

NUREG-1556, Volume 10
External Comments Resolution Table

Comment No.	Commenter	Location in the Volume	Comment	Resolution
1	The DVA	Page iii, Abstract	<p>Recommend revise as indicated for clarification and consistency with current practices.</p> <p>This technical report contains information intended to provide program-specific guidance for existing Master Materials Licenses to apply for an amendment to their license and assist Federal agencies in preparing applications for a Master Materials License. In particular, it describes the types of information needed to complete U.S. Nuclear Regulatory Commission (NRC) Form 313, "Application for Materials License." This document describes both the methods acceptable to NRC license reviewers in implementing the regulations and the techniques used by the reviewers in evaluating the application to determine if the proposed activities are acceptable for licensing purposes. This guidance does not apply to current licensee commitments or require programmatic changes to conform to the guidance.</p>	<p>Comment accepted. However, slight modifications were made to reflect the situations covered by this volume, that is, new applicants and existing MML's amending their license.</p> <p>Comment not accepted.</p> <p>Basis: With the modification made in response to the previous comment, this recommended modification is not necessary.</p>

2	The DVA	Page vi, second paragraph	<p>Recommend revise as indicated for clarification and consistency with current practices.</p> <p>This document provides guidance to Federal organizations preparing a Master Materials License (MML) application and Federal organizations that have MMLs if applying for an amendment to their license. In addition, it provides the criteria NRC license reviewers and other NRC personnel use in reviewing MML applications and requests for amendments to current MMLs. In order for the NRC to issue an MML to a Federal organization, the NRC must ensure that the organization is capable of performing certain functions and activities as a regulator, in much the same manner that the NRC, pursuant to the Atomic Energy Act of 1954, performs these functions and activities. To be granted an MML, a Federal organization must therefore demonstrate that it has a regulatory program that, among other things, can safely issue permits for the possession and use of byproduct, source, and special nuclear material at multiple sites, and has an organizational structure capable of providing adequate oversight and inspection of its permittees. This guidance does not apply to current licensee commitments or require programmatic changes to conform to the guidance.</p>	<p>First comment accepted. However, slight modifications were made to reflect the situations covered by this volume, that is, new applicants and existing MML's amending their license.</p> <p>Second comment accepted.</p> <p>Third comment not accepted</p> <p>Basis: With the modification made in response to the the previous comments, this recommended modification is not necessary.</p>
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3	The DVA	Page 1, first paragraph	<p>Recommend revise as indicated for clarification and consistency with current practices.</p> <p>This report provides guidance to Federal organizations preparing a Master Materials License (MML) application and Federal organizations that have MMLs, if applying for an amendment to their license.</p>	<p>Comment accepted. However, slight modifications were made to reflect the situations covered by this volume, that is, new applicants and existing MML's amending their license.</p>
4	The DVA	Page 1, third paragraph	<p>Recommend revise as indicated for clarification and consistency with current practices.</p> <p>To the extent an applicant chooses to take a different approach, it should justify why the requested information is not necessary in light of the information provided. In the absence of justification, the applicant should opt to use the approach in this document in formatting its application. NRC acknowledges that federal agencies have established administrative and procedural processes that an application should reflect and accepts this as a justification to use different formatting. This guidance does not apply to current license commitments or require programmatic changes to conform to the guidance.</p>	<p>Comment not accepted.</p> <p>Basis: This is already covered in the existing paragraph.</p>

5	The DVA	Page 1, Section 1.1	<p>Recommend delete review criteria for "financial status and stability" since NRC does not have the purview to evaluate this criteria for federal agencies that are funded by the legislative branch of government.</p>	<p>Comment not accepted.</p> <p>Basis: Financial status and stability are relevant considerations that need to be made to determine the viability, and to some extent the sustainability, of a licensee to comply with the regulations before issuing a license. For example, relevant considerations may include the acquisition and proper disposal of licensed materials.</p>
6	The DVA	Page 1, Section 1.2	<p>Recommend add sentence at end of the paragraph for clarification.</p> <p>The permittee functions as an independent entity under the federal agency's organizational structure with responsibility for regulatory compliance under the conditions of the permit issued by the licensee. The licensee establishes a program to provide regulatory oversight consistent with NRC regulations and guidelines.</p>	<p>Comment not accepted.</p> <p>Basis: This document contains guidance for new and existing MMLs, not their permittees. In addition, the next paragraph addresses this comment.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>

7	The DVA	Page 2, second paragraph	<p>Recommend revise second sentence as below.</p> <p>The MML will have expiration dates consistent with all other specific licenses be renewed every 10 years. The MMLs do not have expiration dates. Instead, as part of their biennial inspections, NRC and the licensee will evaluate the need to refresh any specific items in the license, license commitments, or the Letter of Understanding.</p>	<p>Comment accepted, with slight editorial modifications to provide clarity.</p>
8	The DVA	Page 9, section 2.5	<p>Some existing LOUs are not signed documents. Recommend revise last sentence in first paragraph as follows:</p> <p>The LOU is signed should be accepted by representatives from both agencies.</p>	<p>Comment not accepted.</p> <p>Basis: Both parties are required to sign the document.</p>
9	The DVA	Page 11, first and seventh bullets	<p>Recommend substitute "trends or generic issue" for "extent of condition" since the concept of "extent of condition" is ill defined and not applicable for organizational entities such as permittees that are separate and have independent radiation safety programs from each other.</p>	<p>Comment not accepted.</p> <p>Basis: This terminology has been adopted by the NRC and is commonly used throughout the nuclear industry.</p>

10	The DVA	Page 11, response requirement	<p>Strongly recommend delete requirement to describe a corrective action program since that type of program is not required under the regulations for the likely scope of use of radioactive materials for a master materials licensee. Further, the historical regulatory compliance by the current master materials licensees does not support any possible need or usefulness of a new bureaucratic program to track corrective actions.</p> <p>The statement that a corrective action program is one of the elements of a positive safety culture and should be implemented by master materials licensees is not supported by any regulatory requirements and is contrary to previous commission directions to the NRC staff.</p> <p>In the "Policy Issue" for SECY-12-008 (dated January 19, 2012) for the implementation plan for the safety culture policy statement, this paragraph specifically indicates limitations for NRC staff related to implementation.</p> <p>"... SRM-SECY- 11-0005 directed the staff to "obtain Commission approval for any staff activities beyond communication and education."</p> <p>By inserting a specific requirement for the applicant to describe their corrective action program, NRC staff are requiring applicants to commit to safety culture elements that are clearly beyond communication and education.</p>	<p>Comment not accepted; however, this sentence has been deleted because the corrective action program section was re-written as a result of the public comments received at the January 21, 2015 public meeting on this volume.</p> <p>Basis: Although not required, a corrective action program is a common practice among NRC licensees.</p>
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11	The DVA	Page 15, last paragraph	<p>Strongly recommend delete reference to a corrective action program since that type of program is not required under the regulations nor warranted based on the historical regulatory compliance by the current master materials licensees.</p> <p>The statement that a corrective action program is one of the elements of a positive safety culture and should be implemented by master materials licensees is not supported by any regulatory requirements and is contrary to previous commission directions to the NRC staff.</p> <p>In the "Policy Issue" for SECY-12-008 (dated January 19, 2012) for the implementation plan for the safety culture policy statement, this paragraph specifically indicates limitations for NRC staff related to implementation.</p> <p>"... SRM-SECY- 11-0005 directed the staff to "obtain Commission approval for any staff activities beyond communication and education."</p>	[See comment response on next page.]
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11 (cont.)			<p>By inserting a specific requirement for the applicant to describe their corrective action program, NRC staff are requiring applicants to commit to safety culture elements that are clearly beyond communication and education.</p> <p>See proposed revision below.</p> <p>Safety culture traits are may be inherent to federal agencies and expected to be part of an organization's existing radiation safety practices and programs. An MML program is encouraged to incorporate existing agency guidelines for safety culture and a safety conscious work environment into their training guidelines for permittees with appropriate cross reference to NRC guidelines for a safety culture should develop a corrective action program. An MML that develops and implements a corrective action program will be more adept at identifying and fixing safety problems as well as evaluating effectiveness of the corrective action, both immediately and in the long term. Incorporating existing agency guidelines into radiation worker training Developing a corrective action program is an action that may correspond with the safety culture training specified...</p>	<p>Comment not accepted.</p> <p>Basis: This language is consistent with that currently in NRC guidance documents, such as the NUREG-1556 series.</p>
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12	The DVA	Page 17, Section 5	<p>Recommend add paragraph at the beginning of the section to clarify the scope of information that is being requested.</p> <p>The licensee establishes a centrally controlled radiation control program to provide regulatory oversight consistent with NRC regulations and guidelines. The permittee functions as an independent entity under the licensee's organizational structure with responsibility for regulatory compliance under the conditions of the permit issued by the licensee. For purposes of an application, the licensee should provide items that describe what is required at the licensee or radiation control program office level. The licensee through permitting, inspections, and investigations confirms that the permittee has achieved regulatory compliance but is not involved in the day-to-day implementation of radiation safety program at the permittee.</p>	<p>Comment not accepted.</p> <p>Basis: This document contains guidance for new and existing MMLs, not their permittees. The scope of material requested is defined in each respective subsection.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>
13	The DVA	Page 17, Section 5	<p>Recommend delete the second through sixth paragraphs as not being applicable to the organizational structure for the radiation controls program office. These items are adequately addressed in NUREG-1556, Vols. 7, 9, and 11, and are appropriate for permittees who are being authorized by the centralized RPC to possess and use radioactive materials.</p>	<p>Comment not accepted.</p> <p>Basis: This information is required for license application review. The applicant may choose to incorporate these guidance documents into their response.</p>

14	The DVA	Page 22, Section 5.7	<p>Recommend revised paragraph as follows.</p> <p>In addition, as part of the information that should be submitted under Item 7 of NRC Form 313, the applicant should specify any delegations of authority for these positions, as well as the management tool procedures used for the oversight of the program.</p>	Comment accepted, with slight editorial modification for clarity.
15	The DVA	Page 22, Section 5.7.1	<p>Recommend add sentence at end of the last paragraph on this page.</p> <p>This senior management oversight is normally accomplished by the establishment of a Master Radiation Safety Committee with routine participation by a senior management representative and reports to the senior manager for significant programmatic outcomes. Audits or reviews are accomplished under aegis of the master committee and reported, at least annually, to senior management.</p>	<p>Comment accepted.</p> <p>With slight language modifications for clarity.</p>
16	The DVA	Page 23, third paragraph	<p>Recommend revise as indicated.</p> <p>MMLs are required to establish an MRSC and radiation control program that represents management..</p>	Comment accepted.
17	The DVA	Page 24, bullets	<p>Delete the first bullet as being redundant to the fifth bullet. Revise the fifth bullet as follows.</p> <p>Describe the senior management oversight and mechanisms used by management to ensure adequate control over MML activities such as using the Master Radiation Safety Committee to audit and evaluate overall program implementation. The senior management oversight activities should include:</p>	<p>First comment not accepted.</p> <p>Basis: The bullets contain different criteria and intentions.</p> <p>Second comment accepted.</p>

18	The DVA	Page 24, Section 5.7.2	<p>Recommend revise first paragraph as follows.</p> <p>... ensures that adequate resources are provided by licensee management for the committee and radiation control program office, and...</p>	Comment accepted
19	The DVA	Pages 24 and 25, Section 5.7.2	<p>recommend revise bullets as indicated.</p> <p>A senior manager from the applicant's executive management organization to serve as the Chairperson and empowered with full authority to commit licensee resources to support the conduct of the implement the MML by having stop work authority and authority to direct the radiation control program office.</p> <p>A manager from the applicant's finance organization. A senior manager to represent senior management and with access to financial and budgeting officials consistent with the agency's usual funding methods and procedures.</p>	<p>Comment accepted, with slight modification for clarity.</p> <p>Second comment not accepted; however, this wording was revised based on feedback from the January 21, 2015 public meeting on this volume.</p>
20	The DVA	Page 25, bullets	<p>Recommend delete bullet as indicated.</p> <p>Manager(s) who represent permitting and inspecting organizations.</p>	<p>Comment not accepted.</p> <p>Basis: This is an example, not a requirement.</p>
21	The DVA	Page 26, Response from applicant	<p>Recommend revise third bullet as follows.</p> <p>Describe the duties of the MRSC Chairperson and provide commitment that the Chairperson or management representative has access to financial and budgeting officials consistent with the agency's usual funding methods and procedures full authority to commit licensee resources to support the conduct of the NAL.</p>	Comment accepted.

22	The DVA	Page 26, Response from applicant	Recommend delete note that chairperson is to be listed on the master materials license.	Comment accepted.
23	The DVA	Page 27, Response from applicant	Recommend delete fourth bullet as not being applicable to this section.	Comment accepted.
24	The DVA	Page 28, Section 5.8	<p>Recommend delete the last sentence in the paragraph and substitute this revision. Recommend delete requirement for a response from the applicant.</p> <p>The requirements for training and experience for radiation workers is addressed as permitting actions for issuing individual permits to facilities and during inspections. The applicant is not required provide a response for this section.</p>	<p>Comment not accepted.</p> <p>Basis: This document contains guidance for new and existing MMLs, not their permittees. The training program that meets the requirements of the cited regulations needs to be submitted for the MML.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>

25	The DVA	Page 28, Section 5.9	<p>Recommend add this sentence to the paragraph and adjust the bullets as indicated.</p> <p>The requirements for facilities and equipment are addressed during permitting actions for issuing individual permits to facilities and during inspections.</p>	<p>First comment not accepted</p> <p>Basis: This document contains guidance for new and existing MMLs, not their permittees. The required information regarding facilities and equipment regulated by 10 CFR Part 37 must be submitted by the MML in the application process.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>
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25 (cont.)			<p>Identify List all facilities requiring security controls pursuant to 10 CFR Part 37.</p> <p>-Commit that the facility will be required by the radiation control program office(s) to meet the applicable 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 radiation control program office(s) to carry out its activities.*</p> <p>-State in the application where all docketed and required files and records will be maintained by the radiation control program office(s).</p> <p>-Provide a list and description of the laboratory equipment such as counting systems, portable survey equipment, air monitoring, or other devices necessary for conducting the inspection of permittees by the radiation control program office(s).*</p>	<p>Comments two through three partially accepted (the applicable content was deleted).</p> <p>Comments four through six not accepted.</p> <p>Basis: This document contains guidance for new and existing MMLs, not their permittees.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>
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26	The DVA	Page 29, Section 5.10.1, bulleted list	Recommend deleting the fourth bullet on "material control and accounting." Material control and accounting are performed by the individual permittees consist with conditions of their specific permits. The radiation control program office follows NRC guidelines for stating possession limits in permits.	<p>Comment not accepted.</p> <p>Basis: This document contains guidance for new and existing MMLs, not their permittees. MMLs should have material control and accountability to assure compliance with license limits and requirements.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>
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27	The DVA	Page 29, Section 5.10.1, last paragraph	Recommend delete reference to "quality control surveillance" since this appears to be a redundant and extraneous concept not otherwise used in the document. Recommend delete reference to "procurement" since this appears to be more applicable to permittee level activities vice the radiation control program office. These two references should also be deleted where used on page 30.	<p>Comment not accepted.</p> <p>Basis: This document contains guidance for new and existing MMLs, not their permittees. Quality control is important in many areas of radiation safety (e.g., instrument calibration). The MML is responsible for activities conducted by the permittees and therefore oversight of procurement activities to assure they are conducted appropriately.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>
28	The DVA	Page 30, note at top of page	Recommend deleting note. These issues are all addressed in the LOU and do not need to be separately repeated in a response for item 10.	<p>Comment not accepted.</p> <p>Basis: The license and LOU may be developed separately; therefore, this ensures criteria are addressed.</p>

29	The DVA	Page 30, response from applicant, second bullet	Recommend delete reference to material control and accounting since this requirement is addressed during permitting actions to issue permits to individual facilities.	<p>Comment not accepted.</p> <p>Basis: This document contains guidance for new and existing MMLs, not their permittees. MMLs should have material control and accountability to assure compliance with license limits and requirements.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>
30	The DVA	Page 30, response from applicant, third through sixth bullets	Recommend delete these bullets and replace with a note that these elements are to be described in the LOU.	<p>Comment not accepted.</p> <p>Basis: The license and LOU may be developed separately; therefore, this ensures the criteria are addressed.</p>

31	The DVA	Page 31, Section 5.10.3	<p>Recommend add a new sentence at the end of this page as follows.</p> <p>The requirements for material control and accountability are addressed as permitting actions for issuing individual permits for facilities and during periodic inspections of permittees by the radiological control program office.</p>	<p>Comment not accepted.</p> <p>Basis: This document contains guidance for new and existing MMLs, not their permittees. MMLs should have material control and accountability to assure compliance with license limits and requirements.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>
32	The DVA	Page 32, Response from applicant	<p>Recommend delete the first two bullets and revise the fourth bullet as follows.</p> <p>Provide a statement that "We will require permittees to develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times."</p>	<p>Comment not accepted.</p> <p>Basis: This document contains guidance for new and existing MMLs, not their permittees. MMLs should have material control and accountability to assure compliance with license limits and requirements.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>

33	The DVA	Page 33, Section 5.10.5, second paragraph:	<p>Recommend revise sentence as follows.</p> <p>The process should include provisions for submitting updated documents to the NRC for review and license amendment if the document is specifically referenced in the MML. or and causes a material change in the MML policies and procedures.</p>	<p>Comment not accepted.</p> <p>Basis: Tiedowns are commitments made by the licensee that are incorporated into the license, and are thus requirements and must be amended when applicable.</p>
34	The DVA	Page 33, Section 5.10.6, last sentence	<p>Recommend revise sentence as follows.</p> <p>The MRSC provides administrative control regulatory oversight of all NRC licensed radioactive material used by the licensee and its permittees on behalf of senior management and acting through the radiation control program office.</p>	<p>Comment accepted.</p>
35	The DVA	Page 34, first paragraph	<p>Recommend revise first sentence as follows since NRC does not have the purview to evaluate this criteria for federal agencies that are funded by the legislative branch of government.</p> <p>The applicant, as a federal agency, should commit to provide adequate funding demonstrate it is financially qualified to conduct an MML program effectively.</p>	<p>Comment not accepted.</p> <p>Basis: Financial status and stability are relevant considerations that need to be made to determine the viability, and to some extent the sustainability, of a licensee to comply with the regulations before issuing a license. For example, relevant considerations may include the acquisition and proper disposal of licensed materials.</p>

38	The DVA	Pages 36 and 37, Section 5.10.8:	<p>Recommend revisions to the bullets to reflect the appropriate role of the committee for regulatory oversight.</p> <p>The regulatory oversight responsibilities of the MRSC should include, but are not limited to, the following. These actions are normally completed through the radiation control program office.</p> <ul style="list-style-type: none"> -Establishing, Requiring permittees to establish and maintain procedures for the control, use, acquisition, and accountability of byproduct, source, and special nuclear material. -Managing and overseeing Providing regulatory oversight for implementation of the MML. -Monitoring the performance of the RCP and the RCPD, and auditing the implementation of the RCP. -Advising senior management of the results of the MRSC audits and program reviews. -Ensuring that adequate resources are provided to implement the RCP, including implementation of permittee radiation safety programs. - Ensuring that adequate resources are provided for the training of MRSC, RCP, and permittee staff. Recommending funding and resource requirements to senior management for the committee and radiation control program office functions. -Ensuring that permitting and inspection staff are appropriately qualified, as described in IMC 1248, or an equivalent training and qualification program -Maintaining records under the MML 	<p>Comments not accepted.</p> <p>Basis: This document contains guidance for new and existing MMLs, not their permittees. The list lays out typical responsibilities that the MML MRSC is expected to perform.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>
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38 (cont.)			<ul style="list-style-type: none"> -Reviewing permitting actions applications completed by the radiation control program office and recommending follow-up actions, if needed to be taken by the Chairperson or his/her designee. -Meeting quarterly with an established quorum (i.e., Chairperson or his/her designee, RCPD, and two-thirds of the remaining membership) to review the activities of the RCP. -Maintaining a current list of locations permitted to use radioactive materials of quantities, uses, and locations where radioactive material is received, possessed, used, or stored. -Establishing Requiring permittees to establish and maintain procedures to control the procurement and acquisition of radioactive material to ensure compliance with the MML -Ensuring that inspections are conducted to assess permittee compliance with the provisions of the license, NRC regulations, and the specific permits -Establishing enforcement policies and procedures -Advising senior management and the NRC of all non-compliance items potentially categorized at severity levels I, II, or III, as identified in the NRC enforcement policy -Providing copies of permits and inspection reports to the appropriate NRC regional office, if requested -Requesting assistance from appropriate individuals and licensee organizations when necessary to assist the MRSC in the execution of its responsibilities 	<p>Comment not accepted.</p> <p>Basis: This document contains guidance for new and existing MMLs, not their permittees. The list lays out typical responsibilities that the MML MRSC is expected to perform.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>
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38 (cont.)			<p>-Establishing technical committees if necessary to extend staff capabilities for unique or technically complex problems</p> <p>-Establishing decommissioning policies and procedures</p> <p>-Conducting at least annually a review of the program, pursuant to 10 CFR 20.1101.</p>	[See comment response on previous page.]
39	The DVA	Page 37	<p>Paragraph above “Response from applicant” and last two bullets on the page: Recommend revise paragraph as follows and revise last two bullets to be consistent with the revised paragraph.</p> <p>The application should include the organizational and procedural manuals the committee procedures that address each item above; the written delegation of authority for the MRSC; the established quorum requirements (i.e., Chairperson, RCPD, and two-thirds of the remaining membership). The applicant should also describe criteria the conditions under which it will obtain assistance from other subject matter experts technical boards and other entities and identify and describe any existing boards or entities list any current subject matter experts or consultants that it uses to support the MRSC.</p>	Comments accepted, with slight editorial modifications for clarity.

40	The DVA	Page 37, second Note	<p>Recommend revise note as follows.</p> <p>The delegation of authority should state the MRSC's authority to suspend or terminate activities based on poor performance or violation of safety standards and provide assurance of the Chairperson's full authority to commit licensee resources to support the conduct of the MML.</p>	Comment accepted.
41	The DVA	Pages 38 and 39, Section 5.10.10:	<p>Recommend delete this section and incorporate the requirements into Section 5.10.9 since the duties of the permitting and inspection staff are more correctly tasked under responsibilities for the Radiation Control Program Director with the director having the option to then assign tasks to his/her subordinates. The current section is unduly prescriptive in assigning tasks for permitting and inspection staff given the director might assign some of the tasks to ancillary or administrative staff who are not within the category.</p>	<p>Comment not accepted.</p> <p>Basis: This is general guidance for consideration and not meant to be prescriptive in nature.</p>
42	The DVA	Page 40, second set of bullets related to quarterly reports;	<p>Recommend delete the opening sentence and three bullets since this topic does not appear to be related to the requirement for internal procedures.</p>	<p>Comment not accepted.</p> <p>Basis: This is general guidance for consideration and not meant to be prescriptive in nature.</p>

43	The DVA	Pages 40 and 41, Section 5.10.12:	<p>Recommend revise to delete separate requirement for management audits in addition to audits by the master radiation safety committee. See revision as follows.</p> <p>The MRSC should be fully aware of the operations and activities of the RCP. The MRSC should conduct management audits and evaluations of the RCP's performance, including the RCPD. Results of the MRSC's audit and program reviews should be reported to senior management to allow for timely and proactive aggressive-remedial actions sufficient in scope to ensure compliance with NRC regulations and license conditions. As a minimum, the MRSC should report summary audit results to senior management at least annually and for significant program outcomes such as escalated enforcement actions. An MML may also consider establishing MRSC subcommittees to evaluate and audit those areas of the program within their areas of expertise.</p>	Comment accepted, with editorial changes.
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43 (cont.)	The DVA	Pages 40 and 41, Section 5.10.12:	<p>Audits of the inspectors and permit reviewers should be conducted on an annual basis. Guidelines should be established for evaluating inspector and reviewer performance including annual field evaluations for inspectors by the RPCD or inspection staff supervisor with results provided to the MRSC. Management policies and guidelines should be in place for reporting audit results to senior management. In accordance with 10 CFR 30.33, inspectors should demonstrate competence in evaluating health and safety problems and in determining compliance with NRC regulations. Inspectors should demonstrate an understanding of regulations, inspection guides, and policies before conducting inspections independently. The MMR MRSC should establish a system similar to NRC's qualification journal system found in IMC 1248.</p> <p>The RPCD or the inspection staff supervisor should conduct annual field evaluations of each inspector to assess performance and assure use of appropriate and consistent policies and guides.</p>	Comment accepted.
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43 (cont.)	The DVA	Pages 40 and 41, Section 5.10.12:	<p>-Describe how inspectors demonstrate an understanding of regulations, inspection guides, and policy practices before conducting inspections independently.</p> <p>-Describe how permit reviewers demonstrate competence in reviewing applications for permits.</p>	[See comment response on previous page.]
44	The DVA	Page 42, second paragraph, second sentence:	<p>Recommend revise sentence as follows.</p> <p>Permit applicants should be furnished provided access to copies of applicable regulatory guidance by links to the radiation control program office Web site or NRC Web site.</p>	Comment accepted, with slight modification for clarity.
45	The DVA	Page 43, Section 5.10.14:	<p>Recommend add paragraph below for context and to clarify this section. Recommend delete requirement for a response from the applicant.</p> <p>The requirement to minimize contamination at permittee facilities is addressed during permitting actions to issue individual permits to facilities and during inspections. The master materials license applicant should require permit applicants to describe how facility design and procedures for operation will minimize contamination of the facility and environment, facilitate eventual facility decommissioning, and minimize generation of radioactive wastes. No response from the master materials license applicant is required for this item.</p>	<p>Comment not accepted.</p> <p>Basis: This document contains guidance for new and existing MMLs, not their permittees. MMLs should be prepared to provide an overarching description of the types of designs and procedures that will be implemented to minimize contamination at its permittees.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>

46	The DVA	Page 45, Response from applicant	<p>Recommend revise first bullet as follows.</p> <p>Provide decommissioning and permit termination procedures or commit that permit facilities will be decommissioned and permits will be terminated as described in NRC regulations, policies, and the guidance in NUREG-1757 and the Letter of Understanding.</p>	Comment accepted.
47	The DVA	Page 46, Section 5.10.17:	<p>Recommend revise the first paragraph as follows.</p> <p>The licensee radiation control program office should maintain an inspection program adequate to assess permittee compliance with NRC regulations, licensee requirements, and permit conditions. To ensure consistency between the NRC and the applicant's inspection and enforcement programs, the licensee should maintain statistics to enable program management the master radiation safety committee or NRC to assess the status and results of the inspection program on a periodic basis. This statistical information should include the number of inspections conducted, the number overdue, the length of time overdue, and inspection priority categories. The applicant should prepare an inspection plan that ensures that inspections are performed in accordance with IMC 2800, "Materials Inspection Program."</p>	<p>First comment not accepted.</p> <p>Basis: This criterion applies to the MML as the licensee and not the radiation control program office.</p> <p>Second comment accepted.</p>

48	The DVA	Page 47, Section 5.10.18:	<p>Recommend revise this section to be consistent with current practices by master materials licensees and historical programmatic results for those licensees.</p> <p>5.10.18 Corrective Action Program Master Radiation Safety Committee Oversight for Significant Program Outcomes</p> <p>Applicants should develop procedures for the master radiation safety committee a corrective action program to provide oversight for significant program outcomes such as unusual permitting requests, escalated enforcement actions, reports of incidents, or allegations. The goal should be to that will assist the licensee in identifying possible precursors, trends, or generic issues concerns, in order to help prevent violations and events that may impact public health and safety, common defense and security, or and protection of the environment, and to prevent recurrence of violations with similar root causes across all MML activities.</p> <p>The corrective action program oversight for significant program outcomes should, at a minimum, include a description of how the applicant will accomplish the following:</p> <ol style="list-style-type: none"> 1. Identify performance indicators to assist in identifying trends in the significant program outcomes. 2. Evaluate and resolve any identified trends that may impact the regulatory compliance or public health and safety program 	<p>Comment not accepted; however, this section was revised based on feedback from the January 21, 2015 public meeting on this volume.</p> <p>Basis: Although not required, a corrective action program is a common practice among NRC licensees. Therefore, as a result of comments received during the public meeting on January 21, 2015, this section was revised.</p>
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48 (cont.)	The DVA	Page 47, Section 5.10.18:	<p>3. Perform self-assessments or audits of the program performance indicators and other outcome results to identify performance improvements.</p> <p>4. Communicate lessons learned, internally, that were identified through the corrective action program evaluation and review of significant program outcomes.</p> <p>The corrective action program oversight for significant program outcomes should also describe include the applicant's procedures for responding to medical events or other incidents, including its criteria for initiating an investigation, procedures for identification of the basic causes (if warranted by the significance of the event) that contributed to the event, and evaluation of the extent of conditions and potential impacts to other areas of the program possible trends or generic issues and appropriate corrective actions to prevent recurrence. In addition, the corrective action program should address the applicant's procedures for evaluation of any comprehensive actions to prevent recurrence.</p> <p>Response from Applicant:</p> <p>Provide procedures for oversight for significant program outcomes a corrective action program that, at a minimum, addresses the elements described in Section 5.10.18, "Corrective Action Program". Master Radiation Safety Committee Oversight for Significant Program Outcomes. The oversight procedures may be included in the procedures for the committee.</p>	[See comment response on previous page.]
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49	The DVA	Pages 48 and 49, Section 5.10.19	<p>Recommend revise section to be consistent with current practices by master materials licensees and differentiate between the permittee role and the role for the radiation control program office.</p> <p>5.10.19 Incident/Emergency Response Procedures The applicant should require permitted facilities to develop procedures for responding to emergencies, events, or incidents, including, but not limited to a security threat or event involving permitted material, medical events, spills, fires, release or loss of radioactive material, potential or actual overexposures, and contamination of personnel as part of permitting the facility to use radioactive materials at permittee facilities. The applicant permittee procedures should describe its provisions for immediate response and handling of such incidents, including off-hours notification to appropriate licensee staff, state and local authorities, and when applicable, the radiation control program office for notification to NRC. The procedures should define the oversight responsibilities of the RCP management and staff, including actions to be taken by permittees. The procedures should identify the persons responsible for initiating response actions, conducting operations, and performing cleanup. Only qualified and experienced individuals should conduct decontamination and recovery operations.</p>	<p>Comments not accepted.</p> <p>Basis: This document contains guidance for new and existing MMLs, not their permittees. The NRC requires the MML to have an incident/emergency response program in addition to the emergency plans required for permittees when they possess licensed material in excess of specifically listed quantities.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>
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49 (cont.)	The DVA	Pages 48 and 49, Section 5.10.19	<p>Additionally, when permittees request possession of radioactive materials in both unsealed and certain sealed forms in excess of specifically listed quantities, they must prepare an emergency plan. If the applicant determines that there is a need for an emergency plan by certain permittees pursuant to 10 CFR 30.32, the applicant must identify those permittees and submit copies of the approved emergency plans, to the appropriate regional office. Guidance for this submittal is contained in Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities."</p> <p>In accordance with 10 CFR Part 21, "Reporting of Defects and Noncompliance," information on incidents involving failure of equipment must be provided to the agency responsible for evaluation of the device, for assessment of possible generic design deficiency, e.g., the NRC and the U.S. Department of Health and Human Services, Food and Drug Administration.</p> <p>The radiation control program office should develop an emergency response procedure to define the responsibilities of the office in receiving reports from permittees and making notifications to NRC or directing corrective actions by the permittee. The procedures should include possible coordination with local or state officials to provide assistance to the permittee.</p>	<p>Comments not accepted.</p> <p>Basis: This document contains guidance for new and existing MMLs, not their permittees. The NRC requires the MML to have an incident/emergency response program in addition to the emergency plans required for permittees when they possess licensed material in excess of specifically listed quantities.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>
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49 (cont.)	The DVA	Pages 48 and 49, Section 5.10.19	<p>Response from Applicant:</p> <ul style="list-style-type: none"> -Commit to requiring permittees to develop emergency response procedures commensurate with their scope of use during permitting actions -Provide incident/emergency response procedures for the radiation control program office, that address at a minimum, the following: <ul style="list-style-type: none"> -RCP management oversight responsibilities -initial response actions and responsibilities, including safety for RCP management and staff and permittees -list of persons responsible for initiating response actions, conducting operations, and performing cleanup -precautions for persons and property at permittee facilities -permittee facility, and site access control and security -mechanisms and responsibilities for notifying RCP staff and external authorities -provisions for medical and offsite agency assistance -description of emergency response equipment available for use by the RCP <ul style="list-style-type: none"> - office staff -need for onsite review of events -communications between the permittee facility and RCP -communications between the RCP office and the NRC. 	<p>Comments not accepted.</p> <p>Basis: This document contains guidance for new and existing MMLs, not their permittees. The NRC requires the MML to have an incident/emergency response program in addition to the emergency plans required for permittees when they possess licensed material in excess of specifically listed quantities.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>
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50	The DVA	Page 51, first section, last bullet:	<p>Permittees are required to provide training to their staff in accordance with NRC requirements in 10 CFR 19. The radiation control program offices usually follow guidelines in NUREG- 1556 series documents for requiring descriptions from permit applicants for training program elements. Since this NUREG pertains to master materials licensees and staff, recommend revise last bullet to:</p> <p>Provide a description of the training that will be provided to radiation control program office staff to ensure that they understand their right to contact the NRC directly about radiation safety or regulatory issues.</p>	<p>Comment not accepted.</p> <p>Basis: This training should be provided for all employees, and not limited to the MML oversight staff.</p>
51	The DVA	Page 53, section heading	Delete the word "renewals" from section heading. The understanding of the current MMLs is that master materials licenses do not expire and that any changes that might be necessary would be made through a revision to the LOU.	Comment accepted.

52	The DVA	Page 53, first paragraph	<p>The current wording in this section is inconsistent with Section 5.10.4 and current practices allowed for MML's. Recommend that the first paragraph be revised to:</p> <p>It is the licensee's obligation to keep the license current. If any of the information provided in the original application and incorporated by reference into license conditions is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. An exception may be provided in cases where the LOU allows for changes. For example, some LOUs may allow the master materials licensee to make administrative changes to various application documents without submitting a request to the NRC for a license amendment in so far as the changes do not decrease the effectiveness of the radiation safety program, do not result in less stringent requirements than NRC regulations, and the MRSC has reviewed and approved the changes prior to implementation.</p>	<p>Comment accepted, with modification to include the following text that aligns with other NUREG-1556 volumes: "The change is not in effect until the amendment has been issued."</p>
53	The DVA	Page 53, second paragraph and last bullet.	<p>Recommend deleting "or renew" from first sentence and deleting last bullet since the understanding of the current MMLs is that master materials licenses do not expire and renewals are not required. A bullet could be added to discuss possible revisions to or refreshing of the LOU.</p>	<p>Comment accepted.</p>

54	The DVA	Page D-I, format for information:	Recommend revise applicable sections based on corrections to regulatory guide (as indicated above)	Comment accepted.
55	The Navy	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.	Licensees' input is solicited and included during the NRC's comment process.
56	The Navy	Page 1 Section 1.1	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.	Financial status and stability are relevant considerations that need to be made to determine the viability, and to some extent the sustainability, of an licensee to comply with the regulations before issuing a license. For example, relevant considerations may include the acquisition and proper disposal of licensed materials.

57	The Navy	Page 1 Section 1.1	Please clarify as is not clear what is meant by 'the independence of the MML management structure; and its commitment to the MML'.	The intent is that MML management be delegated the necessary authority by senior management to independently make decisions to comply with NRC regulations and conditions of their license.
58	The Navy	Page 2 Section 1.2	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.	Comment accepted.
59	The Navy	Page 2 Section 1.3	<p>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."</p> <p>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.</p>	This is not a probationary period. By having a functioning centrally controlled program for at least 5 years prior to applying for an MML, the NRC can be assured that the applicant is prepared to operate as an MML.

60	The Navy	Page 4 Section 1.5	<p>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"</p> <p>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.</p>	Regardless of the applicant's process, the NRC will evaluate the MML's equivalency to NRC's processes.
61	The Navy	Page 5 Section 1.6	<p>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."</p> <p>Please include examples of reasons the NRC would use to determine that an MML is no warranted.</p>	For example, the NRC would not issue an MML if the applicant fails to demonstrate its ability to meet the criteria described in the guidance.

62	The Navy	Page 10 Section 2.5	<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>	The LOU clarifies and describes the responsibilities between the NRC and the applicant, which may include regulatory requirements.
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63	The Navy	Page 10 Section 2.5	<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>	<p>Comment not accepted.</p> <p>Basis: This document contains guidance for new and existing MMLs, not their permittees. As the licensee, MMLs are responsible to provide copies of these documents on behalf of the permittee.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>
64	The Navy	Page 10 Section 2.5	<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>	<p>Comment accepted.</p>

65	The Navy	Page 10 Section 2.6	<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> <p>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?</p>	The answer is "Yes."
66	The Navy	Page 15 Section 4	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?	The purpose of this section is to emphasize that a licensee should maintain an environment that is consistent with NRC's safety culture policy statement.

67	The Navy	Page 15 Section 4	<p>It states:</p> <p>"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>	<p>The sentence referenced in this comment was revised. Subsequently, the corrective action program was re-written in response to comments at the January 21, 2015 public meeting.</p> <p>Although not required, a corrective action program is a common practice among NRC licensees.</p>
68	The Navy	Page 17 Section 5	<p>It states:</p> <p>"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>	<p>This document contains guidance for new and existing MMLs, not their permittees. The MML needs to represent the activity of all of its permittees in the application process.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>

69	The Navy	Page 17 Section 5	<p>It states:</p> <p>"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> <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>	<p>This document contains guidance for new and existing MMLs, not their permittees. The MML needs to present the program developed to address these requirements, as implemented by permittees.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>
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70	The Navy	Page 20 Section 5.5	<p>It states:</p> <p>"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>	<p>This document contains guidance for new and existing MMLs, not their permittees. MMLs should have material control and accountability to assure compliance with license limits and requirements.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>
71	The Navy	Page 25 Section 5.7.2	<p>It states:</p> <p>"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>	<p>The sentence referenced in this comment was edited based on feedback from the January 21, 2015 public meeting on this volume.</p> <p>This manager should be a person who can address funding issues.</p>
72	The Navy	Page 25 Section 5.7.2	<p>It states:</p> <p>"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>	<p>This does not necessarily mean an occupationally exposed person needs to be a member of the MRSC.</p>

73	The Navy	Page 28 Section 5.8	<p>It states:</p> <p>"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>	<p>This document contains guidance for new and existing MMLs, not their permittees. The facility and training program that meets the requirements of the cited regulations needs to be submitted by the MML.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>
74	The Navy	Page 28 Section 5.9	<p>It states:</p> <p>"In accordance with 10 CFR 30.33, applicants must describe facilities and equipment used by the licensee to facilitate day-to-day operations.</p> <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>	<p>This document contains guidance for new and existing MMLs, not their permittees. MML must submit the information as described, on behalf of the permittee.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>

75	The Navy	Page 29 Section 5.10.1	<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>	<p>This document contains guidance for new and existing MMLs, not their permittees. MMLs should have material control and accountability to assure compliance with license limits and requirements.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>
76	The Navy	Page 30 Section 5.10.1	<p>Para 3: 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>	<p>Comment not accepted.</p> <p>Basis: A description of the controls (not details) for the procurement of licensed materials would suffice.</p>

77	The Navy	Page 31 Section 5.10.3	<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>	<p>This document contains guidance for new and existing MMLs, not their permittees. MMLs should have a material control and accountability to assure compliance with license limits and requirements.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>
78	The Navy	Page 32 Section 5.10.3	<p>It states:</p> <p>"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>	<p>Comment not accepted.</p> <p>Basis: This standard text was kept in the document (with slight editorial changes) to align with other NUREG-1556 volumes and to highlight this regulatory requirement.</p>
79	The Navy	Page 32 Section 5.10.4	<p>It states:</p> <p>"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>	<p>Comment not accepted.</p> <p>Basis: The commitment to follow NRC guidance helps to ensure the MML establishes a program similar to that of the NRC.</p>

80	The Navy	Page 33 Section 5.10.4	<p>It states:</p> <p>"Provide management's written commitment to follow NRC regulations. 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>.</p> <p>These are commitments that are more appropriate for the LOU than for an application. Suggest they are moved to the appendix.</p>	<p>Comment not accepted.</p> <p>Basis: The license and LOU may be developed separately; therefore, this ensures criteria are addressed.</p>
81	The Navy	Page 36 Section 5.10.8	<p>It states:</p> <p>"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>	<p>Comment accepted.</p> <p>However, the statement was combined to make one bullet as follows:</p> <p>Establishing procedures for procurement, acquisition, use, control, and accountability of NRC-regulated radioactive material (e.g., byproduct, source, and special nuclear material) (see Section 5.10.20, "Security Program for Category 1 and Category 2 Radioactive Material" for additional guidance) to ensure compliance with the MML.</p>

82		Page 43, section 5.10.14,	<p>Paragraph 1, it states:</p> <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 a 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>	<p>This document contains guidance for new and existing MMLs, not their permittees. MMLs should be prepared to provide an overarching description of the types of designs and procedures that will be implemented to minimize contamination at its permittees.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document</p>
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83	The Navy	Page 45 Section 5.10.15	<p>Para 1 It states:</p> <p>"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: 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>	Comment accepted, with slight modifications for clarity.
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84	The Navy	Page 45 Section 5.10.15	<p>Para 3 It states:</p> <p>"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 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>	<p>This document contains guidance for new and existing MMLs, not their permittees. The MML must develop a program to assure records are maintained for inspection.</p> <p>The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.</p>
85	The Navy	Page 47 Section 5.10.18	<p>Para 1 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>	<p>Comment not accepted; however, the corrective action program section was re-written as a result of the public comments received at the January 21, 2015 public meeting on this volume.</p> <p>Basis: Although not required, a corrective action program is a common practice among NRC licensees.</p>
86	The Navy	Page 53 Section 6	<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>	<p>Comment accepted.</p>

87	The Navy	C1 Administrative	<p>Para 1 It states in the second sentence:</p> <p>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>	<p>Comment not accepted.</p> <p>Basis: Although true that the licensee is required to implement and comply with regulations on the effective date of the regulation, the licensee is given an additional 90 days from the effective date to change their policies and procedures.</p>
88	The Navy	C1 Administrative	<p>Para 2 It states:</p> <p>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>	<p>Comment not accepted.</p> <p>Basis: The sample LOU in Appendix C is guidance and meant to be a starting point during the licensing process.</p>

89	The Navy	C1 Administrative	<p>Para 3, It states:</p> <p>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.</p> <p>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>	<p>First comment accepted, with modification to "(insert name of centralized organization)" instead of "Radiation Safety Committee."</p> <p>Second comment not accepted.</p> <p>Basis: Timeliness will depend upon the complexity of the request.</p>
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90	The Navy	C1 Administrative	<p>Para 5, It states:</p> <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>	<p>Comment not accepted.</p> <p>Basis: The sample LOU in Appendix C is guidance and meant to be a starting point during the licensing process.</p>
91	The Navy	C1 Administrative	<p>Para 6 It states:</p> <p>"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>	<p>Comment accepted.</p>

92	The Navy	C1 Administrative	<p>Para 6 It states:</p> <p>"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>	Comment accepted.
93	The Navy	C2 Administrative	<p>Para 10 It states:</p> <p>"When practical, the (insert name of centralized 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>	<p>Comment not accepted.</p> <p>Basis: NRC is encouraging the use of newer technologies for communication as they become available.</p>

94	The Navy	C3 Environmental	<p>Para 11 It states:</p> <p>"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.</p> <p>The NRC regulations in 10 CFR 51.45, "Environmental report," set forth the requirements for preparing an ER.</p> <p>Guidance on preparing an ER is set forth in the NRC's NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs,"</p> <p>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>	<p>Comment not accepted.</p> <p>Basis: The sample LOU in Appendix C is guidance and meant to be a starting point during the licensing process.</p>
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95	The Navy	C3 Permitting	<p>Para 12 It states:</p> <p>"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>	<p>Comment not accepted.</p> <p>Basis: The sample LOU in Appendix C is guidance and meant to be a starting point during the licensing process.</p>
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96	The Navy	C4 Permitting	<p>Para 13 In states:</p> <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>	<p>Comment not accepted.</p> <p>Basis: The sample LOU in Appendix C is guidance and meant to be a starting point during the licensing process.</p>
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97	The Navy	C4 Inspection	<p>Para 14 It states:</p> <p>"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>	<p>Comment not accepted.</p> <p>Basis: The sample LOU in Appendix C is guidance and meant to be a starting point during the licensing process.</p>
98	The Navy	C4 Inspection	<p>Para 14 It states:</p> <p>"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>	<p>Comment not accepted.</p> <p>Basis: The sample LOU in Appendix C is guidance and meant to be a starting point during the licensing process.</p>

99	The Navy	C4 Inspection	<p>Para 15 It states:</p> <p>"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> <p>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.</p>	<p>Comment accepted; sentence edited to show a request is only needed if the organization wants to decrease inspection frequency.</p>
100	The Navy	C5 Allegation	<p>Para 18 It states:</p> <p>"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>	<p>Comment not accepted.</p> <p>Basis: All allegations should be addressed as they may be indicative of programmatic issues.</p>

101	The Navy	C5 Allegation	<p>Para 20 It states:</p> <p>"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>	<p>Comment not accepted.</p> <p>Basis: The sample LOU in Appendix C is guidance and meant to be a starting point during the licensing process.</p>
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102	The Navy	C5 Enforcement	<p>Para 24 It states:</p> <p>"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.</p> <p>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>	<p>Comment not accepted.</p> <p>Basis: The sample LOU in Appendix C is guidance and meant to be a starting point during the licensing process.</p>
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103	The Navy	C6 Investigation	<p>Para 25 It states:</p> <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>	<p>Comment not accepted.</p> <p>Basis: The sample LOU in Appendix C is guidance and meant to be a starting point during the licensing process.</p>
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104	The Navy	C6 Investigation	<p>Para 26 It states:</p> <p>"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>	<p>Comment not accepted.</p> <p>Basis: The sample LOU in Appendix C is guidance and meant to be a starting point during the licensing process.</p>
105	The Navy	C7 Decommissioning	<p>Para 27 It states:</p> <p>"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>	<p>Comment not accepted.</p> <p>Basis: The sample LOU in Appendix C is guidance and meant to be a starting point during the licensing process.</p>

106	The Navy	C7 Decommissioning	<p>Para 27 It states:</p> <p>“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 NRC regulations.</p>	<p>Comment not accepted.</p> <p>Basis: The sample LOU in Appendix C is guidance and meant to be a starting point during the licensing process.</p>
107	The Navy	C7 Procedures	<p>Para 28 It states:</p> <p>"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>	<p>Comment not accepted.</p> <p>Basis: The sample LOU in Appendix C is guidance and meant to be a starting point during the licensing process. Furthermore, the license and LOU may be developed separately; therefore, this ensures the criteria are addressed.</p>
108	The Navy	C9 Procedures	<p>Para 31 It states:</p> <p>"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>	<p>Comment not accepted.</p> <p>Basis: The sample LOU in Appendix C is guidance and meant to be a starting point during the licensing process.</p>

109	The AF	Page 1, Para 1.1	Change “license” to “permit”. Rationale: Correct terminology.	Comment not accepted. Basis: At this point an MML has not been issued and there are no permits.
110	The AF	Page 2, Para 2	The paragraph requires that licensees renew on a ten year frequency. At MML counterpart, it was voiced that the renewal was not required for existing MMLs. The document should clearly state that the renewal is not applicable to USN, USAF and VA.	Comment accepted with modification (the sentence referenced in the comment was deleted).
111	The AF	Page 3, Para 1.4	Text should read as ...Committee (MRSC) or “equivalent”,.... Rationale: USAF has a RIC, not MRSC	Comment not accepted. Basis: MRSC is a generic term. Each MML can define its MRSC more specifically.
112	The AF	N/A	Section 2.0 through 7.0 apply to MML application process. If a renewal is not warranted, then an additional section needs to be generated for existing MML...and what requirements they are to meet. If a renewal is not required, very little of this document is applicable to existing MMLs.	Comment not accepted. Basis: These sections may apply to amendment requests.
113	The AF	Page 10, Top, 6 th bullet	Guidance would have to be provided as to what details would be needed in an Emergency Plan. Also listed in section 5.5, 2 nd para.	This is further discussed in Section 5.10.19, which refers to Regulatory Guide 3.67, “Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities”, which contains the details required in an Emergency Plan.

114	The AF	Page 17, #2, all	Do you expect the MMLs to document ALARA considerations for all permitted activities?	The answer is "Yes."
115	The AF	Page 53, Para 6.0	These first two sentences would require ~100 licensee amendments per year if the renewal/313 submission becomes a requirement. The regional offices would not have time to amended all amendment requests.	This document contains guidance for new and existing MMLs, not their permittees. The MML is the NRC licensee. Therefore, the MML is required to address the criteria in this document.
116	Jason Meade	Pg. 4; 1.5 Prelicensing Visit and Readiness Review:	In keeping with the intent of MML licensing, I recommend that "NRC staff may conduct independent site visits at a select number of permittees that will be under the MML" be revised from "may conduct" to "will conduct"	Comment accepted.
117	Jason Meade	Pg. 3; 1.4 Master Materials Licensee Authorizations	Beginning in this section: use of capital letters and periods (.)for bullet point lists are not consistent between sections and, at times, within the same bullet point list. I recommend this minor issue be made consistent throughout the document.	Document reviewed for consistency.

118	Jason Meade	-Pg. 51; 5.10.21 Procedures for Handling Allegations:	<p>Recommend including methods for addressing reprisal concerns in the "Response from Applicant" section</p> <p>Recommend adding a section "5.13: NRC Form 313, Item 13: Certification" with a brief description of who the certifying officer is</p> <p>Under the "Response from Applicant" portion of some sections, a bullet point list is included that is identical to one presented in the main section. Recommend removing the lists from "Response from Applicant" and replacing with wording to the effect of "meets the minimum requirements set forth in section ."</p>	<p>Comment not accepted.</p> <p>Basis: This is covered under Department of Labor regulations and NRC 10 CFR 19.20</p> <p>Comment accepted.</p> <p>Comment not accepted.</p> <p>Basis: Bullets points are provided to clearly delineate what information is to be submitted.</p>
119	Jason Meade	Pg. 3; 1.4 Master Materials Licensee Authorizations:	" <i>Section 2.4, "Letter of Understanding (LOU)"</i> " should read " <i>Section 2.5 "Letter of Understanding (LOU)"</i> "	This volume will be formatted to be consistent with other NUREG-1556 volumes.
120	Jason Meade	Pg. 4; 1.5 Prelicensing Visit and Readiness Review	" <i>(6) of the permitting program</i> " should read " <i>(6) <u>technical quality</u> of the permitting program</i> "	<p>Comment accepted.</p> <p>However, the text will be changed to "status" versus "technical quality"</p>
121	Jason Meade	Pg. 7; 2.1 Paper Application:	" <i>Section 2.3 "Identifying and Protecting Sensitive Information"</i> " should read " <i>Section 2.4, "Identifying and Protecting Sensitive Information"</i> "	This volume will be formatted to be consistent with other NUREG-1556 volumes.

122	Jason Meade	Pg. 9; 2.5 Letter of Understanding (LOU):	Period (.) needed at the end of the sentence " <i>The LOU is signed by representatives from both agencies</i> "	Comment accepted.
123	Jason Meade	Pg. 13; 3. APPLICATION AND LICENSE FEES:	"Refer to <u>10</u> 10 CFR 170.31" delete the repeated number 10	Comment accepted.
124	Jason Meade	Pg. 17; 5. CONTENTS OF AN APPLICATION	"All information submitted . . . Throughout <u>this document</u> , descriptive items ... "the words " <u>this document</u> " should be replaced with "this Consolidated Guidance"	Comment not accepted. Basis: This is consistent with language in other NRC guidance documents.
125	Jason Meade	Pg. 22; 5.6 NRC Form 313, Item 6: Purpose of Use of Licensed Material; Response from Applicant:	" <i>Explain why an MML is needed.</i> • Describe in general terms the purposes for which licensed materials will be used." Bullet (•) needed prior to "Explain why ... " and line space needs to be inserted between the two bullet points	Comment accepted.
126	Jason Meade	Pg. 23; 5.7.1 Senior Management	"The application should include ... Section 5.10, :: "Radiation Safety Program." Delete repeated begin quote quotation mark	This volume will be formatted to be consistent with other NUREG-1556 volumes.
127	Jason Meade	Pg. 24; 5.7.1 Senior Management	"• Provide <u>the</u> point of contact as the liaison" should read "• Provide.... <u>a</u> point of contact as the liaison to"	Comment not accepted. Basis: NRC wants one primary contact.
128	Jason Meade	Pg. 27; 5.7.3 Radiation Control Program Director	"• Good <u>writing</u> and oral communication skills." Should read "• Good <u>written</u> and oral communication skills."	Comment accepted.

129	Jason Meade	Pg. 27; 5.7.4 Other Radiation Control Program Staff:	<i>"Written job descriptions . . . See NRC Inspection Manual Chapter (IMC) 1248 for guidance on such qualifications."</i> First instance in section (IMC 1248): add the title "Qualification programs for federal and state materials and environmental management programs"	This volume will be formatted to be consistent with other NUREG-1556 volumes.
130	Jason Meade	Pg. 28; 5.8 NRC Form 313, Item 8: Training and Experience for Individuals Working In or Frequenting Restricted Areas	<i>"The applicant must ensure . . . of <u>10 CFR Part 19.</u>"</i> First instance in section (10 CFR Part 19): add the title "Notices, Instructions and Reports to Workers: Inspection and Investigations"	Document is formatted per NRC policy.
131	Jason Meade	Pg. 28; 5.9 NRC Form 313, Item 9: Facilities and Equipment	<i>"In accordance with <u>10 CFR 30.33</u> . . ."</i> First instance in section (10 CFR 30.33): add the title "General Requirements for Issuance of Specific Licenses" <i>"• Identify all facilities requiring security controls pursuant to <u>10 CFR Part 37.</u>"</i> First instance in section (10 CFR Part 37): add the title "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"	This volume will be formatted to be consistent with other NUREG-1556 volumes.
132	Jason Meade	Pg. 29; 5.10 NRC Form 313, Item 10, Radiation Safety Program	<i>"The applicant should refer to <u>Section 5.7</u> . . ."</i> First instance in section (Section 5.7): add the title "Individuals Responsible for the Radiation Safety Program"	Document is formatted per NRC policy.
133	Jason Meade	Pg. 29; 5.10.1 Radiation Control Program-An Overview	<i>"In accordance with <u>10 CFR 30.33</u> . . ."</i> First instance in section (10 CFR 30.33): add the title "General Requirements for Issuance of Specific Licenses"	Comment not accepted. Basis: Document is formatted per NRC policy.

134	Jason Meade	Pg. 30; 5.10.1 Radiation Control Program-An Overview	"-material control and <u>accounting</u> " should read "material control and accountability"	Comment accepted.
135	Jason Meade	Pg. 31; 5.10.3 Material Control and Accountability	"In accordance with 10 CFR Part 20 ... See <u>NUREG-1556, Vol. 11</u> ..." First instance in section (NUREG-1556, Vol. 11): add the title "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope"	This volume will be formatted to be consistent with other NUREG-1556 volumes.
136	Jason Meade	Pg. 32; 5.10.4 Regulatory Conformance	"In order for the NRC to approve ... its RCP will be incorporated into the MML in a license condition." Change "in" to "as"	Comment accepted.
137	Jason Meade	Pg. 34; 5.10.6 Management Support and Radiation Control Program Structure:	"The applicant should demonstrate ... support program implementation for <u>such areas as the following:</u> " delete comma "In accordance with <u>10 CFR 30.33</u> ... "	This volume will be formatted to be consistent with other NUREG-1556 volumes.
138	Jason Meade	Pg. 36; 5.10.8 Master Radiation Safety Committee Responsibilities	"• <u>Ensuring that permitting ... as described in IMC 1248</u> ... "	This volume will be formatted to be consistent with other NUREG-1556 volumes.
139	Jason Meade	Pg. 37; 5.10.8 Master Radiation Safety Committee Responsibilities	"Conducting at least annually . . . pursuant to <u>10 CFR 20.1101</u> ." First instance in section (10 CFR 20.1101): add the title "Radiation Protection Programs"	This volume will be formatted to be consistent with other NUREG-1556 volumes.

140	Jason Meade	Pg. 39; 5.10.11 Radiation Control Program Internal Procedures	<p><i>"In order to meet the requirements in <u>10 CFR 30.33</u> ... decommissioning, and other <u>function</u> required of the program."</i></p> <p>First instance in section (10 CFR 30.33): add the title "General Requirements for Issuance of Specific Licenses"</p> <p>Replace "function" with "functions"</p>	<p>First comment not accepted.</p> <p>Basis: Document is formatted per NRC policy.</p> <p>Second comment accepted.</p>
141	Jason Meade	Pg. 40; 5.10.12 Management and Master Radiation Safety Committee Audits	<p><i>"Audits of the inspectors . . . In accordance with <u>10 CFR 30.33</u>, inspectors should . . . establish a system similar to NRC's qualification journal system found in <u>IMC 1248</u>."</i></p> <p>First instance in section (10 CFR 30.33: add the title "General Requirements for Issuance of Specific Licenses"</p> <p>First instance in section (IMC 1248): add the title "Qualification programs for federal and state materials and environmental management programs"</p>	<p>This volume will be formatted to be consistent with other NUREG-1556 volumes.</p>
142	Jason Meade	Pg. 41; 5.10.12 Management and Master Radiation Safety Committee Audits	<p>Bullet (•) needed prior to <i>"Describe how reviewers demonstrate . . ."</i></p>	<p>Comment accepted.</p>
143	Jason Meade	Pg. 42; 5.10.13 Permitting Procedures	<p><i>"To establish the basis for permitting actions, submitted information should document the isotopes, forms, quantities, authorized uses, <u>and</u> permissive and restrictive conditions, and be readily available for audit during pre-permitting visits."</i></p> <p>Delete "and" between "authorized uses," and "permissive and restrictive conditions,"</p>	<p>Comment not accepted.</p> <p>Basis: Sentence is accurate as written.</p>

144	Jason Meade	Pg. 43; 5.10.14 Program to Minimize Contamination at Permittee Facilities	<i>"Applicants are also required . . . in Regulatory Guide 4.22, Decommissioning Planning During Operations."</i> Quotation marks needed around "Decommissioning Planning During Operations."	Comment accepted.
145	Jason Meade	Pg. 43; 5.10.15 Decommissioning of Permit Activities and Permit Termination	<i>"The NRC's requirements for the decommissioning and termination of licenses for radioactive material are described in <u>10 CFR Part 30</u> . . . and Subpart E of 10 CFR Part 20, "Standards for Protection against Radiation," <u>Subpart E</u>"</i> First instance in section (10 CFR 30): add the title "Rules of General Applicability to Domestic Licensing of Byproduct Material" Delete second instance of "Subpart E"	Comment not accepted. Basis: Document is formatted per NRC policy. Comment accepted.
146	Jason Meade	Pg. 44; 5.10.15 Decommissioning of Permit Activities and Permit Termination	<i>"The NRC retains its authority . . . in accordance with NRC guidance in <u>NUREG-1757</u>."</i> First instance in section (NUREG-1757): add the title "Consolidated Decommissioning Guidance"	This volume will be formatted to be consistent with other NUREG-1556 volumes.

147	Jason Meade	Pg. 44; 5.10.15 Decommissioning of Permit Activities and Permit Termination; Initiation and Timeliness of Decommissioning	<p><i>"The licensee must notify the NRC of changes in the operating status of its permittees in accordance with <u>10 CFR 30.36, 10 CFR 40.42</u> . . ."</i></p> <p>First instance in section (10 CFR 30.36): add the title "Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas"</p> <p>First instance in section (10 CFR 40.42): add the title "Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas"</p>	This volume will be formatted to be consistent with other NUREG-1556 volumes.
148	Jason Meade	Pg. 44; 5.10.15 Decommissioning of Permit Activities and Permit Termination; Decommissioning	<p><i>"The approval of simple decommissioning (i.e., decommissioning groups 1 and 2 as defined in <u>NUREG- 1757, Volume 1, Revision 2 Chapter 7</u>"</i></p> <p>First instance in section (NUREG-1757, Volume 1, Revision 2 Chapter 7): add the title "Decommissioning Groups"</p>	This volume will be formatted to be consistent with other NUREG-1556 volumes.
149	Jason Meade	Pg. 44; 5.10.15 Decommissioning of Permit Activities and Permit Termination; Request for Extensions	<p><i>"Guidance on requesting an alternative schedule is provided in <u>NUREG-1757, Volume 3, Sections 2.2 and 2.6</u>"</i></p> <p>First instance in section (NUREG-1757, Volume 3, Sections 2.2 and 2.6): add the titles "Extension or Alternative Schedule for Decommissioning and Review of Extension or Alternative Time Schedule Requests, respectively"</p> <p>Add "Revision 1" after "Volume 3"</p>	<p>First comment response: This volume will be formatted to be consistent with other NUREG-1556 volumes.</p> <p>Second comment accepted.</p>

150	Jason Meade	Pg. 44; 5.10.15 Decommissioning of Permit Activities and Permit Termination; Completion of Decommissioning and Termination of the Permit:	<p><i>"The licensee is required ... FSS report is provided in <u>NUREG-1757, Volume 2, Section 4.5.</u>"</i></p> <p>First instance in section (NUREG-1757, Volume 2, Section 4.5): add the title "Final Status Survey Report"</p> <p>Add "Revision 1" after "Volume 2"</p>	<p>First comment response: This volume will be formatted to be consistent with other NUREG-1556 volumes.</p> <p>Second comment accepted.</p>
151	Jason Meade	Pg. 45; 5.10.15 Decommissioning of Permit Activities and Permit Termination; Environmental Reviews	<p><i>"The applicant should document that ... The licensee should follow the guidance described in <u>NUREG-1757, Volume 1, in preparing the ER.</u>"</i></p> <p>Add "Revision 2" after "Volume 1"</p>	<p>Comment not accepted.</p> <p>Basis: The revision number is not being added to be consistent with other NUREG-1556 volumes.</p>
152	Jason Meade	Pg. 45; 5.10.16 Financial Assurance	<p><i>"In accordance with <u>10 CFR 30.35</u> ... Guidance is provided in <u>NUREG-1757, Volume 3</u>"</i></p> <p>First instance in section (10 CFR 30.35): add the title "Financial assurance and recordkeeping for decommissioning"</p> <p>Add "Revision 1" after "Volume 3"</p>	<p>First comment response: This volume will be formatted to be consistent with other NUREG-1556 volumes.</p> <p>Second comment not accepted.</p> <p>Basis: The revision number is not being added to be consistent with other NUREG-1556 volumes.</p>

153	Jason Meade	Pg. 46; 5.10.16 Financial Assurance	<p><i>"• Describe how the decommissioning financial assurance requirements described in 10 CFR 30.35, 10 CFR 40.36, 10 CFR 70.25 will be met"</i></p> <p>First instance in section (10 CFR 40.36): add the title "Financial assurance and record keeping for decommissioning"</p> <p>First instance in section (10 CFR 70.25): add the title "Financial assurance and recordkeeping for decommissioning"</p>	This volume will be formatted to be consistent with other NUREG-1556 volumes.
154	Jason Meade	Pg. 48; 5.10.19 Incident/Emergency Response Procedures	<p><i>"Additionally, when permittees request . . . plan by certain permittees pursuant to 10 CFR 30.32"</i></p> <p>First instance in section (10 CFR 30.32): add the title "Application for specific licenses"</p>	This volume will be formatted to be consistent with other NUREG-1556 volumes.

155	Jason Meade	Pg. 49; 5.10.20 Security Program for Category 1 and Category 2 Materials	<p><i>"Note: The requirements in <u>10CFR 20.2207</u> are only applicable to those licensees that manufacture, transfer, receive, disassemble, or dispose of Category 1 and Category 2 sources., as specified in <u>Appendix E to 10 CFR Part 20</u>. The regulations in 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," apply to licensees that possess an aggregate amount of category 1 or category 2 quantity of radioactive material., as specified in <u>Appendix A to 10 CFR Part 37</u>."</i></p> <p>First instance in section (10 CFR 20.2207): add the title "Reports of transactions involving nationally tracked sources"</p> <p>First instance in section (Appendix E to 10 CFR 20): add the title "Nationally Tracked Source Thresholds"</p> <p>First instance in section (Appendix A to 10 CFR Part 37): add the title "Category 1 and Category 2 Radioactive Materials"</p>	This volume will be formatted to be consistent with other NUREG-1556 volumes.
156	Jason Meade	Pg. 49; 5.10.20 Security Program for Category 1 and Category 2 Materials	<p><i>"In accordance with <u>10 CFR Part 37</u>, "<u>Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material</u>," licensees authorized . . . "</i></p> <p>Second instance (10 CFR Part 37): remove title "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"</p>	This volume will be formatted to be consistent with other NUREG-1556 volumes.

157	Jason Meade	Pg. 49; 5.10.20 Security Program for Category 1 and Category 2 Materials	<p><i>"Table 1 of Appendix A, "Category 1 and Category 2 Radioactive Materials," to 10 CFR Part 37 lists Category 1 and 2 threshold quantities of radioactive material."</i></p> <p>First instance in section (Table 1 of Appendix A to 10 CFR Part 37): add the title "Category 1 and Category 2 Thresholds"</p> <p>Second instance (Appendix A to 10 CFR Part 37): remove title "Category 1 and Category 2 Radioactive Materials"</p>	This volume will be formatted to be consistent with other NUREG-1556 volumes.
158	Jason Meade	Pg. 50; 5.10.20 Security Program for Category 1 and Category 2 Materials	<p><i>"Per 10 CFR Part 37, Subpart B, licensees must ... "</i></p> <p>First instance in section (10 CFR Part 37, Subpart B): add the title "Background Investigations and Access Control Program"</p> <p><i>"Per 10 CFR Part 37, Subpart C, licensees must ... "</i></p> <p>First instance in section (10 CFR Part 37, Subpart C): add the title "Physical Protection Requirements During Use"</p> <p><i>"Per 10 CFR Part 37, Subpart D, licensees must ... "</i></p> <p>First instance in section (10 CFR Part 37, Subpart D): add the title "Physical Protection in Transit"</p>	This volume will be formatted to be consistent with other NUREG-1556 volumes.

159	Jason Meade	Pg. 50; 5.10.21 Procedures for Handling Allegations	<p><i>"Handling allegations is a shared . . . include procedures for training that clearly articulate the right of any employee to raise <u>his/her</u> radiation safety concerns directly to the NRC, <u>if he/she so desires.</u>"</i></p> <p>Delete "his/her"</p> <p>Replace "if he/she so desires." With "if desired."</p>	Comments accepted.
160	Jason Meade	Pg. 50; 5.10.21 Procedures for Handling Allegations	<p><i>"The applicant should specify whether it will follow the NRC's procedures for handling allegations (<u>NRC Management Directive 8.8</u>)"</i></p> <p>First instance in section (NRC Management Directive 8.8): add the title "Management of Allegations"</p>	Comment accepted.
161	Jason Meade	Pg. 51; 5.11 NRC Form 313, Item 11: Waste Management	<p><i>"In accordance with the waste disposal requirements in <u>10 CFR Part 20</u> . . ."</i></p> <p>First instance in section (10 CFR Part 20): add the title "Standards for Protection Against Radiation"</p>	This volume will be formatted to be consistent with other NUREG-1556 volumes.
162	Jason Meade	Pg. 51; 5.12 NRC Form 313, Item 12: License Fees	<p><i>"There may be <u>an</u> additional annual fees for each Sealed Source Device Registration . . ."</i></p> <p>delete the word "an"</p>	Comment accepted.
163	Jason Meade	Pg. 53; 6. AMENDMENTS AND RENEWALS TO A LICENSE	<p><i>"It is the licensee's obligation to . . . 30 days before the expiration date (<u>10 CFR</u>) 2.109(a)"</i></p> <p>Delete parentheses around "10 CFR"</p>	<p>Comment not accepted.</p> <p>Language was deleted.</p>

164	Jason Meade	Pg. 55; 7. APPLICATIONS FOR EXEMPTIONS	<p><i>"Various sections of the NRC's regulations address requests for exemptions (e.g., 10 CFR 19.31, "Application for exemptions"; 10 CFR 20.2301, "Applications for exemptions"; 10 CFR 30.11, "Specific Exemptions"; <u>10 CFR 40.14</u>, and 10 CFR 70.17, "Specific exemptions")."</i></p> <p>First instance in section (10 CFR 40.14): add the title "Specific Exemptions"</p>	This volume will be formatted to be consistent with other NUREG-1556 volumes.
Please note that the comments below this line were received in April and May 2015 on a revised version of Volume 10, Rev. 1.				

165	The DVA	No specific location indicated.	<p>On behalf of NHPP, we have reviewed the revised draft and provide the following response for NRC's consideration.</p> <p>We appreciate that many of our initial comments were accepted. However, we also acknowledge that many of our initial comments were not accepted by NRC. The comments that were not accepted still stand. We have no new comments to offer on the revised draft but re-emphasize one of our non-accepted comments below. One of our initial comments was that NRC remove the requirement to describe a formal Corrective Action Program (CAP). While we appreciate NRC's position on a CAP and the revised text of Section 5.10.18, we recommend that the "Response from Applicant" section be revised to state, "No response is required from an applicant or licensee. " Our understanding is the information is that section is a recommendation only--not a regulatory requirement. Since there is no regulatory requirement to have a formal CAP, we do not understand why NRC is requiring applicants to provide a written description of a formal CAP. How (using what criteria) will NRC evaluate the description? Would this written description be interpreted as a tie-down/commitment on the license? It seems to us that by requiring a response, the recommendation is being made into a de facto requirement.</p>	<p>The NRC acknowledges this comment.</p> <p>Comment on Corrective Action Program accepted. Applicable content in the "Response from Applicant" sections of Sections 5.10.7 and 5.10.18 was deleted.</p>
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165 (cont.)	The DVA	No specific location indicated.	Thank you for the opportunity to review the revised draft.	
166	The Navy	No specific location indicated.	<p>Thanks for allowing the NRSC take a look at the resolution of our comments. We appreciate that some of the comments were accepted and the rest were considered by the staff. However, the NRSC agrees and echoes the VA's position that the remainder of our comments still stands.</p> <p>We understand that the reviewers of the comments must follow NRC's policy, and therefore cannot properly resolve the comments addressing the differences between a large federal agency and other licensees. We believe that this is still an excellent opportunity to address some of the differences between an MML and a small licensee. However, we understand that you will not redress our comments and will proceed with the publication of the manual. We do hope that in the future we can discuss again our concerns, and share with the staff the considerable experience that MML managers bring to the table on how executive agencies work.</p>	The NRC acknowledges this comment.