisotope production facility accident analysis used consequence and likelihood criteria for potential accidents resulting in chemical exposures.

The staff evaluated SHINE's preliminary radiological and chemical consequence likelihood criteria, safety features and methods of assuring the availability and reliability of safety features.

Since the processes and hazards associated with the SHINE radioisotope production facility are similar to those at fuel cycle facilities, the staff determined that SHINE's use of integrated safety analysis methodologies as described in 10 CFR Part 70 is an acceptable way of both selecting the MHA and demonstrating safety.

Joe Staudenmeier will now discuss the accident analysis considerations for the SHINE irradiation facility.

MR. STAUDENMEIER: Thanks, Steve.

The SHINE irradiation units operate at low power and low pressure and, therefore, have low forces to drive a radiological release.

The target solution vessel and criticality safe dump tank sit in a large pool of water that provides passive decay heat removal.

The irradiated target solution and

associated fission products and the tritium used in the accelerators are the sources of radioactive material that could be released during an accident.

Next slide, please?

SHINE has proposed and analyzed a set of postulated accidents that should be representative of the range of events that might happen in an operating facility. Postulated accidents provide insights into the challenges to the safety systems of the facility.

SHINE also analyzed how the potential accidents might be prevented or mitigated by administrative controls, engineered safety features and trained personnel actions.

The dose consequences were calculated to determine the limiting accident.

Next slide, please?

A typical SHINE accident scenario involves a radioactive release into the irradiation unit pool or atmosphere. The atmosphere in the irradiation unit is connected by ducts to the ventilation system.

There are isolation dampers on the ducts that close in the event of a high radiation signal. Workers are evacuated on a high radiation alarm.

The releases reach the outside environment after passing through filters. The calculated releases are small enough that an acceptable emergency planning zone could be the operational boundary.

Next slide, please?

The limiting accident for the irradiation facility is a large rupture of one target solution vessel. The target solution and associated fission products are released and no credit is given for fission product scrubbing by the pool.

The dose consequences from the limiting accident in the irradiation facility are bounded by the limiting accident in the radioisotope production facility.

This accident is a rupture of all noble gas removal system storage tanks where gases produced in the irradiation process are stored while short-lived radioisotopes decay.

The calculated total effective dose equivalent is 3.59 rems for workers, 82 millirems for members of the public at the site boundary and less than 12 millirems at the nearest residence.

The calculated doses meet the 10 CFR Part 20 acceptance criteria of five rem for workers and 100 millirem for members of the public.

Kevin Morrissey will now provide details on the staff's evaluation of SHINE's radioisotope production facility accident analysis.

Next slide, please?

MR. MORRISSEY: Thank you, Joe.

In order to satisfy the 50.34 requirement that a preliminary safety analysis report must assess the risk to the public health and safety, SHINE performed an Integrated Safety Analysis of the radioisotope production facility.

This analysis included radiological and chemical hazard and accident analyses for this portion of the facility.

The accident analyses determined the facility hazards that needed to be protected against and help establish the design basis for this area.

The purpose of the staff's review was to determine that the proposed design of the radioisotope production facility incorporated adequate capabilities and features to prevent or mitigate potential accidents and to protect the health and safety of the facility workers and the public.

The staff's evaluation included review of the following, the integrated safety analysis team, the hazard evaluation process, the integrated safety analysis methodology, the completeness of identification of credible accident sequences, defense in depth features of the design and safety related design features such as process cells and facility structures.

Next slide, please?

The staff reviewed multiple accident event types such as radiological accidents including tank or pipe failures and equipment malfunctions, chemical accidents including tank or vessel failures and exothermic reactions, criticality accidents, fires and external events.

The review of SHINE's non-radiological accidents included chemical safety related accidents and determination of chemical safety controls.

The staff review looked at the equipment and facilities that protect against releases of and chemical exposures to licensed material or hazardous chemicals produced from licensed material.

The staff also reviewed chemical risks of plant conditions that affect the safety of licensed material.

The staff determined that SHINE's preliminary facility design proposed process operations and safety controls for radiological and chemical safety will perform their expected safety function as intended and, thus, they will be adequate to protect public health and safety and the environment.

The staff concludes that, for the purposes of issuing a Construction Permit, there is reasonable assurance that the proposed preliminary accident analysis of the SHINE facility adequately assessed the risk to public health and safety.

The analysis also acceptably supports the determination of the facility hazards in the preliminary safety design including the engineered safety features that protect the health and safety of workers and the public.

This concludes the staff remarks for Safety Panel 2. And we are prepared to respond to any questions at this time.

CHAIRMAN BURNS: Okay, thank you.

What I'd ask the staff witnesses to do is maybe, Mr. Staudenmeier, if you can move to that seat, move a little closer to the secretary and Mr. Morrissey and Mr. Lynch and this way then we can all see each other -- good visual from there and maybe just a little bit closer to the secretary. That's good, that's good.

I believe we start the questioning, Commissioner Baran.

COMMISSIONER BARAN: Thanks.

Steve and Joe, I wanted to -- now you're very far apart -- but, I wanted to ask you about the Maximum Hypothetical Accident for the irradiation facility.

As you mentioned, this involves failure of one of the eight irradiation units. Now, in response to pre-hearing questions five and six, the staff stated that the irradiation units have been designed to withstand any events that could cause multiple units to fail simultaneously.

That's a pretty strong statement and I wanted to give you a chance to talk to us about how you reached that conclusion.

MR. STAUDENMEIER: Okay. As you said, the units were isolated from each other, they're in robust concrete shielding structures and they are designed to withstand any design basis event like seismic or other loadings on the system. And, there's no real way for a failure in one to trigger failures in others or a chain reaction.

COMMISSIONER BARAN: So, the staff looked at tornados, earthquakes, floods, fires, aircraft impacts, loss of offsite power and the staff concluded that none of these events could cause more than one irradiation unit to fail, is that right?

MR. STAUDENMEIER: Well, in terms of

aircraft impact, the smaller aircraft that the type that land at that airport, I know the facility is designed to withstand impacts from those.

I don't think a large aircraft crash was within the design basis of the facility.

COMMISSIONER BARAN: Okay, so with respect to design basis events of those types?

MR. LYNCH: Yes, that is correct.

COMMISSIONER BARAN: Okay. Are there any other kind of beyond design basis events besides larger aircraft that you particularly have in mind that could be an issue?

MR. LYNCH: Not at this time, no.

COMMISSIONER BARAN: Okay. And, you alluded to this a little bit, Joe, but are there -- could any of the common fill drain or off gas line shared by the eight units result in an accident worse than the Maximum Hypothetical Accident because of a common mode failure?

MR. STAUDENMEIER: No, not that I'm aware of. I mean, there's one common mode failure for cooling to the TOGS system, I think, in long term, but the cells would be isolated by that time and SHINE was going to look at that for, I think they had a survival time of four hours maybe for power lasting and they were going to look at that in the Operating License Review.

COMMISSIONER BARAN: Okay. Well, let me just give SHINE a chance if you wanted to add anything on the Maximum Hypothetical Accident for the irradiation units that the staff didn't cover.

MR. VAN ABEL: We did look at potential for other events involving multiple units and we didn't identify any potential events that would be worse than the Maximum Hypothetical Accidents.

COMMISSIONER BARAN: Okay, thanks.

Pre-hearing question 29 asked about safety features for the transfer of the target solution to the radioisotope production facility after irradiation.

I'd like to ask the staff, what criticality risks exist when the target solution is transferred and how is that risk mitigated?

MR. LYNCH: Yes, I think Chris Heysel did a review on engineered safety features. If you would like to say a few words on that?

CHAIRMAN BURNS: Again, identify yourself and confirm that you were previously put under oath.

MR. HEYSEL: For the record, my name is Chris Heysel, I'm a Consultant with ISL. And, I did take the oath earlier.

CHAIRMAN BURNS: Please be seated.

MR. HEYSEL: The engineering safety features are integral to both the IUs and the RPFs. So, the both passive and active features will provide the engineering safety features to mitigate normal and upset conditions.

The design of those features will control a criticality accident due to the geometries associated with them.

COMMISSIONER BARAN: And, will the criticality accident alarm system include coverage for the entire path that the target solution travels during transfer?

MR. HEYSEL: I am not the correct witness to talk about the criticality alarm system.

COMMISSIONER BARAN: Okay.

Very quickly, anyone on the staff would care to answer that?

MR. LYNCH: Chris Tripp, would you like to discuss the criticality accident alarm system and the areas of coverage?

COMMISSIONER BARAN: Just briefly.

CHAIRMAN BURNS: Identify yourself.

MR. TRIPP: Chris Tripp and I did take the oath.

Yes, we don't have the design details of the criticality alarm system in detail. However, SHINE has not identified any areas where they'd be taking exceptions.

So, anywhere there is special nuclear material present, we understand that they would have coverage of those areas.

COMMISSIONER BARAN: Okay, great. Thank you.

Thanks, Mr. Chairman.

CHAIRMAN BURNS: I had a couple of questions in terms of the review and the accident analysis.

What are, and I think SHINE and/or the staff can address this, what are the most significant natural hazards that you had to focus your design on?

MS. KOLB: I guess we can go first.

So, we looked at natural hazards involving flooding, as I spoke about earlier today. We looked at the design basis aircraft, that's not really a natural hazard, that's an external event.

We looked at the tornados, historical maximum tornados. We used guidance from Regulatory Guide, I believe it's 1.76 for the -- that's used for power reactors for the spectrum and the wind speeds for tornados.

We looked at tornado missiles. Anything else I'm missing? I mentioned flooding.

CHAIRMAN BURNS: Okay. And, staff, do you want to add on to that?

MR. LYNCH: The one other thing that SHINE did look at this as well in addition to staff was the rain-snow load on the facility as well as an external event.

CHAIRMAN BURNS: In terms of the roof of the building?

MR LYNCH: Yes, yes.

CHAIRMAN BURNS: Okay.

MR. LYNCH: Yes.

CHAIRMAN BURNS: Okay.

There's just -- actually, part of our discussion focused on not only radiological hazards, but chemical hazards and, I think in the description of the facility, for example, sulfuric acid is used in part of the process.

What are the significant potential chemical hazards that are involved with the facility?

MR. VAN ABEL: For SHINE.

We looked at a variety of chemical hazards in the facility. We do have sulfuric acid, nitric acid, other acids and bases.

We identified 24 chemicals of concern that we use throughout the process and 11 of them were explicitly modeled because of their -- either their toxicity, their dispersibility or inventory. And that includes things like the acids I mentioned, calcium hydroxide, caustic soda, ammonium hydroxide, N-dodecane, potassium permanganate, tributyl phosphate which is part of the UREX process and uranyl nitrate and a couple of proprietary chemicals as well.

CHAIRMAN BURNS: Okay. From the -- go ahead, Mr. Lynch.

MR. LYNCH: Yes, I would just say as far as the chemical hazards and concern, the staff is expecting hazardous chemicals to be in very small quantities at the facility.

The only chemicals that could exceed large quantities which we're considering to be greater than 1,000 pounds would be nitric acid or sulfuric acid. And, there are a number of processes that we are evaluating that involve these chemical hazards and this includes the preparation of the target solution vessel, the radioisotope production, extraction and purification system, target solution clean up and any waste operations.

CHAIRMAN BURNS: Okay. In terms of the

control of those types of hazards, do we look primarily to the regulatory footprint or authority of other agencies or how is that integrated in terms of what the staff would evaluate in terms of acceptability for both the Construction Permit, but looking forward, if we came to a point of an Operating License, what would we do?

MR. MORRISSEY: Well, typically, we evaluate chemical hazards in Part 70 under 70.61. So, we use that and SHINE, that is one acceptable way of doing things and SHINE preferred to take that way.

CHAIRMAN BURNS: Okay.

MR. MORRISSEY: And so, 70.61 provides guidance through 1520 on, you know, how to do chemical safety evaluations.

CHAIRMAN BURNS: Okay. And, just to confirm my understanding on the Maximum Hypothetical Accident that was described is, I understand, or the slides in the presentation, in that event, the expectation would be that a worker dose would be less than the normal occupational dose that is permitted under Part 20, is that correct? I thought I heard something like 3 point X rem.

MR. VAN ABEL: Yes.

CHAIRMAN BURNS: Okay.

MR. VAN ABEL: That's correct.

CHAIRMAN BURNS: And then, the site boundary dose to the public would be 82 millirem as opposed to the 100 millirem? So, then what we're -- at least from our understanding at this point for purposes of Construction Permit, is you have doses that are actually below what we'll call normal dose limitations?

MR. LYNCH: Yes, that is correct.

CHAIRMAN BURNS: Okay.

There was a comment with respect to, and again, looking forward, we're not deciding emergency preparedness requirements in this context today, but there was a comment made and I don't -- I think it may have been one of the staff witnesses, but it may have been SHINE, with respect to the size the -- or the, I guess, not size but, perhaps, boundary of an emergency planning zone was described as the operational boundary.

Can you describe for me what that means? Does that mean the building or does that mean the owner -- what I would call the owner controlled area?

MR. LYNCH: Yes, the operational boundary would be the building itself. And, just to clarify, that is something the staff is still evaluating as to what in the Operating License.

CHAIRMAN BURNS: No, I understand, but I

appreciate that clarification.

That's all I have.

Commissioner Svinicki?

COMMISSIONER SVINICKI: Thank you for your presentations on this panel which were principally regarding Chapter 13 Accident Analysis.

In my preparation between reviewing the record itself and the supplements given in the response to pre-hearing questions, I found there to be a very complete and exhaustive discussion of the Maximum Hypothetical Accident. So, I was satisfied with answers to my questions on those points.

So, I do have two questions that relate to Chapters 11 and 12. And, Chapter 11 addresses waste management issues.

This is for, I think both of my questions will be for the Applicant witnesses.

SHINE has indicated that greater than Class C low level waste would be generated as a result of operating the facility, is that correct?

MS. KOLB: Yes, we do have that in our PSAR.

COMMISSIONER SVINICKI: Okay. So, my question is, if there is no national disposal pathway for your greater than Class C waste, would you have adequate ability to store that on your site for the lifetime of the operations of the facility?

MS. KOLB: Before I answer that --

COMMISSIONER SVINICKI: If not, what is your other alternative plan?

MS. KOLB: So, our designations of greater than Class C waste are two small waste streams and that's based on our preliminary design and some conservative assumptions.

It's possible when we refine the design that we may limit or eliminate that waste stream but, as it stands, we've had discussions with some licensed disposal facilities that have the ability to store greater than Class C waste.

If SHINE did not have a commercial path, either at Waste Control Specialists or some other commercial disposal or storage facility, then the provision of the American Medical Isotope Production Act has a provision to accept the wastes from medical isotope productions and that's what we would --

COMMISSIONER SVINICKI: And that --

MS. KOLB: And that would be our fallback position.

COMMISSIONER SVINICKI: And that provision in the Act is for the Department of Energy or U.S. Government to take that waste?

MS. KOLB: The Department of Energy, that's correct.

COMMISSIONER SVINICKI: Okay, thank you.

And then Chapter 12 is conduct of operations, but broadly, as SHINE looks to the future and the possible need for qualified operators, very conceptually, what do you envision as the skills, knowledge and abilities of the types of experience that a qualified operator for this type of facility would have? Is it someone who has operated power reactors or research and test reactors? Would that be in general the requisite skill set or is it only requiring some sort of smaller set of knowledge skills and abilities?

MR. COSTEDIO: I mean, certainly, we'd entertain the hiring folks with prior power reactor experience and that would be good. Also, nuclear Navy and engineers out of college.

We plan on having a training program in accordance with NUREG-1478 for research and test reactors, that's how they license their operators.

We do have to do some work, you know, with the staff on that to line that up with what we do. But, we certainly plan on having a rigorous SAT-based, you know, training process with exams and very, very similar to what the research and test reactors do now.

COMMISSIONER SVINICKI: Would you envision having any sort of partnership with local maybe technical colleges or others to develop a kind of a qualified worker base for this facility going forward? Is that something you've thought about?

MR. COSTEDIO: Yes, with Blackhawk College, we've talked with them.

Do you have more?

MR. HENNESSY: We have been working with the local technical colleges. There's one up in Northeast Wisconsin which is in partnership with the one down by Janesville that has done a lot of training for RP personnel to work at the power plants that are up there.

And so, they've been looking at transferring those programs down to the Janesville area and we expect that will be very useful to us to help find good staff to staff our facility.

COMMISSIONER SVINICKI: Okay, thank you.

Thank you, Mr. Chairman.

CHAIRMAN BURNS: Thank you.

Commissioner Ostendorff?

COMMISSIONER OSTENDORFF: Thank you, Mr. Chairman.

I'm going to start off with the Applicant, please.

I recognize the unique nature of SHINE that we’ve conceptually looked at today. Is there anything in the radiation detection arena as far as equipment monitoring instrumentation that you would characterize as never tried before or first-of-a-kind engineering or first-of-a-kind instrumentation?

MR. VAN ABEL: No -- we have various radiation area monitors in the facility, continuous air monitors, standard off-the-shelf type technology.

We're looking at neutron flux detectors to monitor the reactivity and the neutron population in the TSV during irradiation.

And, we're talking to existing vendors who supply research reactors with that technology and it's all within normal --

COMMISSIONER OSTENDORFF: So, as far as neutron detectors, you expect to be able to use some technology that's already on the market for that?

MR. VAN ABEL: Oh, yes, yes, that is correct.

COMMISSIONER OSTENDORFF: Okay.

Real quick, did the staff see any challenges in this area for either radiation protection or detection device approaches?

MR. LYNCH: As of now, we have not.

COMMISSIONER OSTENDORFF: Okay.

All right, let me go back to the Applicant real quick.

On your slide four, several times there's reference to the isolation dampers. I know dampers seem pretty straightforward, but dampers can be complex. Are these manually operated? Are they operated by some solenoid or hydraulic system or can you talk about, in an accident scenario, how they'd be operated?

MR. VAN ABEL: We haven't selected the dampers yet. They would not be manually operated, they'd be operated by some actuation mechanism, hydraulic or pneumatic.

We've looked at vendors that supply these for the nuclear industry and there are many choices available that we think will meet our criteria, but they would be automatic actuated by the safety systems and they would be fail close so their fail position would be closed if you lose offsite power, they would close automatically.

COMMISSIONER OSTENDORFF: And the use of the word redundant in front of isolation dampers, does that mean there's more than one damper in the flow path of the ventilation?

MR. VAN ABEL: It means -- yes, nominally there would be two dampers at every place that you need an isolation capability.

COMMISSIONER OSTENDORFF: All right, thank you.

I have no further questions.

CHAIRMAN BURNS: I was about to -- I did this last time, last year, I always went to Commissioner Baran again, to redo a round, but I take it without anything else, we'll dismiss this panel.

Thank you for your testimony and we'll call up the environmental panel.

(Whereupon, the above-entitled matter went off the record at 2:06 p.m. and resumed at 2:08 p.m.)

CHAIRMAN BURNS: Well, thank you, again.

And, we'll, again, with this panel, we'll have the testimony of the Applicant and then the staff testimony, then proceed to questioning.

Again, I remind all the witnesses that they remain under oath and I'll ask you, when you start again and ask you to introduce yourselves, first for the SHINE witnesses.

MS. PITAS: Certainly. My name's Katrina Pitas. I'm the Vice President of Business Development for SHINE.

CHAIRMAN BURNS: Okay.

MR. HENNESSY: Bill Hennessy, Manager of Engineering for SHINE.

MS. KOLB: Catherine Kolb, Engineering Supervisor.

MR. KRAUSE: I'm Tim Krause. I'm an Environmental Coordinator for the project.

CHAIRMAN BURNS: Okay. And, why don't you all start?

MS. PITAS: Thank you.

So, I'm going to give the environmental overview for SHINE today.

Next slide, please?

On this first slide, you will see some pictures of some of the site characterization work that was done. We began that work back in October of 2011 at the Janesville site which was chosen for the SHINE facility.

And, we did that site characterization work to develop the environmental report which followed the final Interim Staff Guidance augmenting NUREG-1537.

Next slide, please?

This table shows the structure and the content of the Environmental Report. After introducing the project, the Environmental Report goes on to discuss the proposed action. It then goes into a detailed description of the affected environment and the resources of the chosen site, Janesville.

Then, it goes on to analyze both the impacts and the benefits of the SHINE technology on the chosen site.

And then, it compares the impacts of the SHINE technology at the Janesville site with the impacts of the no-action alterative, what the impacts of the SHINE technology would be at two alternative sites, Chippewa Falls and Stevens Point.

And then, it looks at the impacts of two alternative technologies.

It then goes on to discuss the conclusions reached by the report.

Next slide, please?

The field investigations we needed to do to gather the information to complete the environmental report were thorough and very extensive.

In addition to a Phase I environmental site assessment and general site reconnaissance, the geotechnical investigation consisted of 15 soil borings, one of which was used for seismic characterization, four of which were converted to groundwater monitoring wells.

A Phase I archaeological investigation, a baseline visual assessment and a wetland delineation were all performed as well as ecological investigations that consisted of quarterly field surveys over the course of one year. Those looked at both aquatic ecology and terrestrial ecology.

And, monthly ground and surface water monitoring that looked at both water quality and water levels.

Next slide, please?

The context for our data acquisition varied depending on which resource was being analyzed. Many of the investigations looked just at the SHINE parcel itself which, as has been mentioned, is a 91-acre parcel on the south side of Janesville, Wisconsin.

Some of the investigations looked a little bit broader at the project area which we consider to be the one mile radius from the site center point.

And then, other investigations looked at the entire region surrounding the SHINE site, often up to five miles in all directions from the center point.

And then, for some of the resources like geology and air quality, we looked at even larger contexts as was appropriate to the resource.

For socio-economic impacts, we looked at what is known as the region of influence. That corresponds to the area that incurs the greatest impacts to community services that result from the SHINE facility and the people who work at the SHINE facility. We determined that to be Rock County, Wisconsin.

Next slide, please?

We also conducted a number of consultations in preparation for the environmental report.

We talked to the City of Janesville, Rock County, the Wisconsin Department of Natural Resources, the Wisconsin State Historic Preservation Office, the Wisconsin Department of Transportation, the U.S. Fish and Wildlife Service, the Federal Aviation Administration, the Bureau of Indian Affairs and we also contacted 13 Native American Tribes including two Tribes located within the State of Wisconsin and 11 Tribes that were non-Wisconsin Tribes.

Next slide, please?

In addition to the impacts of constructing and operating the SHINE facility at the Janesville site, SHINE analyzed two alternative sites and the no-action alternative.

The SHINE project, as has been discussed, results in a number of local, national and global benefits. These include the socio-economic benefits for the local community consisting of tax benefits and increased job opportunities.

The SHINE project also lends support for U.S. Government policies to encourage domestic production of medical isotopes and nonproliferation.

But, most of all, the SHINE project results in health benefits from a reliable, stable supply of technetium-99m, for patients around the globe.

So, in light of these benefits, the no-action alternative is not preferable to the construction and operation of the SHINE facility.

Although the no-action alternative would avoid the environmental impacts associated with the SHINE project, because all of these impacts are small for the SHINE technology, avoiding these impacts is not significant.

And, the no-action alternative would not impart the important benefits that I mentioned before.

Looking at the two alternative sites, Chippewa Falls and Stevens Point, neither alternative site would reduce or avoid adverse impacts as compared with the SHINE site.

As shown in this table, the Janesville site is the preferred site from an environmental perspective, given that it has small impacts to all resource categories while the alternatives had moderate impacts to some resource categories during construction.

Next slide, please?

SHINE also analyzed two -- the environmental impacts of two alternative technologies, both the linear accelerator technology that would be creating moly-99 from enriched or natural molybdenum targets and a low enriched uranium aqueous homogeneous reactor.

Both of these technologies are considered reasonable alternatives to the SHINE technology for the Janesville site from an environmental perspective. But, neither of the alternative technologies would reduce or avoid adverse impacts as compared with the SHINE technology.

Next slide, please?

In mid-2013, the NRC staff conducted an environmental site audit. SHINE gave the staff presentations on the SHINE technology and our site selection process.

The staff then made a number of visits to places of interest in the community. Those included the Janesville site and the surrounding area. We went on a driving tour of about 4.4 miles around the site.

We visited the Rock River. We visited the sites that were used for sampling along the nearby unnamed tributary. We visited the Janesville Wastewater Treatment Facility which included a look at the outfall structure to the Rock River.

And, we looked at both alternative sites. We traveled both to Stevens Point and to Chippewa Falls.

Next slide, please?

SHINE believes the relationships between the company, the City of Janesville and the State of Wisconsin are incredibly important and we worked very hard to build and continuously strengthen those relationships via a policy of transparency and frequent engagement.

Supporting these principles, we ensure a minimum of four public meetings with the community per year, as I had mentioned earlier. And, actually, the most recent of those happened on December 9th.

As a result of these activities and these efforts, we have a relationship with the community that's based on trust, mutual respect and, I believe, genuine enthusiasm for the SHINE project.

Next slide, please?

In conclusion, the SHINE environmental

review was conducted pursuant to 10 CFR Part 51 and is adequate. The requirements of Sections 102(2)(A), (C) and (E) of the National Environmental Policy Act have been satisfied and SHINE's weighing and balancing of the environmental, technical and other costs and benefits of the SHINE facility supports issuance of the Construction Permit.

Thank you.

CHAIRMAN BURNS: Okay, thank you.

We'll proceed now with the staff testimony and I'd ask the staff witnesses to identify themselves and then you can proceed.

MS. MARSHALL: My name is Jane Marshall. I'm the Deputy Director for the Division of License Renewal in the Office of Nuclear Reactor Regulation.

MR. WRONA: I'm David Wrona, the Chief of the Environmental Review Branch in the Office of NRR.

MS. MOSER: My name is Michelle Moser. I'm the Environmental Project Manager in NRR.

CHAIRMAN BURNS: Okay, thank you. Proceed.

MS. MARSHALL: Okay, thanks.

If I can have -- you've got my slide, thank you.

Good afternoon. I'm Jane Marshall and

with me today to discuss the environmental review of the SHINE facility are Dave Wrona and Michelle Moser.

Next slide, please?

As I mentioned during my presentation earlier this morning, part of the staff's review of the SHINE Construction Permit Application included an environmental review which was conducted in parallel with the safety review that you heard about earlier today.

The staff performed the environmental review in accordance with the National Environmental Policy Act of 1969, commonly referred to as NEPA.

In doing it's NEPA review, the staff followed the environmental review process for preparing an Environmental Impact Statement, commonly referred to as an EIS, as described in 10 CFR Part 51 and in the Interim Staff Guidance augmenting NUREG-1537.

The following presentations provide an overview of the environmental review for the SHINE Application while highlighting the unique aspects of this review.

The three novel issues that we will highlight today include the staff's decision to prepare an EIS, the inclusion of the Department of Energy as a cooperating Agency and the NRC staff's analysis to determine the range of reasonable alternatives analyzed in the EIS.

And now, I turn it over to Dave Wrona.

MR. WRONA: Thank you, Jane.

One of the first steps in the environmental review process was determining the appropriate methodology for the environmental review and the level of detail for staff findings.

Environmental reviews for licensing actions fall into one of three categories, those identified as categorical exclusions and not requiring further evaluation, those requiring the preparation of an environmental assessment, commonly referred to as an EA and those requiring the preparation of an EIS.

Licensing actions that require an EIS are described in 10 CFR 51.20. The proposed issuance of a Construction Permit for a medical radioisotope production facility is not specifically listed in 10 CFR 51.20.

Such licensing actions would require an EA or an EIS, depending on project-specific activities and site-specific conditions that could impact the action's potential to significantly affect the quality of the human environment.

After reviewing SHINE's environmental

report, the staff made a project-specific determination that an EIS would be appropriate to assess the environmental impacts of the proposed action.

This determination was made because of the potential for potential significant impacts and unique considerations of a first-of-a-kind application for a medical radioisotope production facility using a unique application of technologies.

The EIS process also allowed for multiple opportunities for public involvement in the environmental review.

In the EIS, we evaluated potential impacts from the proposed action, that is, the proposed construction of the SHINE facility.

Consistent with the Council on Environmental Quality's regulations implementing NEPA, the staff considered connected or related actions and evaluated the potential impacts from operations and decommissioning.

A discussion of potential impacts from operations is also consistent with previous environmental reviews conducted by the staff for Construction Permit Applications, such as the Final Environmental Statements for the Columbia Generating Station and for Arkansas Nuclear One.

Next slide, please?

After publishing the Notice of Intent to Prepare an EIS, the environmental review started with the 60-day scoping period. Scoping is the process by which the staff identifies the specific impacts and significant issues to be considered in the preparation of an EIS.

During this time, we held two public scoping meetings in Janesville, Wisconsin to gather input from the public, federal, state, local agencies and tribes regarding issues to consider in the EIS.

Five attendees provided oral statements at the public scoping meetings, including members of the public, a member of the Janesville City Council and a representative from Congressman Mark Pocan's office.

In addition, the staff received six written letters from members of the public, the Wisconsin Department of Natural Resources, the U.S. Environmental Protection Agency and the Forest County Potawatomi community.

The comments were related to a variety of environmental issues including the potential from aircraft or from accidents due to aircraft collisions, potential contamination to groundwater and nearby agricultural lands, conversion of farmland and alternative sites and technologies.

The staff responded to all comments received during the scoping period in a Scoping Summary Report. It included relevant information from in scope comments and the draft EIS.

Next slide, please?

Another part of the scoping process was to determine if other governmental agencies had expertise or jurisdiction over the proposed project.

For SHINE, two federal agencies were obligated to conduct environmental reviews.

NRC was required to conduct an environmental review to decide whether to grant SHINE a Construction Permit.

The Department of Energy, or DOE, was required to conduct an environmental review for providing financial support to SHINE.

Our coordination with DOE is another unique aspect of this review. The coordination with DOE was unique for two reasons.

First, the NRC typically does not consult with DOE to our separate roles and responsibilities.

Second, the American Medical Isotopes Production Act directs the DOE and the NRC to ensure to the maximum extent practicable that environmental reviews for facilities to produce medical radioisotopes are complimentary and not duplicative.

Therefore, NRC and DOE developed a Memorandum of Agreement to make effective and efficient use of federal resources during the review of the SHINE Construction Permit Application.

The goal of the agreement was to develop a single EIS that would evaluate the impacts of NRC's licensing process and the DOE funding process.

The Memorandum of Agreement designates the NRC as the lead federal agency and DOE is a cooperating agency for developing the EIS for the proposed SHINE facility.

Under NEPA, the lead agency, or NRC in this case, has the primary role in preparing the EIS while the cooperating agency, DOE, is responsible for assisting in the development.

Michelle Moser will now describe the preparation of the EIS and the staff's conclusions.

MS. MOSER: Thanks, Dave.

In developing the EIS, the staff reviewed the information included in SHINE's environmental report, visited the site, considered scoping comments and conducted an independent review to characterize the environmental features at the proposed site in

Janesville, Wisconsin.

The environmental resources described in the EIS includes aspects of both the human and natural environment such as ecological resources, water resources and the socio-economic conditions surrounding the proposed site.

As Jane described this morning, the proposed site is currently an agricultural field. The site has been previously disturbed due to decades of agricultural activities and is currently zoned for light industrial use.

The proposed site does not contain any surface water features, threatened or endangered species or historic or cultural resources.

Next slide, please?

For the proposed SHINE facility at the Janesville site, the impacts to all resource areas, except for traffic, would be small.

A variety of project-specific activities and site-specific conditions is the basis for the small findings.

For example, the condition of the previously disturbed site, the current zoning designation for light industrial use, the relatively limited ground disturbance that would occur during construction, operations and decommissioning, the use of a public water system to obtain and discharge water and adequate controls to ensure that radiological exposures to workers and the public would be within regulatory limits.

The impacts to traffic would range from small to moderate based on the noticeable increase in average daily traffic flow. The addition of up to 1,000 trips per day from construction activities and up to 580 trips a day from decommissioning activities at the proposed SHINE site would result in increased traffic volume near the facility.

During operations, a slight degradation of service, also known as traffic delays, would occur at an intersection near the facility during peak morning hours of commuting.

Slide nine, please?

In addition to describing the existing environment and assessing the potential impacts at the proposed site, the staff assessed potential alternatives.

The need to compare the proposed site with alternatives arises from one of the requirements in Section 102 of NEPA.

The NRC implements this requirement

through its regulations in 10 CFR Part 51 and in its Interim Staff Guidance augmenting NUREG-1537.

The regulations and associated guidance state that an EIS will include an analysis that considers and weighs the environmental effects of the proposed action, the environmental impacts of alternatives to the proposed action and alternatives available for reducing or avoiding adverse environmental effects.

As part of the EIS, the staff considered the environmental impacts of the no-action alternative or if the NRC denied the Construction Permit.

The staff also examined potential impacts at two alternative sites, Chippewa Falls and Stevens Point. Both of these sites are in Wisconsin.

In addition, the staff examined alternative technologies to produce molybdenum-99 which was a unique aspect of the SHINE review.

Next slide, please?

The alternative technologies analysis was novel for the SHINE review because the staff developed a methodology to narrow down the large number of potential alternative technologies given that several entities have proposed new technologies to produce molybdenum-99.

The proposed new technologies are at various stages of development and several entities currently produce molybdenum-99.

The Council on Environmental Quality's regulations implementing NEPA provides guidance when a large number of potential alternatives exist.

In such situations, NEPA only requires that an agency analyze a reasonable number of examples covering the full spectrum of alternatives in the EIS.

To begin the alternative technology evaluation, the staff initially considered the large number of possible alternatives or various methods to produce molybdenum-99 such as currently existing technology and proposed technologies.

The staff initially narrowed the alternatives technology analysis to the three technologies other than SHINE that DOE's National Nuclear Security Administration awarded cooperative agreements for financial support.

The National Nuclear Security Administration based its decision to award cooperative agreements in part on an evaluation of technical feasibility. Thus, these three technologies appear to be reasonable.

The staff also selected new technologies because no entity has proposed constructing a new facility in the United States using technology that is currently in use in other countries.

Additionally, the staff concluded that the three entities awarded cooperative agreements covered the spectrum of alternatives based on the general land use requirements, power levels and other environmental factors.

The three alternative technologies that were selected included neutron capture technology, aqueous homogeneous reactor technology and linear accelerator based technology.

The staff further narrowed the alternatives examined in depth by considering whether sufficient environmental data existed to conduct a meaningful alternatives analysis for each of the three alternative technologies.

For example, the staff looked for publicly available documents that describe the air emissions, estimated dose exposures, water use, building heights and footprints and other environmental parameters to assess the environmental impacts for each alternative technology.

DOE's environmental assessment for the North Star facility provided sufficient environmental data to conduct a meaningful, in depth analysis for the linear accelerator based technology.

The staff did not identify any publicly available documents with sufficient data to assess the environmental impacts for a reactor using neutron capture or an aqueous homogeneous reactor. Therefore, these two technologies were eliminated from further detailed analysis.

Slide 11, please?

In accordance with 10 CFR 51.105(a), the staff weighed the environmental, economical and technical costs and benefits for the proposed action alternative sites, the alternative technology and the no-action alternative.

The main costs included environmental costs as well as the financial costs of construction, operations and decommissioning.

The main benefits included medical and economic benefits.

Next slide, please?

The staff considered the environmental costs of construction, operation and decommissioning. For the proposed SHINE facility at the Janesville site, the impacts to all resource areas, expect for traffic, would be small. The impacts to traffic would be small to moderate because of the noticeable increase in average daily traffic flow.

The staff determined that the environmental impacts would be the same if the linear accelerator based alternative was constructed and operated on the Janesville site.

The environmental impacts at both alternative sites would be small for most resource areas. However, the impacts to noise would be small to moderate at both Chippewa Falls and Stevens Point in part because the nearest resident would be closer than at the Janesville site and, therefore, the noise would be more audible to the closest resident.

The impacts to visual resources would be small to moderate at the Stevens Point site because the site and much of the surrounding area is forested. In clearing onsite forests during construction would increase the visibility of the new facility, especially in contrast to the surrounding forested area.

Similar to the proposed Janesville site, the impacts at both Chippewa Falls and Stevens Point would be small to moderate for traffic.

Therefore, the staff concluded that the Janesville site would be the environmentally preferable alternative.

Under the no-action alternative, no changes would occur to the proposed SHINE site in Janesville, Wisconsin. The site would remain zoned for light industrial use. Therefore, impacts on all resource areas would be small.

However, the no-action alternative does not meet the stated purpose and need to provide a medical radioisotope production option that could help meet the need for a domestic source of molybdenum-99.

Slide 13, please?

In terms of the benefits considered, the proposed action would result in several societal, medical and economical benefits.

For example, the proposed action is in accordance with U.S. policy to ensure a reliable supply of medical radioisotopes while minimizing the use of highly enriched uranium.

In addition, the production of molybdenum-99 would increase availability of medical radioisotopes for U.S. public health needs.

And, lastly, constructing and operating the proposed SHINE facility would result in economic benefits such as tax revenue and employment opportunities to communities located near the Janesville site.

Based on the small environmental impacts associated with the proposed SHINE facility at the Janesville site and the benefits to the U.S. medical community, the efforts to support U.S. policy to produce a domestic supply of molybdenum-99 using low enriched uranium and the economic tax and employment benefits associated with construction and operation of the SHINE facility, the staff determined that the benefits outweigh the small environmental costs.

Next slide, please?

In addition to NEPA, the NRC may address other regulatory requirements within its EIS. For example, the staff conducted a review of potential impacts to the threatened and endangered species as required by the Endangered Species Act.

Under this Act, the staff must consult with the U.S. Fish and Wildlife Service to determine whether threatened and endangered species could occur on the proposed site and, if so, if the proposed action would affect such species.

The proposed action would have no effect on threatened and endangered species because the proposed site is primarily an agricultural field and does not provide suitable habitat for any threatened or endangered species.

In a letter to the NRC, the U.S. Fish and Wildlife Service stated that no federally listed proposed or candidate species would be expected within the project area and no further action is required by the Endangered Species Act if SHINE constructs the proposed facility on the Janesville site.

Under Section 106 of the National Historic Preservation Act, the staff is required to first determine whether historic properties would be affected by the proposed action.

If historic properties would be affected, then the staff determines whether the effects would be adverse.

The proposed action would have no impact on known historic and cultural resources because the staff did not identify any historic and cultural resources eligible for protection under the National Historic Preservation Act.

In July 2015, the Wisconsin Historical Society concurred with the staff's determination that no historic properties would be affected.

Slide 15, please?

On May 11, 2015, staff issued the draft EIS for public comment. During this comment period, the staff requested input from the public and other federal, state and local agencies regarding the data analyses and conclusion in the draft EIS.

During this comment period, the NRC held two public meetings in Janesville, Wisconsin. One member of the public provided an oral statement at the meetings.

In addition, the staff received eight written letters from members of the public, Wisconsin Department of Natural Resources, the U.S. Environmental Protection Agency, Peoria Tribe of Indians of Oklahoma and from SHINE.

In-scope comments addressed a variety of environmental issues including the potential impacts from accidents due to aircrafts, storage of radioactive waste, greenhouse gases and climate change, potential contamination to nearby agricultural lands and alternative sites and technologies.

The staff responded to all comments in the final EIS which was published on October 16, 2015. The staff revised the final EIS based on the in-scope comments and based on newly available information since the publication of the draft EIS.

Next slide, please?

In accordance with 10 CFR 51.105(a), the staff weighed the environmental, economical and technical costs and benefits for the proposed action, alternative sites and the alternative technology and the no-action alternative.

Based on the small environmental impacts associated with the proposed SHINE facility at the Janesville site and the societal, medical and economic benefits associated with the proposed SHINE facility, the staff determined that the benefits outweigh the small environmental costs.

Therefore, in the EIS, the staff recommends the issuance of the Construction Permit.

Slide 17, please?

The issuance of a Construction Permit is a separate licensing action from the issuance of an Operating License. If the NRC issues a Construction Permit, 10 CFR part 50 requires that SHINE submit a separate Application for an Operating License.

If SHINE were to submit an Application for an Operating License for a production or utilization facility, the staff would prepare a supplement to the EIS in accordance with 10 CFR 51.95(b).

The supplement to the final EIS would update the environmental review by discussing issues or topics not included in the final EIS and any new and significant information regarding matters discussed in the final EIS.

The staff would follow the environmental review process outlined in 10 CFR Part 51 in preparing the supplement to the EIS, including scoping, requesting comments on the EIS and updating the supplement to the EIS based on public comments received.

This concludes the staff's remarks in the Environmental Panel. We are prepared to answer any questions you may have.

CHAIRMAN BURNS: Okay. And, what I might ask you to do is do a little bit of shuffle again so we can all see.

And, I'll start off with questions.

I found it interesting, Mr. Wrona, that there was a -- your testimony discussed the question of whether or not an Environmental Impact Statement would have been prepared for this site.

Was there really a serious question that there would not have been an EIS for a project of this kind?

For example, if this were a research reactor, would that have normally required an EIS?

MR. WRONA: The issuance of a Construction Permit for a research reactor would not, again, be in 10 CFR Part 51.20 as required to have an EIS issued.

We look at these on a case by case basis. So, it would depend on what the proposed action is and what is going on at the site where they're proposing.

CHAIRMAN BURNS: Okay. So, in sum, you would say that the two major factors or the major factors that led the staff to conclude that an EIS was an appropriate means of addressing our NEPA obligation were what?

MR. WRONA: It was, for the SHINE case, the unique first-of-a-kind application was one of the things and the main thing that led us to develop an EIS for SHINE. That was pretty much the main issue for development of an EIS.

CHAIRMAN BURNS: Okay, all right, thanks.

I think, Ms. Moser, you, in discussing the alternative technologies, one thing I think I heard you say is that the staff excluded from consideration as alternative technologies, technologies used outside of the United States.

I'm trying to understand that because what that includes, is that basically using what is currently the source, which are research reactors?

MS. MOSER: Correct. We excluded that from further detailed studies.

CHAIRMAN BURNS: Okay, so there isn't some other newer technology that's being considered at this point? I'm just trying to understand the scope of what -- it was interesting how you said that.

So, basically, what it was, you were not considering production in a research reactor such as is currently conducted is what you're saying?

MS. MOSER: Correct, outside of the -- yes, that is currently occurring outside of the United States and we eliminated that from further study within our alternative technology analysis.

CHAIRMAN BURNS: Okay.

One of the things you also just spoke to in terms of describing the comments was comments that were within scope. I presume were some of the comments what you considered out of scope and what would they be? Where, ''I don't like any of this kind of technology,'' is that what I should conclude from that?

MS. MOSER: Yes, we received a few comments that expressed opposition to the facility which we considered out of scope for the environmental impact statement.

Other out of scope comments included --

CHAIRMAN BURNS: But, why were they out of scope? They can -- it's fine to be against the facility but you have to have some -- I presume there has to be some content there that is relevant to the considerations we take into account?

MS. MOSER: Correct. If it would have described environmental concerns that should have been -- that were within the scope of what we analyzed in the Environmental Impact Statement such as concerns from potential accidents, then that we would have considered within scope and that we would have analyzed within the EIS.

CHAIRMAN BURNS: Okay.

You said that there were no historic or archaeological or the impact on historic or archaeological resources wasn't an identified.

You did receive one, maybe two comments from Tribal organizations. What was the nature of those comments?

MS. MOSER: Both of the Tribes that submitted comments to us expressed that they wanted to know additional information if any studies occurred or if there was an inadvertent find of something like human remains, they wanted to be notified.

CHAIRMAN BURNS: Okay. So, they want to be informed if further studies were done or significant remains of some kind?

MS. MOSER: Well, to clarify, one of them asked for a copy of the study that was conducted onsite.

CHAIRMAN BURNS: Okay, okay. All right, thanks.

I wanted -- the last question I have, I want to understand in terms of the assessment of alternative sites and the Chippewa Falls site and the Stevens Lake or Stevens Point, thank you, Commissioner, Stevens Point site.

You described and I saw also in the Applicant's presentation that the differences in impacts were moderate or described as moderate with respect to the Stevens Point and Chippewa site.

And, I think you describe it that that became moderate because of noise consideration. Is that the only thing that reached your assessment that it would become a moderate impact?

MS. MOSER: At Stevens Point, it was noise, visual resources --

CHAIRMAN BURNS: Oh, visual, that's right.

MS. MOSER: -- and traffic.

CHAIRMAN BURNS: Okay.

MS. MOSER: And, at Chippewa Falls it was noise and traffic.

CHAIRMAN BURNS: But, the traffic, it sounded like the traffic at all three sites --

MS. MOSER: Exactly.

CHAIRMAN BURNS: -- is more or less the same?

MS. MOSER: Yes, at all three sites.

CHAIRMAN BURNS: What tips over into a moderate impact in terms of noise? Is it the population near to the -- you said -- I know you described that whoever has their house nearest to that site is closer than at the Janesville site or the proposed site.

Is it also a factor of population in those areas?

MS. MOSER: Two main factors drove that. One was, as you mentioned, how close the nearest resident is because that would affect how audible the noise is.

The second factor is what's the change in noise? So, the amount of noise would be similar across all three sites, but because at the alternative sites, the background noise is less. The delta, the change in noise would be more noticeable.

CHAIRMAN BURNS: And, is this noise primarily during the construction period or demolition period or is it normal operations?

MS. MOSER: Primarily during construction and decommissioning.

CHAIRMAN BURNS: Okay. All right, thank you very much.

Commissioner Svinicki?

COMMISSIONER SVINICKI: May I testify, Mr. Chairman, that both Chippewa Falls and Stevens Point and Janesville are very lovely locations. And, just as someone who will be traveling to Wisconsin next week, I would commend to you that the State of Wisconsin has a really impressive state park and trail system.

And, to Commissioner Ostendorff, for those of us into cycling, distance cycling, Wisconsin has some of the earliest rails to trails conversions that are paved and really extensive. Some of them go through old railroad tunnels.

Now, I did note that the Applicant's photos of site characterizations showed everyone bundled up and shivering in the cold. The staff's visit in July, those were lovely photos that tell you the beauty, the natural beauty, of the State of Wisconsin and the Janesville area.

This is the environmental panel, so this is all germane to our discussion here.

I do thank everyone for their presentations and for all of their hard work that is underlying these evaluations that have been done.

To the staff, interestingly, I came at your elective choice to do an EIS from the complete opposite perspective of a question that the Chairman asked you. An EIS was not strictly required here and given that, one can always elect to do more because there's never anyone who's going to prohibit you from doing the EIS versus the environmental assessment.

How does the staff establish a system of discriminating elements that you don't always default to doing something, doing the EIS, the more involved process? It does increase the resource investment and, you know, has the potential to increase the time duration of the review process as a whole, depending on how the safety review is proceeding in parallel.

You know, how does the -- what would be backstops when the staff would say yes, an environmental assessment is indeed the appropriate thing to do if you have the elective choice?

MS. MARSHALL: One of our points of consideration was how well the staff understood the impacts before performing the assessment. Because this was a first-of-a-kind application for this technology, the staff was not certain with what the outcome of the assessment would be.

If we had performed an environmental

assessment and produced a finding, we would have had to do the Environmental Impact Statement following the assessment. So, that would have increased the time line.

We also considered what actions we would take which included public involvement even in an environmental assessment and the time lines for either an EA or an EIS came out very similar.

COMMISSIONER SVINICKI: That is an important point and I appreciate you mentioning it that an EA can lead to an EIS, so it is not necessarily an either or. You may end up doing the Environmental Impact Statement even if you begin with the environmental assessment process.

So, thank you for the answer on that.

Again, the Applicant has discussed the fact that they have a policy of transparency and outreach. They touched on that in the overview and they touched on it here in this panel with their testimony.

I would ask the Applicant, could you elaborate on your separate and distinct outreach and just creating awareness of the proposed facility and what it would do separate from the staff's outreach under -- to Tribal entities under Tribal outreach for the EIS? Could you discuss any specific outreach you did to the Potawatomi Tribe or to the Ho-chunk Nation and what form that took? Did you make overtures of your own as the Applicant?

MS. PITAS: We did. So, we sent letters to all of the 13 Tribes that I mentioned in my presentation. And then, when we failed to receive responses from the majority of them, actually made phone calls and, in most cases, left voice mail messages with most of them.

COMMISSIONER SVINICKI: Okay.

MS. PITAS: And maybe even all of them. I think probably all of them.

COMMISSIONER SVINICKI: Okay, thank you.

And, I'll just close by just saying, Jane, you should go to Janesville. Did you go on the trip to Janesville? If there was a Kristinesville, I would definitely go.

MS. MARSHALL: I really wanted to go during the --

COMMISSIONER SVINICKI: Oh, and he should go to Stevens Point.

CHAIRMAN BURNS: They spell it differently.

MS. MARSHALL: But no, I do hope to go in the future.

COMMISSIONER SVINICKI: Okay. All right,

thank you.

Thank you, Mr. Chairman.

CHAIRMAN BURNS: Thank you, Commissioner.

Commissioner Ostendorff?

COMMISSIONER OSTENDORFF: Well, since we're still on the travelogue, I think Commissioner Svinicki and I share a common experience every -- twice a day, every day, as we drive from Northern Virginia into the NRC via the American Legion Bridge listening to the WTOP Traffic on the Eights or looking at the Waze display on our iPhones, is it a fair statement that the traffic in Janesville is less than in this area?

COMMISSIONER SVINICKI: It is, but I appreciate that the staff has looked at not replicating the Washington traffic in Janesville, which I don't think any Janesvillian would appreciate.

COMMISSIONER OSTENDORFF: Good, thank you.

I thought that was the case, but I appreciate your clarification.

So, let me turn to the Applicant and I'm going to ask Katrina a question on outreach as well. And, it really gets into the unique nature of this facility.

Certainly, Wisconsin's had experience with the Kewaunee Nuclear Power Plant and Point Beach commercial power reactors. But here, we're talking about, you know, deuterium bombarding tritium and generating 14 MeV and, you know, neutrons and the whole nuclear physics chain. And, the source term is very different from commercial power reactors.

What can you tell us about the understanding from your perspective with the SHINE organization of the local community's appreciation for what this is and what it's not compared to a commercial power reactor? Does that make sense to you?

MS. PITAS: It does. And, it's a difficult question to answer because I think there is a wide range of understanding within the community. I think the community especially appreciates the global impact of the product, medical isotopes, in particular.

We've done our best to develop materials that are simple enough that they increase the understanding of someone without an expert level understanding of nuclear processes and work hard to bring those to our outreach meetings with the community. So, we have posters, brochures.

In terms of understanding maybe the hazards of the facility --

COMMISSIONER OSTENDORFF: Well, I think on your slides and the overview panel earlier today talks about the source term being a factor of hundreds less than for existing isotope production reactors elsewhere.

So, looking at the relative scale of the radiological source, do people understand that?

MS. PITAS: Yes, so I think so. It's one of the key talking points that we use with the public is in comparison to current production methods, the amount of radioactivity produced per useful medical isotope is hundreds of times less than -- yes, people see that as a major benefit and a step forward for global medical isotope production.

COMMISSIONER OSTENDORFF: Okay. Let me stay with the Applicant for a separate question.

You know, our staff talked about the complementary environmental impact statement work between the NRC staff and the Department of Energy. As far as the SHINE organization's concerned, did you see a fairly consistent approach or did you see evidence that different approaches between NRC type questions and Department of Energy questions or how would you characterize that experience?

MS. PITAS: I'm not sure I know. I'm not very -- yes, go ahead, we'll call Greg Piefer to the stand.

MR. PIEFER: So, Greg Piefer, still under oath.

I think, you know, DOE largely let the NRC process drive the show here and I think the NRC process was very thorough. I assume there were some negotiations behind the scenes in terms of making sure DOE specific assessments were included in the NRC process.

But, you know, I think it worked out pretty well in this case and I think the NRC EIS time line was within sort of the Construction Permit Safety Review time line and so, it didn't add any time.

And, you know, the DOE EIS process who knows what would have happened if they had chosen to do an EIS. And so, I think, you know, ultimately, it worked out well in this case.

COMMISSIONER OSTENDORFF: Okay, thank you.

My final comment relates to the NRC staff and goes to Michelle. Your comments and the Chairman's comments on the alternative technologies, I appreciate it.

It seems like the staff has exercised a very commonsense approach. If there's not something there to evaluate then we shouldn't evaluate it. And so, it looks like you all made a judgment call that there was not sufficient evidence to look at some of these other alternative technologies, so I just wanted to comment favorably on the approach being taken.

Thank you. Thank you all.

CHAIRMAN BURNS: Thank you, Commissioner.

Commissioner Baran?

COMMISSIONER BARAN: Thanks.

Michelle, the staff's answer to pre-hearing question 53 stated that it took climate change into account when examining impacts to the affected resources. The staff explained that it looked at annual mean temperature increases and the increase in the frequency, duration and intensity of droughts.

I really appreciate that you did that, that the staff did that analysis. I think we should be factoring in climate change impacts into our environmental reviews more often. So, I commend you all for doing that.

Can you tell us a little bit more about what you did and how you did it?

MS. MOSER: Certainly. In Section 4.2 of the EIS is where we analyzed emissions that could potentially contribute to climate change. And, in

Section 4.13, we conducted a cumulative impacts analysis where we looked at what the overlapping impacts could be from climate change on the environmental resources that could also be affected by the proposed SHINE facility.

COMMISSIONER BARAN: Thank you.

I also wanted to follow up on Commissioner Svinicki's question about greater than Class C waste that she asked earlier.

In response to that question, SHINE, you noted that under the American Medical Isotope Production Act, DOE would take title to and dispose of any radioactive waste without a disposal path.

My question is, have you had any discussions with DOE about how this program would work? Are they committing to physically take possession of the waste or make arrangements to store it or dispose of it at another location within a certain time frame?

MS. PITAS: We'd like to call Vann Bynum to the stand to talk about that.

CHAIRMAN BURNS: And, again, state your name and confirm that you've been put under oath.

MR. BYNUM: My name's Vann Bynum and I did take the oath this morning.

COMMISSIONER BURNS: Okay.

MR. BYNUM: We've had a number of discussions with DOE both at NNSA side and the EM side for the lease and take back program. They've provided us a draft contract template for the take back and we're expecting a revised draft coming in January when the program's supposed to be stood up. So, there's been extensive discussions with them.

COMMISSIONER BARAN: Okay. And is this a matter of them taking formal title to the waste or are they physically going to take it off your hands somehow?

MR. BYNUM: Physically take it off our hands.

COMMISSIONER BARAN: Okay. So, when you all kind of are looking at how long you would expect to potentially need to store it onsite, you're factoring in that DOE is committing to actually take it offsite for you?

MR. BYNUM: Yes.

COMMISSIONER BARAN: Yes? And it's a relatively short time frame?

MR. BYNUM: We hope.

COMMISSIONER BARAN: You hope? Okay. Fair enough.

That's all I have. Thank you.

MR. BYNUM: Thank you.

COMMISSIONER BARAN: Thank you, Mr. Chairman.

CHAIRMAN BURNS: Well, thanks --

COMMISSIONER BARAN: I should just note, I don't have any tourism related questions. At some point on this panel, I'm like, wow, when did I join the Wisconsin Tourism Commission? But, I'll just --

COMMISSIONER SVINICKI: We should be so lucky.

COMMISSIONER BARAN: I'm from the Chicagoland area. Wisconsin's lovely.

COMMISSIONER SVINICKI: So, you're from Chicagoland and you've never vacationed in Wisconsin? You are the only person from Illinois that on a nice weekend is not up there clogging all the highways into Wisconsin.

COMMISSIONER BARAN: I did not say that --

COMMISSIONER SVINICKI: And owning all the prime real estate.

COMMISSIONER BARAN: I don't have any prime real estate in Wisconsin. I have vacationed there, I just wasn't, you know, like advocating vacationing there in the same way.

CHAIRMAN BURNS: And, I engaged in some other -- I told Commissioner Svinicki, I actually represented staff in proceedings in Wisconsin on the La Crosse reactor which is --

COMMISSIONER SVINICKI: And, I do recall you said it was beautiful there.

CHAIRMAN BURNS: And, it was beautiful, it's a gorgeous area.

So, we'll have travel brochures as you exit today.

But, I want to thank the environmental panel.

We're going to take about a five, ten minute break here. Try to be back in about five or six minutes. And then we'll have the closing presentations from both the Applicant and from the staff.

And, for both the Applicant and the staff, I would say if there is any clarification, before your closing statement, if there's any clarification you want to make to the presentations, that would be the time. We can make time to do what you feel you're prepared to do today.

And, with that, we'll, again, adjourn for about ten minutes.

(Whereupon, the above-entitled matter went off the record at 3:00 p.m.)

CHAIRMAN BURNS: Well, good afternoon

again. This is the closing portion of the hearing and we'll start first with the Applicant and I think, Mr. Piefer, you're going to do -- is there any other supplement that you all wanted to do to your testimony or --

MR. PIEFER: No, we have no additions --

CHAIRMAN BURNS: Okay.

MR. PIEFER: -- or changes.

CHAIRMAN BURNS: Then please proceed.

MR. PIEFER: Yes. So I have very little to say at this point. I just wanted to thank you guys again for your time, your consideration in this very important matter.

I did want to offer thanks and commendation to the staff for very transparent and straightforward communications throughout this process. I think our team has been very impressed and wanted to let you guys know that. So thank you again for your time today and really appreciate the consideration.

CHAIRMAN BURNS: Thank you. Mr. Dean, you're on for the staff, but there may be some supplement that the staff would like to make at this point?

MR. DEAN: Yes, thank you, Chairman. Yes, this morning we had I think a few open questions, open issues where we didn't either cleanly answer the question or maybe we left a question open, so we thought it would be beneficial if Steve Lynch could provide you responses to the five particular areas where we think we needed to provide more clarification. So if you don't mind, I'll have

Steve --

CHAIRMAN BURNS: Okay. Mr. Lynch, please proceed.

MR. LYNCH: Yes, I'll run through these very quickly. The first was with respect to the size of aircraft that were analyzed for our review. Just wanted to clarify that the staff examined -- there were three main categories of aircraft that were broadly military, small and large. And the analysis was probabilistic on this looking at both those types of aircraft that would land at the airport and those that would be passing overhead in the corridors. So for this analysis no matter whether the aircraft was landing at the SHINE site, or at the airport across the street, or overhead, if the probability was less than the threshold, it was excluded from examination. The only types of aircraft were two small aircraft, the Challenger 605 and the Hawker 400, that SHINE analyzed as being above the threshold and the facility has been designed to withstand those aircraft impacts.

The second issue we had identified was the natural gas pipelines. To clarify, yes, the staff did look at natural gas pipelines near the SHINE facility and at the SHINE facility. These are provided in figures both in the staff's SER and SHINE's PSAR in chapter 2. There's also a table in SHINE's PSAR in chapter 2 that gives distances and sizes of the natural gas pipelines surrounding the facility. While the sizes of the pipelines are proprietary information, the distances are given.

The next issue I had, I wanted to clarify some statements that we made with respect to differentiating between the irradiation facility and the production facility. In our Interim Staff Guidance we had initially assumed that the irradiation facility or an irradiation-like facility would be dependent functionally on the production facility in order to perform and make medical radioisotopes. So that is why in our guidance we'd initially thought that a single production facility license could be issued for the entire facility.

After reviewing SHINE's application we came to the understanding that the irradiation facility and radioisotope production facility could operate separately and independently, meaning SHINE can irradiate as much uranium as they want at the irradiation facility without impacting the function of the production facility. They don't even need to be in the same building. They could be in different states. So because of that we understood that the irradiation facility is licensed as irradiation units and the production facility is separately licensed as the production facility.

The next issue I wanted to address were distinguishing between commitments and conditions. Items that are identified in SHINE's Corrective Action Program that they provided to the staff and that the staff determined could be reasonably left for later consideration in the final safety analysis report, those represent the regulatory commitments that SHINE has made. The conditions on the other hand are issues that the staff would like more information on during construction. And we'd like to emphasize that the conditions, unlike the commitments, cannot be changed without prior NRC approval.

And then the final item that I would like to provide clarification on were the differences between the soluble uranium intake concentrations of 10 milligrams per week for occupational limits and 30 milligrams for accident conditions. So that's essentially it. We think these two limits are compatible and that for an occupational worker if you're receiving 10 milligrams per week per the regulations you could receive up to 520 milligrams of soluble uranium and still be in line with the regulations each year.

The 30-milligram intake in contrast to that is assuming an acute exposure from a highly unlikely accident, meaning this is an event that has a 10 to the minus 5 likelihood of occurring over a 24-hour period. So we think the differences between routine occupational exposure versus an acute accident exposure explained the differences and that they are consistent with one another.

And those are all the comments that I have to make.

CHAIRMAN BURNS: Okay. Mr. Dean, proceed with your --

MR. DEAN: Thank you. And in light of the previous discussion, I have been to Williamsburg. I don't know if that counts --

(Laughter)

MR. DEAN: Kristinesville and Barantown. I don't know.

The staff's review of the SHINE construction permit application supports the national policy objectives of establishing a domestic supply of molybdenum-99. The SHINE review presented a number of unique technical and licensing considerations for the staff. The timely completion of this review required the expertise, cooperation and dedication of staff throughout the agency. The thoroughness of the staff's evaluation is reflected by the Advisory Committee on Reactor Safeguards' recommendation to issue the construction permit.

I'd particularly like to commend our staff given the fact that this was a first of a kind, unique review and the fact that they were able to accomplish it in a short time frame, within two years. And I particularly want to commend the individual on my right, Mr. Lynch, who has been the project manager for the SHINE. He has just done a tremendous job in terms of overseeing that. So I wanted to take the opportunity to do that at this time.

The staff evaluated SHINE's preliminary design to ensure sufficiency of information to provide reasonable assurance that the final design will conform to the design-bases. The staff considered the preliminary analysis and evaluation of the design and performance of structures, systems and components of the SHINE facility with the objective of assessing the risk to public health and safety resulting from operation of the facility.

Structures, systems and components were evaluated to ensure that they would adequately provide for the prevention of accidents and the mitigation of consequences of accidents. And the staff also considered the potential environmental impact of the facility in accordance with the National Environmental Policy Act.

The objective of the staff's evaluation was to assess the sufficiency of information contained in the PSAR for the issuance of a construction permit. As such, the staff's evaluation of the preliminary design and analysis of the SHINE facility does not constitute approval of the safety of any design features or specifications. Such approval will be made following the evaluation of the final design of the facility as described in the FSAR as part of SHINE's operating license application. An in-depth evaluation of the SHINE design will be performed following the staff's receipt of SHINE's FSAR.

Based on the findings of the staff's review as documented in the Safety Evaluation Report and the final EIS, Environmental Impact Statement, and in accordance with 10 CFR Parts 50 and 51, the staff concludes that there is sufficient information for the Commission to issue the subject construction permit to SHINE. And that concludes my closing remarks.

CHAIRMAN BURNS: Thank you. And for closing, any closing questions or remarks, we'll start with Commissioner Svinicki.

COMMISSIONER SVINICKI: Well, again I want to thank everyone for their presentations. And, Bill, I appreciate that you've been to Williamsburg. And all I have to say, at the risk of sounding like John Belushi in Animal House, if there's a Barantown, I got one thing to say: Road trip. I think we should move immediately that the Commission make a road trip there.

On a more serious note, I think we don't get to this stage in the licensing process or the issuance of a construction permit without tremendous dedication to the task by both the Applicant and the staff, and tremendous professionalism I think was displayed, not only today, but was evident in the description in the engagements both with external parties and with each other that we've heard about in the answers to the questions throughout the mandatory hearing here today.

Again, I'd just note for anyone listening unfamiliar with this process, this hearing and the Q & A we conducted is not the totality of the record. There is tremendous analytical record that backs up all of the responses that we heard today. It is voluminous. And then there were prehearing materials and testimony that was provided to all members of the Commission, which we began with a presumption today that the Commission already knew that, but that was hundreds of pages I think in and of itself.

So I thank again, especially looking inwardly to the NRC, all of the NRC staff that contributed. And that's everyone, both the technical staff, the legal staff, but all those in support roles that make it possible to conduct a hearing like this. And I think that the Commission is well-served to make a very efficient deliberation and hopefully a timely decision on this matter. Thank you, Mr. Chairman.

CHAIRMAN BURNS: Thank you. Commissioner Ostendorff?

COMMISSIONER OSTENDORFF: Thank you. I have no questions. My comments are very similar to Commissioner Svinicki's for SHINE and the organization. I appreciate the professionalism and the attention to detail that you've obviously provided in your application.

To the NRC staff, I am pleased to be part of an organization looking at a new technology and looking at things that are different from what we've done in the past. And so I think that aspect that's been highlighted by many at this table today is very significant. And being able to take a good look at what our regulations require, what's the spirit and the intent and how to apply those to areas where perhaps all the Is may not be dotted and all the Ts may not be crossed, but in a way to execute our responsibilities in a common sense approach when there may not be complete word-for-word coverage that's identical to what we've dealt with in the past. So that's I think a significant accomplishment.

And I do appreciate the work of all the staff, as Commissioner Svinicki noted, across the entire agency. Well done.

CHAIRMAN BURNS: Thank you. Commission Baran?

COMMISSIONER BARAN: Well, just briefly I want to join my colleagues in thanking the NRC staff and SHINE for all of your hard work throughout the review of this application. We appreciate the significant amount of preparation that goes into one of these mandatory hearings, so thank you for all that work.

I think today's hearing's been valuable. It's a valuable part of the process and I thank everyone for their efforts.

CHAIRMAN BURNS: Thank you. And I'll conclude by echoing the comments of my colleagues. As well I appreciate the effort, both the Applicant SHINE, as well as the staff have put into it. And as Commissioner Svinicki said, we're really just doing a sampling here today. There's a much deeper record on which the decision making will be based as we consider whether or not to allow issuance of a construction permit under the Atomic Energy Act for this facility. But it reflects a lot of hard work and thoughtful work by both the Applicant and the staff.

I also want to conclude by thanking behind the scenes support we get as well from the Office of Commission Appellate Adjudication and the Office of the Secretary that assure the smooth flow of these proceedings.

And with that, I will mention two other things, and hopefully not be considered Scrooge in announcing them. And that is that you may expect -- the Applicant and staff may expect the Secretary to issue an order with post-hearing questions by about December 22nd. And the deadline for the responses will likely be December 30th. So you can do it before the new year.

And then also obviously we've had a

transcript made of the proceedings here today and the transcript will be provided by the Secretary with an order requesting proposed corrections. That order will probably be issued around December 21st with a one-week deadline for transcript corrections on December 28th.

Part of the reason for that is the Commission I think in its -- in my experience, both as general counsel and now returning to the agency in the last year with my colleagues presiding over these proceedings is the Commission is dedicated to making decisions in a timely fashion in these proceedings. And in saying that, I do expect us to issue a final decision promptly with due regard to the complexity of the issues before us.

Again, thank you, everyone. And we are adjourned.

(Whereupon, the above-entitled matter went off the record at 3:23 p.m.)

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of)
)
SHINE Medical Technologies, Inc.) Docket No. 50-608-CP
)
(Mandatory Hearing))

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing **ORDER (Adopting Proposed Transcript Corrections, Admitting Post-Hearing Exhibits, and Closing the Record of the Proceeding)** have been served upon the following persons by the Electronic Information Exchange.

U.S. Nuclear Regulatory Commission
Office of Commission Appellate Adjudication
Mail Stop: O-7H4
Washington, DC 20555-0001
E-mail: ocaamail@nrc.gov

U.S. Nuclear Regulatory Commission
Office of the Secretary of the Commission
Mail Stop: O-16C1
Washington, DC 20555-0001
Hearing Docket
E-mail: hearingdocket@nrc.gov

Morgan, Lewis & Bockius, LLP
1111 Pennsylvania Ave., NW
Washington, DC 20004
Counsel for the Applicant
Paul M. Bessette, Esq.
Stephen J. Burdick, Esq.
Andrea N. Threet, Esq.
Mary Freeze, Assistant
Audrea Salters, Legal Secretary

E-mail:
pbessette@morganlewis.com
sburdick@morganlewis.com
andrea.threet@morganlewis.com
mfreeze@morganlewis.com
asalters@morganlewis.com

U.S. Nuclear Regulatory Commission
Office of the General Counsel
Mail Stop - O-15 D21
Washington, DC 20555-0001
Mitzi A. Young, Esq.
Catherine E. Kanatas, Esq.
Edward L. Williamson, Esq.

E-mail:
mitzi.young@nrc.gov
catherine.kanatas@nrc.gov
edward.williamson@nrc.gov

OGC Mail Center :
OGCMailCenter@nrc.gov

[Original signed by Brian Newell]
Office of the Secretary of the Commission

Dated at Rockville, Maryland
this 14th day of January, 2016