

**REGION I PROCESS FOR THE REVISED APPENDIX C of NUREG-1556,
Volume 20**

REVIEWER DETERMINATION OF APPLICABILITY OF LICENSING CHECKLISTS

	Checklists:	√ if Applicable	√ if Not Applicable
1.	License Status Change Control	XX	
2.	Identification of Significant Licensing Action and/or Program Code Change		XX
3.	Risk – Significant Radioactive Material (RSRM) *		XX
4.	National Source Tracking System (NSTS) Update		XX
5.	Basis for Confidence / Pre-Licensing Visit		XX
6.	Renewal		XX

* If applicable, add OFFICIAL USE ONLY – SECURITY RELATED INFORMATION banners and change SUNSI review to A.3.

Reviewer Notes: The reviewer can provide additional information here:

Signature and Date Required:

HBermúdez

5/15/2014

Reviewer

Date

SUNSI Review													
Document Availability:	<input checked="" type="checkbox"/> Non-Public												
Document Sensitivity: <i>(select "1" value to the right using the SUNSI Table on pg 2 of this doc. which was adapted from the SUNSI Website)</i>	<table border="0"> <tr> <td><input checked="" type="checkbox"/> Non-Sensitive</td> <td><input checked="" type="checkbox"/> MD 3.4 Non-Public B.1 (Non-Sensitive)</td> </tr> <tr> <td><input type="checkbox"/> Non-Sensitive Copyright</td> <td><input type="checkbox"/> MD 3.4 Non-Public A.3 (Sensitive Security Related)</td> </tr> <tr> <td><input type="checkbox"/> Sensitive – Proprietary</td> <td><input type="checkbox"/> MD 3.4 Non-Public A.4 (Sensitive-Proprietary)</td> </tr> <tr> <td><input type="checkbox"/> Sensitive – Privacy Act (includes Personally Identifiable Information (PII))</td> <td><input type="checkbox"/> MD 3.4 Non-Public A.5 (Sensitive-Privacy Act)</td> </tr> <tr> <td><input type="checkbox"/> Sensitive – Internal, Periodic Review required (All Other Sensitive Internal Info.)</td> <td><input type="checkbox"/> MD 3.4 Non-Public A.6 (Sensitive-Federal, State, etc)</td> </tr> <tr> <td><input type="checkbox"/> Sensitive – Security-Related-Periodic Review Required</td> <td><input type="checkbox"/> MD 3.4 Non-Public A.7 (Internal)</td> </tr> </table>	<input checked="" type="checkbox"/> Non-Sensitive	<input checked="" type="checkbox"/> MD 3.4 Non-Public B.1 (Non-Sensitive)	<input type="checkbox"/> Non-Sensitive Copyright	<input type="checkbox"/> MD 3.4 Non-Public A.3 (Sensitive Security Related)	<input type="checkbox"/> Sensitive – Proprietary	<input type="checkbox"/> MD 3.4 Non-Public A.4 (Sensitive-Proprietary)	<input type="checkbox"/> Sensitive – Privacy Act (includes Personally Identifiable Information (PII))	<input type="checkbox"/> MD 3.4 Non-Public A.5 (Sensitive-Privacy Act)	<input type="checkbox"/> Sensitive – Internal, Periodic Review required (All Other Sensitive Internal Info.)	<input type="checkbox"/> MD 3.4 Non-Public A.6 (Sensitive-Federal, State, etc)	<input type="checkbox"/> Sensitive – Security-Related-Periodic Review Required	<input type="checkbox"/> MD 3.4 Non-Public A.7 (Internal)
<input checked="" type="checkbox"/> Non-Sensitive	<input checked="" type="checkbox"/> MD 3.4 Non-Public B.1 (Non-Sensitive)												
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<input type="checkbox"/> Sensitive – Internal, Periodic Review required (All Other Sensitive Internal Info.)	<input type="checkbox"/> MD 3.4 Non-Public A.6 (Sensitive-Federal, State, etc)												
<input type="checkbox"/> Sensitive – Security-Related-Periodic Review Required	<input type="checkbox"/> MD 3.4 Non-Public A.7 (Internal)												
Immediate Release	<input type="checkbox"/> Normal Release Date: _____ <input type="checkbox"/> Delayed Release Date: _____												
SUNSI Review Completed by: HBermúdez													

NOTE: If the reviewer determines that checklists 1 through 6 are not applicable, this one page will serve to document the license reviewer checklist. If a section applies, the reviewer should complete that appropriate section following the implementing guidance and submit with this page. Always complete the SUNSI review.

**Checklist 1
License Status Change Control
(For Terminated, Expired & Retired Licenses)**

Purpose: To verify proper transfer/disposal of radioactive materials, change license status, and archive of records.

Expiration Date: 10/31/2021

Date of Contact: 3/24/2014

Licensee Contact: Dr. Vázquez

Title of Contact: Owner

Basis for Termination or Retirement: Per licensee's request. Received confirmation of transfer of sources from Cardinal Health

Verification:	YES, NO, N/A
(1) NRC Form 314 or Equivalent	Yes
(2) License No. <u>52-25121-01</u> has received material, including any generally licensed sources/devices and NARM, and is authorized for it; document verification method either by letter or telephone call. Documentation to support: ML14091A472	Yes
(3) Close-out survey by licensee required (NUREG-1757) ADAMS ML#:14091A472	Yes
(4) Close-out survey by NRC required (NUREG-1757) ADAMS ML#:	No
(5) NRC Close-out survey performed and approved by Supervisor	N/A
(6) Licensee submitted records (10 CFR 30.36(k)(4); 40.61; 70.51)	No
NRC action(s) to be taken:	YES, NO, N/A
(1) Retire/Terminate license	Yes
(2) Change to retired/expired status in WBL	Yes
(3) Remove from the Materials Docket room after 6 months	Yes
(4) License No. _____ replaces/supersedes License No. _____	N/A
(5) Were the Financial Assurance documents returned	N/A
(6) Were the Increased Controls (IC)/National Source Tracking System (NSTS)/Nuclear Materials Management and Safeguards Systems (NMMSS) databases updated	N/A
(7) If subject to Risk-Significant Radioactive Material (RSRM), notify FSME: (e-mail:Security_Orders.Resource@nrc.gov)	N/A
(8) If CAT 1 or CAT 2 RSRM, notify Materials Security & Industrial Branch Chief to update information in Hurricane Response Binder located in Incident Response Center.	N/A

License Reviewer Approval & Date: HBermúdez
5/29/2014

May 29, 2014

Supervisor Approval & Date: James P. Dwyer

LAT & TL Initials & Date entered into WBL: RLJ 05/15/2014

cc: Expired License No. _____
New License No. _____

Checklist 2

Identification of Significant Licensing Action and/or Program Code Change

Purpose: To determine if a change in frequency to perform an on-site inspection is warranted.

An onsite inspection of the licensee identified above must be considered due to a recent significant licensing action involving one or more of the criteria described below (*Ref. IMC2800*). In addition, a change or addition of program codes may change the next inspection date and should be evaluated here.

Examples of significant licensing actions:	YES or NO
Increased types, quantities, and uses of radioactive material. See Checklist 3 if Risk Significant Radioactive Material (RSRM) is involved.	
Physical move of a facility.	
Authorization of new (i.e., since the previous inspection) facility, including temporary job sites, where materials will be used or stored.	
Increased types of uses or disposal (i.e., incineration or decay-in-storage) authorization.	
Significant increase or decrease in the number of authorized users.	
Change of Radiation Safety Officer	
Cessation of licensed activities at entire site or in any building or area (<i>Ref. 10 CFR 30.36(d, h, & j) – See checklist 1 if termination</i>).	
Change in program code(s) that affect next inspection due date Enter new program code(s) here: _____ (make sure it matches program code(s) listed on WBL printout)	

If "YES" is indicated in the last column above, complete the following and mark this form as applicable:

Date of the last inspection	
Result of last inspection (Clear, 591, # of violations)	
Date of the next inspection	

Reviewer Recommendation and Justification

<input type="checkbox"/>	Change date of next inspection:	Justification/Basis: _____
<input type="checkbox"/>	No Change:	_____

License Reviewer Approval: _____ Date: _____

Change date of Next Inspection?

<input type="checkbox"/>	No	
<input type="checkbox"/>	Yes - Next Inspection Date:	_____

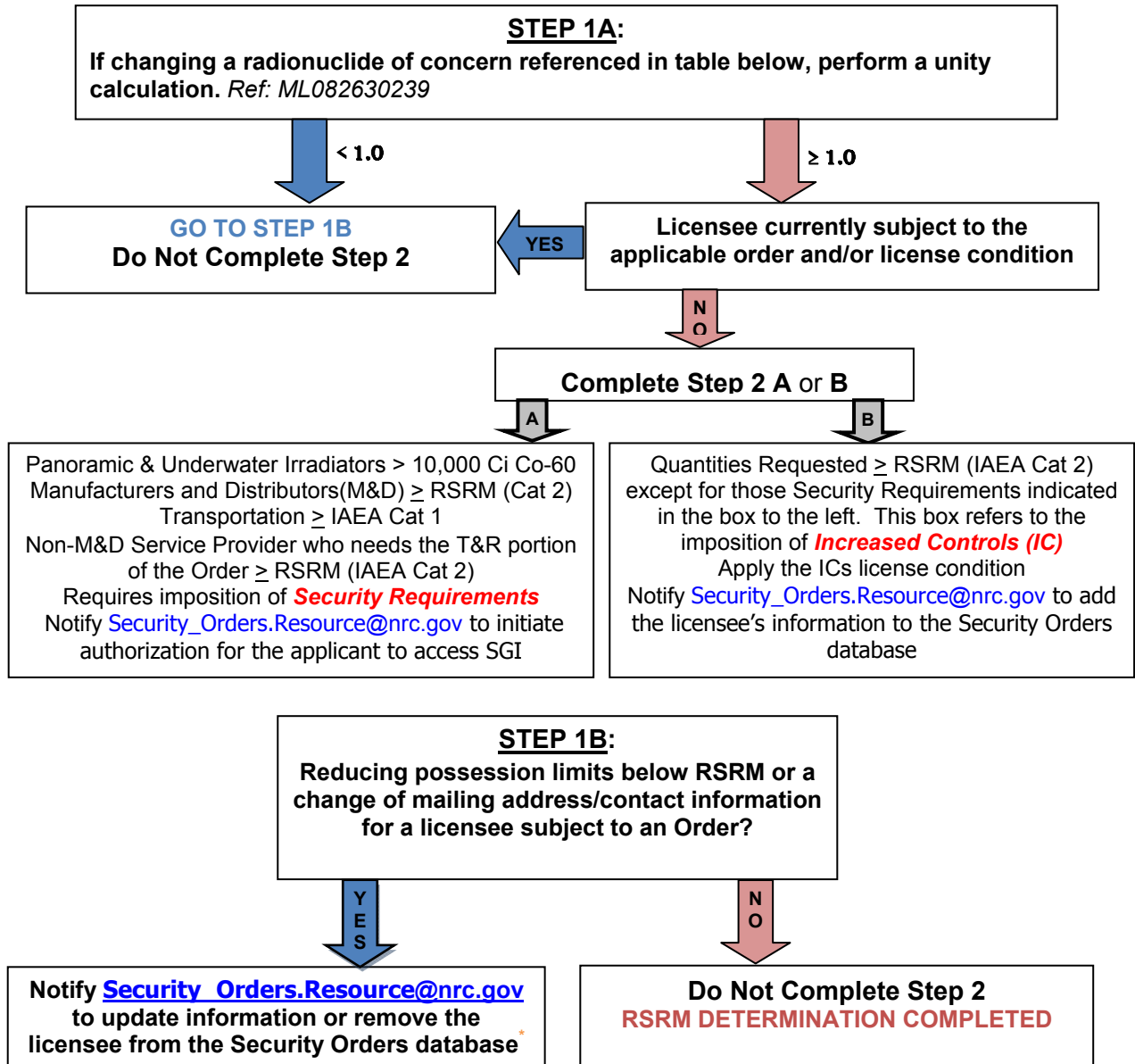
Supervisor Approval:

(Approval from the responsible inspection branch chief is only required when Next Inspection Date is recommended to be changed)

Date: _____

Checklist 3 Risk-Significant Radioactive Material (RSRM)

Purpose: To ensure that additional security measures are applied when necessary and that database is current.



IAEA = International Atomic Energy Agency
 Cat = Category
 T&R = trustworthy and reliable
 SGI = Safeguards Information
 RSRM = Risk-Significant Radioactive Material (IAEA Category 2 quantities and higher)
 Security Requirements = Requirements mandated by regulation, Order, license condition, or other legally binding requirements for certain licensees possessing or shipping RSRM.

* If CAT 1 or CAT 2 RSRM, notify Materials Security & Industrial Branch Chief to update information in Hurricane Response Binder located in Incident Response Center.

RSRM (Category 2 Quantities, IAEA Safety Guide No. RS-G-1.9, Categorization of Radioactive Sources, August 2005)

Radionuclide	Quantity (TBq ¹)	Quantity (Ci ¹)	Radionuclide	Quantity (TBq ¹)	Quantity (Ci ¹)
Am-241	0.6	16	Pm-147	400	11,000
Am-241/Be	0.6	16	Pu-238	0.6	16
Cf-252	0.2	5.4	Pu-239/Be	0.6	16
Cm-244	0.5	14	Ra-226 ²	0.4	10.8
Co-60	0.3	8.1	Se-75	2	54
Cs-137	1	27	Sr-90 (Y-90)	10	270
Gd-153	10	270	Tm-170	200	5,400
Ir-192	0.8	21.6	Yb-169	3	81

¹The primary values are TBq. The curie (Ci) values are for informational purposes only.

²The Atomic Energy Act, as amended by the Energy Policy Act of 2005, authorizes NRC to regulate Ra-226 and NRC has amended its regulations for discrete sources of Ra-226.

	Indicate YES or No
Calculations of the Total Activity and/or the Unity Rule was completed.	

	Indicate YES or No If "YES" indicated, then this section should be marked applicable; proceed to steps 2 and 3.
Licensee implementing Security Requirements or Increased Controls for first time?	
Licensee implementing Security Requirements or Increased Controls at a <u>new</u> location for the first time?*	

*If yes, complete Checklist 2: Identification of Significant Licensing Action

Signature and Date for Step 1:

Reviewer

Date

Checklist 3 Continued
Risk-Significant Radioactive Material (RSRM)

Instructions for Step 2: Check the appropriate box(es) below and follow the corresponding instructions.

<input type="checkbox"/> A. Security Requirements	<p>Security Requirements apply if the applicant: (1) is requesting a Panoramic or Underwater Irradiator with a possession limit greater than 10,000 curies of cobalt-60, or (2) is a Manufacturer and Distributor requesting a possession limit greater than or equal to RSRM table values (IAEA Category 2 quantities), or (3) will possess and transport radionuclides in quantities greater than or equal to (100 x RSRM table values) which is IAEA Category 1 quantities, or (4) is a non-M&D Service Provider who needs the T&R portion of the Order.</p> <p>The reviewer or supervisor will send an email to Security_Orders.Resource@nrc.gov requesting FSME/DMSSA/SSSB to <u>prepare security orders</u> to accompany the specific license and providing the applicant's contact information.</p> <p>OR</p> <p>The reviewer or supervisor will send an email to Security_Orders.Resource@nrc.gov notifying FSME/DMSSA/SSSB of mailing <u>address change</u> and request to update the Security Orders database. Provide the applicant's contact information.</p> <p>If CAT 1 or CAT 2 RSRM, notify Materials Security & Industrial Branch Chief to update information in Hurricane Response Binder located in Incident Response Center.</p>
<input type="checkbox"/> B. Increased Controls	<p>Increased Controls apply if the application requests greater than or equal to the RSRM table values (IAEA Category 2 quantities).</p> <p>The reviewer or supervisor will send an email to Security_Orders.Resource@nrc.gov requesting FSME/DMSSA/SSSB to update the Security Orders database for the specific licensee. Provide the applicant's contact information.</p> <p>The reviewer will add the Increased Controls/fingerprint license condition to the license.</p> <p>If CAT 1 or CAT 2 RSRM, notify Materials Security & Industrial Branch Chief to update information in Hurricane Response Binder located in Incident Response Center.</p> <p>Remember: SUNSI review should place <i>Official Use Only – Security-Related Information (OUO-SRI)</i> banners on license.</p>

Instructions for Step 3: If the licensee will implement any Security Requirements or Increased Controls for the first time or implement at a new location – make arrangements for a pre-licensing site visit to ensure that the licensee understands and will comply with the Order(s). Provide your justification here if a visit is necessary. If a visit is necessary go to Checklist 5 (Basis For Confidence which includes Pre-licensing Visit). (Ref.: IMC 2800 Section 05.03)

New location	<input type="checkbox"/> No <input type="checkbox"/> Yes, provide address for WBL worksheet: _____
Site visit	

Signatures and Dates:

Reviewer

Date

Supervisor

Date

Checklist 4
National Source Tracking System (NSTS) Update

Purpose: Ensure NSTS is updated with current and correct information.

Risk-Significant Radioactive Material – that which is listed in Category 1 and Category 2 of Appendix E to 10 CFR Part 20, “Nationally Tracked Source Thresholds” and is required to be entered into the NSTS. Answer the questions in the following table: If you check “Yes” to any of the following, then provide the required information:

If:	YES	Then:
New license authorizing NSTS materials		Provide all NSTS information in the table below and inform licensee that they must meet the 10 CFR 20.2207 requirements
Existing license, amended to authorize <u>new</u> NSTS materials (i.e., new nuclide or change in possession limit)		Provide all NSTS information in the table below and inform the licensee that they must meet the 10 CFR 20.2207 requirements
Existing license, amended to <u>add</u> a location for NSTS materials.		List all location address(es) to be added in the table below.
Existing license, amended to <u>remove a</u> location for NSTS materials.		List all location address(es) to be removed in the table below.
Existing license, change of NSTS-required administrative information.		Provide the new/changed information in the table below.
Existing license, amended to <u>remove all NSTS materials</u>		Notify NSTS to remove from database PRIOR to issuing license.

The following administrative information is required to be in the NSTS for licensees possessing NSTS materials. This information will be entered into the NSTS only by the designated NRC staff. Licensees may have multiple contact persons and multiple locations of use.

NSTS data field	New/changed information
NSTS contact person name and title	
NSTS contact person telephone number	
NSTS contact person facsimile number	
NSTS contact person e-mail address	
Licensee Name	
Licensee Mailing Address	
ADD Location(s) of Use: Street/city/state/zip code	
DELETE Location(s) of Use	

Signature and Date for NSTS – Checklist 4:

_____	_____
Reviewer	Date
_____	_____
NSTS Regional Representative	Date

Checklist 5
Basis for Confidence/Pre-licensing Visit
Ref: ML082630238

Purpose: Determine if the applicant is a known entity or transfer of control is to a known entity.

STEP 1 – INITIAL SCREENING WORKSHEET

<p>Instructions for Step 1: Complete Step 1 for all new applications and applications for transfer of control (change of ownership). Use information in the application as well as sources of information that are outside of the application to obtain information to answer the questions. If the answer to <u>any</u> of the questions in the Worksheet is “YES,” then do <u>NOT</u> proceed to Step 2; sign and date the completed form and add it to ADAMS as Non-Sensitive and Non-Publicly Available. Otherwise if “NO” to all of the questions, proceed to Step 2.</p>	<p>YES or NO</p>
<p>1. Does the applicant have a current Agreement State or NRC license? The reviewer should 1) contact the appropriate regulatory authority to confirm that a valid license exists for the applicant; 2) compare the existing license to the new application to confirm that the application represents a reasonable expansion of the licensee’s existing operation (i.e., medical facility adding a gamma knife or an Agreement State licensee obtaining an NRC license in order to work in NRC jurisdiction without filing reciprocity); and 3) contact the licensee’s corporate office to confirm that it has knowledge of and approves of the new application.</p> <p>Describe:</p>	
<p>2. Does the applicant have a current State or federal government license/registration/authorization for other operations within the scope of its proposed licensed activities? If so, have they undergone regular inspection visits from the state or federal government? (e.g., a company authorized by a State for mining that is now requesting authorization to use fixed gauges) The reviewer should contact the appropriate government office to confirm that the license/registration/authorization is valid, and to determine how long it has been in place and whether the established location of use is the same as that now being proposed for the license, and to determine if the applicant has had regular inspections from the state or federal government (enforcement history). The reviewer should take into account how long the license/registration has been in place, and the results of the last inspection from the state. The reviewer should also contact the applicant’s corporate office to confirm that it has knowledge of and approves of the new application to possess radioactive materials.</p> <p>Describe:</p>	
<p>3. Is the applicant a local, State or federal government entity? The reviewer should contact the local, State or federal government agency to confirm that the applicant is a government entity.</p> <p>Describe:</p>	
<p>4. Does the application only involve the relocation of an existing licensee, or its mailing address, to another State? This includes new licenses created from existing licenses listing locations in multiple States, in preparation for transfer of licenses to States that will shortly sign an Agreement with the NRC.</p> <p>Describe:</p>	
<p>5. Is the application only the result of a licensee failing to submit a renewal application in a timely manner?</p> <p>Describe:</p>	

Signature and Date for Step 1:

Reviewer

Date

Checklist 5 Continued
Basis for Confidence/Pre-licensing Visit

STEP 2 – ADDITIONAL SCREENING

Instructions for Step 2: Use information in the application as well as sources of information that are outside of the application to make a determination regarding the basis for confidence that the radioactive material will be used as specified on the license. **Document the review of each applicable item under “Reviewer Notes” below.** Write "YES," "NO," or "NA" in the last column as a preliminary indicator as to whether the item provides a basis for confidence that the requested materials will be used as specified in a license. Summarize the review at the bottom of the Step 2 and sign, date, and place the completed form as the Official Agency Record in ADAMS, as Sensitive and Non-Publicly Available. If “NO” (meaning no basis for confidence), go to Step 3.

	Reviewer Notes <i>Ref: ML082630238</i>	Basis for Confidence (Indicate YES, NO, or NA)
Request for Materials		
Former Licensee or Authorized User		
Ownership/Senior Management		
Radiation Safety Officer		
Authorized User		
Fee Payment		
Financial Assurance		
Deficiency Correspondence		
Communication with the Applicant		
Public Web Sites/Information		
Additional Check of Applicant Information		
Local Law Enforcement		
Security		
Summary: Based on the information described above, the reviewer was provided a basis for confidence that the requested radioactive materials will be used as specified on the license and an additional evaluation of a potential security risk is <u>not</u> needed. [NOTE–If “NO” is indicated in the last column, provide rationale below, then complete Step 3 without delay.]		YES or NO
Supporting rationale for an additional evaluation (Step 3): <i>(example: based on a preponderance of inconsistent information, the reviewer was not provided a basis for confidence that radioactive material will be used as specified on the license)</i>		

Checklist 5 Continued
Basis for Confidence/Pre-licensing Visit

STEP3 – PRE-LICENSING SITE VISIT

<p><u>Instructions for Step 3: Provide justification to clearly describe why a pre-licensing visit is needed or not needed.</u></p>	<p>Reviewer Notes <i>Ref: NRC Inspection Manual (IMC) 2800</i></p>	<p>Basis for Confidence (Indicate YES, NO, or NA)</p>
<p>Pre-Licensing Site Visit (<i>if visit conducted complete pre-licensing visit record</i>)</p>		

STEP 4–NOTIFY NRC HEADQUARTERS AT FSME/DMSSA (SSSB)

<p>Instructions for Step 4: If the reviewer is NOT provided a basis for confidence by the information obtained in Step 2 that the material requested by the applicant will be used as specified on the license, complete a Technical Assistance Request.</p>	
<p>Request for additional evaluation of the applicant</p>	<p>Complete Technical Assistance Request (TAR) in accordance with NUREG-1556, Volume 20, TAR for Materials Licensees and include the completed Step 2 with the TAR package.</p>
<p>Date TAR package transmitted to SSSB:</p>	
<p>Due date of TAR response from SSSB:</p>	

Signatures and Dates:

<p>_____</p> <p>Reviewer</p>	<p>_____</p> <p>Date</p>
<p>_____</p> <p>Supervisor</p>	<p>_____</p> <p>Date</p>

Checklist 5 Continued
Basis for Confidence/Pre-licensing Visit

Purpose: To gather additional information to make a determination that the radioactive materials will be used as specified on the license.

Date(s) of site visit: _____

Item A. Applicant Personnel Contacted During the Pre-Licensing Visit:

	Name	Title
1.		
2.		
3.		
4.		
5.		

Item B. Summary of Observations, Findings, and Conclusions (see Step 2 Additional Screening)
Ref.: ML082630167

Business Operations	
Facility – Visit all storage and use locations identified on the application	
Radiation Safety Operations	
Personnel	
Overall Assessment NOTE: If there is not sufficient information to conclude that licensed material will be used as specified on the license, immediately go to Step 4 of Checklist 4 and notify headquarters.	

Signatures and Dates for Pre-licensing Visit:

Reviewer / Reviewer Code

Date

Supervisor

Date

Checklist 6 Renewal

Purpose: To assist license reviewer in performing complete review of renewal action.

When "NO" is indicated, document the deficiency at the end of the checklist	YES, NO, or NA
NRC-313 or appropriate equivalent signed and dated by senior licensee representative.	
Possession limits checked to ensure decommissioning financial assurance, emergency plans, NSTS, NMMSS, and increased controls remain adequate or are not required.	
Licensee name and address match the current license.*	
Place of use is a physical location (i.e., not P.O. Box, etc.).	
RSO and key personnel are appropriately qualified.	
Facilities and equipment are adequate.	
The remainder of the application found that the major areas discussed in the appropriate NUREG-1556 series are present.	
All uses qualify for a categorical exclusion in 10 CFR Part 51.	
Organizational structure conforms to applicable regulations and NUREG-1556 guidance.	
New authorizations requested by the licensee (including NARM) and any major program changes conform to applicable regulations and NUREG-1556 guidance, or NRC website guidance.	
New technologies, including high risk technologies, requested by the licensee conform to applicable regulations, NUREG-1556 guidance, or NRC website guidance.	
Sealed sources and/or devices have correct model numbers listed. Review applicable Sealed Source and Device Registration certificates.	
Inspection records were reviewed for issues to be resolved during licensing.	
Previous license reviewed to ensure that any licensed material removed was appropriately disposed of and that any areas of use, included in license tie-downs, removed were appropriately decommissioned.	
Records for the 5 years preceding this renewal application were reviewed and/or appropriate staff were interviewed with respect to the following performance indicators (If any applies, as designated by a YES, explain and discuss whether issues were addressed during renewal and , if not, why not).	
Escalated Enforcement, or OI or OIG investigation occurred or ongoing.	
Lost control of licensed materials presumed in public domain that is reportable or resulted in a violation.	
Unauthorized disposal or release of material that is reportable or resulted in a violation.	
An overexposure that resulted in a violation.	
Area(s) of Focused or Thorough Review:	
Additional information was requested, and an adequate response was received. Provide justification, if needed:	

* Change in Control (Ownership) must conform to applicable regulations and NUREG-1556 guidance. Financial assurance documents can be affected by a change of ownership.

Checklist 6 Continued
Renewal

Signatures and Dates for Comprehensive Review:

_____	_____
Reviewer / Reviewer Code	Date
_____	_____
Supervisor	Date

**This product has been endorsed by the ILWG
May 2013**