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29 May 2014

Cindy Bladey
Office of Administration
Mail Stop: 3WFN-06-A44MP
Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Ms. Bladey:

SUBJECT: DOCKET ID NRC-2014-0068; DRAFT NUREG-1556, VOLUME 10,
REVISION 1

I am forwarding the Naval Radiation Safety Committee comments on the subject NUREG revision in the attached enclosure. We believe that the draft NUREG would benefit from a joint re-write endeavor between the Master Material License (MML) licensees and the Naval Radiation Committee (NRC) staff.

Listed below are some general comments on the draft document:

1. There seems to be a lack of understanding of how a large federal agency gets funding from congress or how the acquisition process in the federal government works.

2. It promotes a 10 year renewal policy that has not been approved elsewhere, and is contrary to the current understanding and agreement between the Navy and the NRC.

3. There is a large amount of redundancy that seems to be superfluous.

4. There are requirements that are more appropriate for the permittees than to the master materials licensees.

5. There are some sections of the document that seem to regard the MML as a broadscope license issued to a university rather than to large federal organization with facilities throughout the world.

Subj: Docket ID NRC-2014-0068; draft NUREG-1556, Volume 10,
Revision 1

Thank you for the opportunity to comment and we look forward to discussing them with your staff or in an open forum along with the other MML licensees. If you have any questions, please contact me at (703) 695-5259 or Dr. Lino Fragoso at (703) 695-5272.

Sincerely,



D. W. FLETCHER, Ph.D.
Commander, MSC, U.S. Navy
Executive Secretary
Naval Radiation Safety Committee

Enclosure (1)
Copy to: Region II

Comments on Draft NUREG 1556 vol. 10

Page	Section	Para	Comment
ALL	ALL	ALL	The U.S. Navy non-concurs with this NUREG as written. We recommend that the NRC does not go forward with publishing this document. There are significant issues with many aspects of the document. We highly recommend that the NRC rewrites this document with current MML partners to develop an acceptable template.
1	1.1	2	Financial status and stability are irrelevant considerations. Only federal agencies may have an MML and they all depend on congressional monetary allocations. Also a license reviewer does not have the qualifications to determine if a federal agency is properly funded.
1	1.1	2	Please clarify as is not clear what is meant by "the independence of the MML management structure; and its commitment to the MML".
2	1.2	2	Delete the second sentence that states that an MML will have an expiration period of 10 years. This is contrary to the original commitments between the Navy and the NRC and to our current dialogue.
2	1.3	2	States "Before filing an MML application, the Federal organization should have a centrally controlled program in place for 5 years. The applicant should describe in general terms the purposes for which it will use licensed material and explain why an MML is needed." It seems that a probationary period of 5 years is excessive especially since it takes several years to process an MML. It is not clear why a federal agency must explain or justify why an MML is wanted beside the desire to have a certain uniformity across its permittees.
4	1.5	2	States "In the readiness review, NRC staff will examine the operational and administrative performance of the centrally controlled RCP with regard to:...incident and allegation handling programs" Federal agencies have allegation processes, including inspector generals that are charged with investigating all allegations. These IG programs have very specific procedures and training of personnel to respond to allegations. Therefore denial of a license may happen because applicant must abide by their IG procedures as opposed to the NRC's.
5	1.6	1	It states "If the NRC determines that the issuance of an MML is not warranted, the applicant may continue with its existing licensed activities and may submit an application for an MML at a later date without prejudice."

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			Please include examples of reasons the NRC would use to determine that an MML is no warranted.
10	2.5	1	<p>It states:</p> <p>'Submit environmental assessment reports pursuant to 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions."</p> <p>Submit alternate disposal requests in accordance with 10 CFR 20.2002, "Method for obtaining approval of proposed disposal procedures."</p> <p>Submit decommissioning financial assurance in accordance with 10 CFR 30.35, "Financial assurance and recordkeeping for decommissioning."</p> <p>These statements are not needed in an LOU as they are already requirements that a licensee must abide by. We suggest that the LOU states exceptions to the requirements or sharing of responsibilities as opposed to what is already a requirement. Otherwise is not clear why these regulations are more important than any of the other requirements in the CFR.</p>
10	2.5	1	<p>It states:</p> <p>Submit an emergency plan for possession of licensed materials pursuant to 10 CFR 30.32, "Application for specific licenses."</p> <p>This requirement is more appropriate for a permittee than for the MML management.</p>
10	2.5	2	<p>It states:</p> <p>The LOU will be finalized and signed by the applicant and the NRC prior to issuance of a new or renewed license.</p> <p>Delete the word renewed since the MMLs are not required to be renewed.</p>
10	2.6	3	<p>It states:</p> <p>"An MML will be issued only to organizations with a good regulatory performance record, based on NRC licensing and inspection of prior activities; and with experience in centralized management oversight, and coordination of permitting, inspection, enforcement efforts, and decommissioning activities, as applicable. Management oversight and coordination experience will also be assessed during the readiness review."</p>

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			In order for an applicant to be able to meet this statement it must have a properly trained staff that can run the program. Will the NRC allow the staff of an applicant to attend the required courses offered by the NRC training center?
15	4	All	We are not clear on what is the purpose of this section if it is not needed for an application. How is the NRC going to evaluate that an applicant organization has leaders that show a commitment to safety?
15	4	4	<p>It states: "An MML program should develop a corrective action program."</p> <p>We are not clear what is meant or required by a "corrective action program". It seems that a corrective action program is more appropriate for a permittee than the MML licensee. If it is a new program for the MML rather than the permittee, does it mean that additional staff will be required for the corrective actions program? Additionally we are concerned because this may mean transferring the responsibility from the permittee to the licensee.</p>
17	5	1	<p>It states: "All items in the application should be completed in enough detail for the NRC to determine that if the proposed equipment, facilities, training and experience, and radiation safety program satisfy regulatory requirements and are adequate to protect public health and safety and minimize danger to life and property."</p> <p>This statement seems to apply more to a permittee rather than to the MML licensee.</p>
17	5	3-5	<p>It states: "10 CFR 20.1406, "Minimization of contamination," requires applicants for licenses to describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment; facilitate eventual decommissioning; and minimize, to the extent practicable, the generation of radioactive waste. As with ALARA considerations, applicants should address these concerns for all aspects of their programs.</p> <p>10 CFR 20.1801, "Security of stored material," states that licensees shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.</p>

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			<p>10 CFR 20.1802, "Control of material not in storage," states that licensees shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage."</p> <p>These statements seem to apply more to a permittee rather than to the MML licensee.</p>
20	5.5	1	<p>It states: "The applicant should provide a list of the manufacturer and model number of all Category 1 and 2 sealed sources used in devices (e.g., self-contained irradiators, panoramic irradiators, instrument calibrators, and radiography cameras). The applicant should specify whether the device(s) is/are registered or not registered in accordance with 10 CFR 32.210, "Registration of product information".</p> <p>These statements seem to apply more to a permittee rather than to the MML licensee. If this becomes a requirement, every time a permittee has a request to amend then it becomes necessary to amend the MML.</p>
25	5.7.2	1	<p>It states: "A manager from the applicant's finance organization."</p> <p>This may not be possible nor effective in many federal agencies, since control of money may reside at different levels with different controls.</p>
25	5.7.2	2	<p>It states: "Representative(s) of occupationally exposed workers."</p> <p>In a federal agency that does logistics, quality assurance, industrial, medical, and research across many commands it would create an unworkable situation for the MML radiation safety committee.</p>
28	5.8	1	<p>It states: "If applicable, to meet the requirements of 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," applicants must ensure that the facility meets the appropriate requirements and the assigned individuals are properly trained before permitting the facility."</p> <p>This statement seems to apply more to a permittee rather than to the MML licensee.</p>
28	5.9	1	<p>It states: "In accordance with 10 CFR 30.33, applicants must describe facilities and equipment used by the licensee to facilitate day-to-day operations.</p>

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			<p>Response from Applicant:</p> <p>Identify all facilities requiring security controls pursuant to 10 CFR Part 37.</p> <p>Commit that the facility will meet the appropriate requirements under 10 CFR Part 37, before permitting the respective facility.</p> <p>Provide location and description of all facilities used by the MML to carry out its activities.</p> <p>These statements seem to apply more to a permittee rather than to the MML licensee.</p>
29	5.10.1	1	<p>It states:</p> <p>In accordance with 10 CFR 30.33, applicants for MMLs must have established administrative controls that should include, at a minimum:</p> <ul style="list-style-type: none"> • central organization and management structure • procedures • recordkeeping • material control and accounting • management review • training qualification plan <p>This needs to be clarified because material control and accounting is the main responsibility of the permittee rather than the licensee.</p>
30	5.10.1	3	<p>This paragraph requires a description of procurement, which is a highly complicated issue in the federal government and one that the radiation safety staff has no control over. Suggest that it is deleted.</p>
31	5.10.3	1	<p>It states:</p> <p>In accordance with 10 CFR Part 20, "Standards for Protection against Radiation," and 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," licensees must develop, implement and maintain written procedures for ensuring control and accountability of licensed material. See NUREG-1556, Vol. 11, for additional useful information on control and accountability.</p> <p>This needs to be clarified because material control and accounting is the main responsibility of the permittee rather than the licensee.</p>

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32	5.10.3	1	<p>It states: "Provide a statement declaring that, "We will comply with the NSTS reporting requirements as described in 10 CFR 22.2207, 'Reports of transactions involving nationally tracked sources'."</p> <p>We do not understand why a statement to obey this regulation is needed as opposed to all the other regulations. Suggest that it is deleted.</p>
32	5.10.4	2	<p>It states: "The applicant should commit to following specific NRC guidance documents in implementing its licensing and inspection programs."</p> <p>If an applicant commits to following the NRC guidance in its application it effectively makes them obligatory and therefore regulatory. Suggest that either the statement is deleted or modified.</p>
33	5.10.4	1	<p>It states: "Provide management's written commitment to follow NRC regulations.</p> <p>Confirm that licensing and inspection programs will be implemented in accordance with NRC licensing and inspection criteria (i.e., NRC regulations, policies and guides), or submit any alternative procedures."</p> <p>These are commitments that are more appropriate for the LOU than for an application. Suggest they are moved to the appendix.</p>
36	5.10.8		<p>It states: "Establishing procedures for the control, use, acquisition, and accountability of byproduct, source, and special nuclear material."</p> <p>and</p> <p>"Establishing procedures to control the procurement and acquisition of radioactive material to ensure compliance with the MML"</p> <p>The statement above is redundant to the first statement, recommend deleting the second statement. Notwithstanding, the acquisition process for a federal agency is controlled by the Federal Acquisition Regulations and not by the radiation safety committee, recommend you delete acquisition or procurement from the sentence.</p>
43	5.10.14	1	<p>It states:</p>

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			<p>“Existing MMLs and their permittees and applicants for an MML should consider the importance of designing and operating their facilities to minimize the amount of radioactive contamination generated at a site during its operating lifetime and to minimize the generation of radioactive waste during decontamination. Licensees are also required by 10 CFR 20.1501, “General,” to make or cause to make such surveys as are necessary to comply with the regulations in Part 20 in accordance with 10 CFR 20.1406, “Minimization of contamination,” the applicant must describe how facility designs and procedures for operation will minimize, to the extent practicable, contamination of the permittees’ facilities and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.”</p> <p>This requirement is more appropriate for a permittee rather than an MML licensee. It is not reasonable to describe every facility that permittees have in an application for an MML.</p>
45	5.10.15	1	<p>It states: “The applicant should document that it recognizes that environmental reviews (i.e., National Environmental Protection Act (NEPA) reviews) for decommissioning would be conducted by the NRC using input provided by the licensee. The licensee does not have the authority to conduct the NEPA review, e.g., CATX/EA/EIS, for any site under the MML. The NRC retains the responsibility for implementing this NEPA requirement.”</p> <p>Edit to clarify: Decommissioning of Permit Activities and Permit Termination Environmental Reviews The applicant should document that it recognizes that environmental reviews (i.e., National Environmental Protection Act (NEPA) reviews) for decommissioning would be conducted by the NRC using input provided by the licensee. The licensee does not have the authority to conduct the NEPA review, e.g., CATX/EA/EIS, FOR TERMINATION OF A LICENSE AT any site under the MML. The NRC retains the responsibility for implementing this NEPA requirement.</p>
45	5.10.15	3	<p>It states: “In accordance with 10 CFR 30.51, “Records,” 10 CFR 40.61, “Records,” or 10 CFR 70.51, “Records requirements,” the MML must keep records showing the receipt, transfer, and disposal of byproduct materials. The NRC will review licensee records on a biennial</p>

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			<p>basis to verify that the licensee's records meet the intent of the regulations."</p> <p>This is an issue for the permittees and not for the MML. Recommend you either delete or modify to reflect</p>
47	5.10.18	1	<p>Corrective Action Program</p> <p>This new program is going to require new staffing the rewriting of procedures and new funding and in addition it has not been discussed before with any of the MML licensees. Recommend that this new requirement is deleted or better explained and discussed with the current MML licensees.</p>
53	6	All	<p>AMENDMENTS AND RENEWALS TO A LICENSE</p> <p>The MMLs do not have an expiration date, therefore renewals are not necessary. Recommend you delete the word "renewal".</p>
C1	Administrative	1	<p>It states in the second sentence: When the NRC has promulgated a rule revising its regulations, the (insert name of centralized organization) and (insert name of MML) permittees will implement and comply with the revised regulations by the effective date of the final rule. The (insert name of centralized organization) will incorporate changes to its policies and procedures within 90 days after the effective date of the final rule to reflect the revisions to the regulations.</p> <p>This sentence is redundant since it is already covered by the first sentence. Recommend that is deleted.</p>
C1	Administrative	2	<p>It states: The MML does not relieve the (insert name of centralized organization) from complying with any other applicable Federal or State law or regulation.</p> <p>This sentence is unnecessary since it has nothing to do with the stated purpose of the LOU in the introduction.</p>
C1	Administrative	3	<p>It states: The NRC shall provide the requested legal and technical advice to the Radioisotope Committee (RIC) as soon as practicable.</p> <p>Change Radioisotope Committee(RIC) to the more common term of Radiation Safety Committee as used elsewhere in the document. Please also commit to a specific time when you will answer the requested advice (eg. 30 days, 6 months, 5 years, etc.) since "as soon as possible" is not a commitment.</p>
C1	Administrative	5	<p>It states:</p>

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			<p>"The (insert name of centralized organization) shall ensure that the transportation of licensed material is in accordance with NRC and the U.S. Department of Transportation (DOT) regulations regarding the shipment of radioactive materials. The (insert name of centralized organization) MML is exempt from Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) Part 71, "Packaging and Transportation of Radioactive Material," requirements when using the DOT exemptions issued to the U.S. Department of Defense for purposes of national security or national defense."</p> <p>This requirement is unnecessary since it is already covered by requirement number 1. An LOU with the NRC should not be covering the responsibilities of the licensee with other federal agencies. Suggest this section is deleted.</p>
C1	Administrative	6	<p>It states: "The (insert name of centralized organization) shall promptly notify the NRC of, or report to the NRC as appropriate, any events as required by applicable NRC regulations."</p> <p>This requirement is unnecessary since it is already covered by requirement number 1</p>
C1	Administrative	6	<p>It states: "The (insert name of centralized organization) shall ensure that (insert MML) permittees will make any required notifications or reports directly to the (insert name of centralized organization) as required by (insert MML procedure including procedure number), to allow the (insert name of centralized organization) to make the subsequent notification or report to the NRC as required by the applicable regulation."</p> <p>Shorten this sentence to: "The (insert name of centralized organization) shall ensure that (insert MML) permittees will make any required notifications or reports directly to the (insert name of centralized organization)."</p> <p>There is no need to quote internal procedures in an LOU, and the statement "as required by the applicable regulation" is redundant with the first requirement.</p>
C2	Administrative	10	<p>It states: "When practical, the (insert name of centralized</p>

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			<p>organization) and the NRC shall use electronic means to conduct official business.”</p> <p>This statement does not need to be in an LOU between two principals, especially since it is non-committal.</p>
C3	Environmental	11	<p>It states: “As provided in NRC regulations, certain license amendment requests are required to be accompanied by an applicant-prepare environmental report (ER) that will aid the NRC staff performing its responsibilities under the National Environmental Protection Act of 1969, as amended (NEPA) as implemented by 10 CFR Part 51. The (insert name of centralized organization) shall submit an ER if the criteria of 10 CFR 51.60 “Environmental report—materials licenses,” applies. The NRC regulations in 10 CFR 51.45, “Environmental report,” set forth the requirements for preparing an ER. Guidance on preparing an ER is set forth in the NRC’s NUREG-1748, “Environmental Review Guidance for Licensing Actions Associated with NMSS Programs,” Chapter 6. The NRC may also require that environmental information be submitted in accordance with 10 CFR 51.41”</p> <p>Delete these sentences as they are redundant with the commitment in section 1.</p>
C3	Permitting	12	<p>It states: “The (insert name of centralized organization) shall incorporate into its permitting program the most current version of the NRC’s guidance (NUREG-1556 series, “Consolidated Guidance about Materials Licenses”), and the guidance provided in the applicable Licensing Guidance Toolkits, which are located on the NRC Web site (http://www.nrc.gov), in order to ensure compatibility with NRC’s licensing program.”</p> <p>This statement is unacceptable since it transforms guidance documents into regulatory documents and essentially any deviation becomes a violation.</p>
C4	Permitting	13	<p>It states:</p>

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			<p>"The (insert name of centralized organization) may approve the use of licensed materials in a permit by individuals who are not (insert name of licensed entity) personnel if the (insert name of centralized organization) determines that such individuals are qualified to use such licensed materials under the permit in accordance with applicable NRC requirements, applicable procedures established by the (insert name of centralized organization), the (insert name of centralized organization) issued permit, and any (insert name of licensed entity) facility procedures. The work space of individuals covered by this paragraph must be under the control of the (insert name of licensed entity) (i.e., the work space must be owned by or leased to the United States, under the administrative control of the [insert name of licensed entity]). The individuals covered by this paragraph include, but are not limited to, (insert name of licensed entity) contractors, students in training, and visiting professionals."</p> <p>It is unclear why this condition needs to be in an LOU since it is already a common practice with other broadscope licenses.</p>
C4	Inspection	14	<p>It states: "The (insert name of centralized organization) shall incorporate the current NRC Manual Chapter 2800, "Materials Inspection Program," and applicable NRC inspection procedures in its inspection program to ensure compatibility with NRC's inspection program."</p> <p>This statement makes it obligatory not to deviate an NRC document. Recommend change to: The (insert name of centralized organization) shall incorporate applicable NRC inspection procedures in its inspection program to ensure compatibility.</p>
C4	Inspection	14	<p>It states: "The (insert name of centralized organization) may telephonically inspect permits with sole commodities (e.g., chemical agent detectors and chemical agent monitors) under program code 03124, according to NRC Manual Chapter 2800."</p> <p>Delete this statement since it is superfluous to an LOU, and covered by other more general statements.</p>
C4	Inspection	15	<p>It states: "The (insert name of centralized organization) shall request authorization through the NRC region (XX) office to alter the inspection frequency to meet the MML's priorities."</p>

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			The LOU already states that the MML licensee can be more restrictive, but this statement implies that permission must be requested in order to be more conservative.
C5	Allegations	18	<p>It states: "The (insert name of centralized organization) will inform the NRC region (XX) office within 5 calendar days of each allegation received."</p> <p>This statement should be modified to the following: The (insert name of centralized organization) will inform the NRC region (XX) office within 5 calendar days of each radiation safety allegation received involving licensed material.</p>
C5	Allegations	20	<p>It states: "The (insert name of centralized organization) should establish a safety conscious work environment in which employees and contractors are free to raise potential or actual issues within NRC jurisdiction that may involve operations, radiological releases, radiation protection or other matters relating to NRC-regulated activities, to their management and to the NRC without fear of retaliation."</p> <p>This statement is already a federal policy and doesn't need to be repeated in an LOU detailing the relationship between the NRC and the licensee.</p>
C5	Enforcement	24	<p>It states: "The (insert name of centralized organization) may take enforcement action against any (insert name of centralized organization) permittee for violations of NRC regulations, MML conditions, or (insert name of centralized organization) permit conditions. However, the (insert name of centralized organization) may not issue a civil penalty to its permittee. The NRC region (XX) office will disposition (insert name of centralized organization) identified apparent escalated violations and NRC identified violations through the normal NRC enforcement process. The NRC reserves the right to impose civil penalties on the MML in accordance with the Enforcement Policy."</p> <p>This statement is unnecessary since very few agencies may issue civil penalties.</p>
C6	Investigations	25	It states:

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			<p>“The (insert name of centralized organization) shall report all suspected wrongdoing or violations of NRC requirements to the NRC region (XX) office. The (insert name of centralized organization) shall address immediate and ongoing safety/security issues promptly and subsequently discuss the safety/security issues with the NRC region (XX) office by telephone, followed by a written report to the NRC region (XX) office within 30 days of the telephonic notice. “Wrongdoing” is defined in 10 CFR 30.10, “Deliberate misconduct.”</p> <p>Recommend that it is reworded to: ...followed by a written report 30 days after finishing the investigation. Making a report within 30 days may be useless paperwork if the investigation is ongoing.</p>
C6	Investigations	26	<p>It states: “The (insert name of centralized organization) shall notify the NRC of any suspected deliberate violations. The (insert name of centralized organization) shall not initiate any criminal investigation into suspected deliberate violations without first receiving approval from NRC’s Office of Investigations (OI).The NRC’s OI may evaluate whether to conduct its investigation in coordination with the (insert name of licensed entity) investigative agency. In accordance with the Memorandum of Understanding between the NRC and the Department of Justice (DOJ), the NRC shall refer substantiated wrongdoing violations to DOJ for prosecutorial consideration.”</p> <p>Change or delete this section. The NCIS procedures and requirements are independent of the regulations governing the MML and criminal intent. The NCIS will determine when they have to investigate criminal activity independently and without permission from the NRC.</p>
C7	Decommissioning	27	<p>It states: “d. To ensure compliance with 10 CFR 30.36, the (insert name of centralized organization) shall ensure that its permittees:...”</p> <p>This section is redundant since statement #1 already commits the licensee to comply with NRC regulations.</p>
C7	Decommissioning	27	<p>It states: “e. To ensure compliance with 10 CFR 30.36, the (insert name of centralized organization) shall:...”</p> <p>This section is redundant since statement #1 already commits the licensee to comply with</p>

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			NRC regulations.
C7	Procedures	28	<p>It states: "The (insert names of licensed entity and centralized organization) will reference its programmatic procedures for the implementation of the MML program."</p> <p>Delete this section since this is more appropriate for an application than an LOU.</p>
C9	Procedures	31	<p>It states: "The NRC and the MML will review this LOU periodically.</p> <p>Change to: Upon mutual consent the NRC and the MML will review the LOU.</p>