



UNITED STATES
NUCLEAR REGULATORY COMMISSION
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(FSME-06-114, December, Program, Pre-Licensing Guidance)

December 21, 2006

ALL AGREEMENT STATES, NEW JERSEY, PENNSYLVANIA, VIRGINIA

IMPLEMENTATION OF PRE-LICENSING GUIDANCE (FSME-06-114)

Enclosed are copies of the pre-licensing guidance, i.e., "C.6–Checklist to Ensure that Radioactive Materials Will Be Used As Intended" (Checklist) and the associated implementation guidance for materials license reviewers. The Checklist will be inserted into NUREG-1556, Volume 20, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Administrative Licensing Procedures," Appendix C. The pre-licensing guidance was initially implemented in May 2006 and was finalized in November 2006. No substantive changes resulted from the initial implementation period. Materials license reviewers will continue to implement the pre-licensing guidance as described in the enclosures.

Under [Management Directive 5.3](#), "NRC/Agreement State Working Groups" (July 24, 2002), the Working Group developed the pre-licensing guidance to modify the process of issuing a specific license. The guidance is specifically related to the NRC's response to the U. S. Government Accountability Office (GAO) Report, entitled, "Nuclear Security Federal and State Action Needed to Improve Security of Sealed Radioactive Sources," (August 2003; GAO-03-804). Recommendation 3 of the GAO report states, "Modify NRC's process of issuing specific licenses to ensure that sealed sources cannot be purchased before NRC's verification—through inspection or other means—that the materials will be used as intended." The Checklist and implementation guidance modified the licensing process to provide the mechanism for the reviewer and cognizant supervisor to request an evaluation of a potential security risk.

The Working Group resolved comments from the Regional Offices and the Agreement States and coordinated the pre-licensing guidance with the Implementation of Increased Controls Working Group that has developed the program for increased controls for sources. The Steering Group addressed concerns that were raised by the Official Board of the Organization of Agreement States.

If you have any questions regarding this correspondence, please contact me at 301-415-3340 or the individual named below.

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Enclosures:

1. C-6 Checklist
2. Implementation Guidance

Enclosure 1

Checklist to Ensure That Radioactive Materials Will Be Used As Intended

[NUREG-1556, Volume 20, Appendix C]

ML063480221

C.6 Checklist to Ensure that Radioactive Materials Will Be Used As Intended

Applicability: The Checklist is applicable to materials license reviewers and is not intended for reviewers who authorize sources for reactor programs.

Instructions to Reviewers:

The Checklist modifies the process of issuing a specific license. Refer to the Implementation Guidance (ML063480256) which contains requirements and specific guidance to achieve the two essential objectives, below:

1. to ensure that a new applicant (e.g., an entity that has never had a license before or is unknown) requesting a specific license or a licensee requesting transfer of control to a new applicant and all applicants requesting risk significant quantities of certain radioactive materials (all forms, sealed and unsealed) indicated in the Checklist (Step 1, Table of Risk Significant Quantities) and that have not been subject to a Security Order or the additional requirements for increased controls will not be approved until the NRC or an Agreement State has determined with reasonable assurance that the requested materials will be used as intended (e.g., as authorized in a specific license), and
2. to notify the NRC Office of Federal and State Materials and Environmental Management Programs (FSME), Division of Materials Safety and State Agreements (DMSSA), Source Safety and Security Branch (SSSB) of a request for a specific license for a type of use that is under a Security Order or subject to the additional requirements for increased controls.

Complete the Checklist, as follows. Complete Step 1 (Radioactive Materials and Quantities Requested) for **all** applications. If the responses in Items A and B are "NO", do not complete Step 2 or Step 3. If Item A or B is "YES" then complete Step 2 (Screening Criteria) as per the next paragraph. If the applicant requested a type of use that is under a Security Order then complete Step 3 (Notify NRC Headquarters), Item A, without delay. SSSB will contact the applicant directly to provide the instructions about the requirements for initial access authorization for Safeguards Information. SSSB will issue the Security Orders to the applicant when the NRC regional office or the Agreement State issues the specific license to the applicant. Security Orders for certain types of use are indicated on the NRC web site at the following link, <http://www.nrc.gov/reading-rm/doc-collections/enforcement/security/index.html>.

Complete Step 2 (Screening Criteria) to identify inconsistencies between the safety-related information in the application and additional sources of information about the applicant that are already publicly available. For each criterion, indicate the publicly available information that was considered and whether there is a concern for a potential security risk and the basis for the concern. The screening criteria may be used during a licensing site visit to document the additional review of an applicant. If a particular screening criterion is "not applicable" for the review of a particular application, just indicate "NA" in the last column instead of leaving it blank.

Complete Step 3, Item B, to notify SSSB without delay after making the decision to apply or void the additional requirements for increased controls. Refer to the "Guide for Applying the Additional Requirements for Increased Controls," (ML063470434) which is available in the Increased Controls Toolbox.

Complete Step 3, Item C, without delay if the reviewer is not reasonably assured that the requested materials will be used as intended. SSSB will coordinate an additional evaluation of the applicant with the Office of Nuclear Security and Incident Response (NSIR).

NOTE—If the case is turned over to NSIR, do not contact the applicant until further notice. In particular, do not attempt a licensing site visit while NSIR is completing an additional

evaluation of an applicant. Following a determination that there is no security risk, SSSB will notify the reviewer to proceed with the licensing process. The additional evaluation, site visit (if needed), and reply to the reviewer will be completed within 60 days so that the licensing process is not significantly delayed.

Sign, date, and place each completed form in ADAMS as the Official Agency Record (OAR), profiled as Sensitive and Non-Publicly Available, except when all responses are "NO" for Step 1, the profile should be marked as Non-Sensitive and Non-Publicly Available. Alternatively, when all responses for Step 1 are "NO," it is acceptable to annotate the licensing action summary sheet to certify that Step 1 was completed.

DOCKET FILE INFORMATION
C.6 Checklist to Ensure That Radioactive Materials Will Be Used as Intended
(ML063480221)

Applicant Information:

Control No. XXXXXXXX

Name:	Type of Request: New, Renewal, or Amendment Program Code(s):
Location:	License No.: Docket No.:

STEP 1–Radioactive Materials and Quantities Requested:

Instructions for Step 1: Complete Step 1 for all applications. If Step 1, Items A and B, are “NO” then do not complete Step 2. Sign and date the completed form and add it to ADAMS as Non-Sensitive and Non-Publicly Available. If a “YES” response is indicated for Item A or Item B, add the completed form to ADAMS as Sensitive and Non-Publicly Available, and complete Step 2 (Screening Criteria). If the type of use is subject to a Security Order complete Step 3, Item A, without delay. If the additional requirements for increased controls will be applied or voided, complete Step 3, Item B, without delay.	YES or NO
A. The applicant is an entity or a licensee transferring control to an entity that has never had a license or is unknown.	
B. The applicant is requesting certain radionuclides and quantities that equal or exceed the Risk Significant Quantity (TBq) values in the table, below, as “highlighted” by the reviewer and has not been subject to a security order or additional requirements for increased controls.	

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

Radionuclide	Risk Significant Quantity (TBq ¹)	Risk Significant Quantity (Ci ¹)	Radionuclide	Risk Significant Quantity (TBq ¹)	Risk Significant 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	11
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	22	Yb-169	3	81

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

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

Calculations of the Total Activity or the Unity Rule were completed. NOTE–If an amendment of an existing license is being requested, the calculations will include the previously authorized quantities for the radionuclide(s).	YES , NO, or Not Applicable (NA)
Total Activity–multiple activities are requested for a single radionuclide and the sum of the activities equals or exceeds the Risk Significant Quantity (TBq) for the radionuclide.	
Unity Rule–multiple radionuclides are requested and the sum of the ratios equals or exceeds unity, e.g., [(total activity for radionuclide A) ÷ (risk significant quantity for radionuclide A)] + [(total activity for radionuclide B) ÷ (risk significant quantity for radionuclide B) + etc. ÷ etc.] ≥ 1.0.	

Signature and Date for Step 1:

License Reviewer and Date

DOCKET FILE INFORMATION
C.6 Checklist to Ensure That Radioactive Materials Will Be Used as Intended
(ML063480221)

STEP 2–Screening Criteria:

Control No. XXXXXXXX

Instructions for Step 2: Complete Step 2 for any application that yielded a “YES” response in Step 1, Item A or Item B. Use safety information in the application as well as sources of information that are outside of the application. Document the review of each applicable screening criteria below. If a criterion is not applicable in a particular case, mark “NA” in the last column for that criterion. Otherwise, provide a preliminary indication in the last column as to whether an additional evaluation may be needed to reasonably assure that the requested materials will be used as intended. Summarize the review at the bottom of the table and sign, date, and place the completed form as the OAR in ADAMS, as Sensitive and Non-Publicly Available.		
Refer to the Guidance (ML063480256) for each criterion, below.	Review Notes	Indicate YES, NO, or NA
A. Request for Materials		
B. Former Licensee or Authorized User		
C. Ownership/Senior Management		
D. Radiation Safety Officer		
E. Authorized User		
F. Fee Payment		
G. Financial Assurance		
H. Deficiency Correspondence		
I. Contacts to the Applicant		
J. Public Web Sites		
K. Pre-Licensing Visit		
L. Security		
Summary	Within the context of the entire set of screening criteria, the reviewer was not reasonably assured that the requested radioactive materials will be used as intended and an additional evaluation of a potential security risk is needed. [NOTE–If “YES” is indicated in the last column then complete Step 3, Item C, without delay.]	
Supporting rationale for an additional evaluation.		

Signatures and Dates for Step 2:

_____ License Reviewer and Date _____ Supervisor and Date

DOCKET FILE INFORMATION

**C.6 Checklist to Ensure That Radioactive Materials Will Be Used as Intended
(ML063480221)**

STEP 3—Notify NRC Headquarters at FSME/DMSSA (SSSB): Control No. XXXXXXXX

Instructions for Step 3: Mark the type of notification below and attach a copy of the additional information, as appropriate. Place the completed form with attachments as the OAR in ADAMS, as Sensitive and Non-Publicly Available. Designated staff will reply to the incoming email or TAR package and indicate the proposed action(s) and schedule to closure.

- A. Security Orders The cognizant supervisor sent an email to SECURITY_ORDERS@NRC.GOV requesting SSSB to prepare Orders to accompany the specific license and providing the applicant's contact information. A copy of the email is attached.
- B. Increased Controls The cognizant supervisor sent an email to SECURITY_ORDERS@NRC.GOV requesting SSSB to update the National Source Interim Inventory to apply or void the increased controls. The following update information was provided: license number, docket number, license name, address (city, state, and zip code), main contact name, title of contact, phone number, email (if available), date the license condition is effective, ADAMS accession number. A copy of the email is attached.
- C. Request for additional evaluation of the applicant As per NUREG-1556, Volume 20, Section 4.14, Technical Assistance Request—Materials Licensees, the cognizant supervisor sent a TAR package to SSSB after Step 2 was completed. Based on a preponderance of inconsistent information, the reviewer was not reasonably assured that radioactive material will be used as intended. The package included the TAR form, the completed Step 2 form, and the relevant information from the application. The TAR package from an Agreement State supervisor was routed through the NRC Regional State Agreements Officer as per Management Directive 5.7, "Technical Assistance for Agreement States," (revised November 19, 2004).

Signatures and Dates for Step 3: _____
License Reviewer and Date Supervisor and Date

Enclosure 2

Implementation Guidance to Ensure That Radioactive Materials Will Be Used as Intended

ML063480256

IMPLEMENTATION GUIDANCE (ML063480256)

NUREG-1556, Volume 20, Appendix C,

C.6, Checklist to Ensure That Radioactive Materials Will Be Used as Intended (ML063480221)

Applicability: The Checklist is applicable to materials license reviewers and is not intended for reviewers who authorize sources for reactor programs.

C.6-01 OBJECTIVES

01.01 To ensure that a new applicant (e.g., an entity that has never had a license or is unknown) requesting a specific license or a licensee requesting transfer of control to a new applicant and all applicants that are requesting risk significant quantities of certain radioactive materials (all forms, sealed and unsealed) indicated in the Checklist (Step 1, Table of Risk Significant Quantities) and that have not been subject to a Security Order or the additional requirements for increased controls will not be approved until the NRC or an Agreement State has determined with reasonable assurance that the applicant's commitments will be implemented and the requested materials will be used as intended (e.g., as authorized in a specific license).

01.02 To notify the NRC, Office of Federal and State Materials and Environmental Management Programs (FSME), Division of Materials Safety and State Agreements (DMSSA), Source Safety and Security Branch (SSSB) of a request for a specific license for a type of use that is under a Security Order or subject to the additional requirements for increased controls.

C.6-02 REQUIREMENTS AND REVIEW METHODOLOGY

To satisfy the objectives above, a reviewer shall complete the requirements indicated in 02.01 and 02.02, below, that generally describe the 3-step process in the C.6 Checklist. Specific guidance is in Section C.6-03. The checklist contains a separate form corresponding to each step in the process. The forms will be completed as per the specific guidance provided in Section C.6-03 and will be included in the documentation of a reviewer's evaluation of an application for a specific license. ADAMS is the repository for all Official Agency Records (OAR). A completed form will be placed in ADAMS as the OAR.

10 CFR 30.33, General requirements for issuance of specific licenses, provides general requirements for approval of an application for a specific license. NUREG-1556, Volume 20, "Consolidated Guidance about Materials Licenses—Guidance about Administrative Licensing Procedures," (December 2000) contains instructions for license reviewers in Chapter 4 and forms in Appendix B and checklists in Appendix C. To implement the general requirements in 10 CFR 30.33, license reviewers use the instructions, forms, and checklists.

The guidance given here is consistent with the NRC's response to the U. S. Government Accountability Office (GAO) Report, entitled, "Nuclear Security Federal and State Action Needed to Improve Security of Sealed Radioactive Sources" (August 2003; GAO-03-804). Recommendation 3 of the GAO report states, "Modify NRC's process of issuing specific licenses to ensure that sealed sources cannot be purchased before NRC's verification—through inspection or other means—that the materials will be used as intended." The NRC agreed with the recommendation and established an NRC-Agreement State working group to develop a process to ensure that high-risk radioactive sources cannot be obtained before verification through inspection or other means that the materials will be used as intended.

- 02.01 Provide reasonable assurance that a new applicant (e.g., an entity that has never had a license or is unknown) requesting a specific license or a licensee requesting transfer of control to a new applicant or an applicant requesting risk significant quantities of certain radioactive materials and that has not been subject to a Security Order or the additional requirements for increased controls will use the requested materials as intended, e.g., as authorized in a specific license.
- a. Complete Step 1 (Radioactive Materials and Quantities Requested) for all applications. If the responses in Items A and B are “NO”, do not complete Step 2 or Step 3. If Item A or B is “YES” then complete Step 2 (Screening Criteria) as per the next paragraph. The completed Step 1 form will be signed, dated, and placed in ADAMS as the OAR (profiled as Sensitive and Non-Publicly Available unless all responses are “NO” the profile will be Non-Sensitive and Non-Publicly Available). Alternatively, when all responses for Step 1 are “NO,” it is acceptable to annotate the licensing action summary sheet to certify that Step 1 was completed.
 - b. Complete Step 2 (Screening Criteria) to identify inconsistencies between the safety-related information in the application and additional sources of information about the applicant that are already publicly available. For each criterion, indicate the publicly available information that was considered and whether there is a concern for a potential security risk and the basis for the concern. The screening criteria may be used during a licensing site visit to document the additional review of an applicant. If a particular screening criterion is “not applicable” for the review of a particular application, just indicate “NA” in the last column instead of leaving it blank. If the reviewer is reasonably assured by information which indicates that the materials will be used as intended then no further review is necessary for the C.6 Checklist. If the reviewer is not reasonably assured by the information obtained in Step 2 then complete Step 3, Item C, as per the next paragraph. The completed Step 2 form will be signed, dated, and placed in ADAMS as the OAR (profiled as Sensitive and Non-Publicly Available).
 - c. Complete Step 3 (Notification of NRC Headquarters at FSME/DMSSA [SSSB]), Item C, to initiate the technical assistance request (TAR) process as per NUREG-1556, Volume 20, Section 4.14. The TAR process is appropriate for requesting an additional evaluation to determine whether the radioactive materials will be used as intended. SSSB will reply to the reviewer within 60 days. During the 60-day period, SSSB will coordinate the request with the Office of Nuclear Security and Incident Response (NSIR) which may result in direct contact with the applicant to obtain additional information and a site visit to evaluate a potential security risk. The completed form for Step 3 will be signed and dated and placed in ADAMS as the OAR (profiled as Sensitive and Non-Publicly Available).
- 02.02 Notify SSSB about receipt of an application for a specific license to authorize a type of use that is under Security Orders or subject to the additional requirements for increased controls.

Because NRC requires Security Orders for certain materials licenses described at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/security/index.html>, the reviewer will complete Step 3 without delay to notify SSSB after an application for such a type of use is received.

- a. Complete Step 3 (Notification of NRC Headquarters at FSME/DMSSA [SSSB]), Item A,

without delay to notify SSSB to prepare the Orders which will accompany the specific license. SSSB will contact the applicant directly to provide the instructions for the requirements for initial access authorization for Safeguards Information. SSSB will prepare the Orders while the reviewer continues the technical review of the application and the 3-Step process detailed in 02.01, above. Before issuing the license to the applicant, coordinate with SSSB to issue the Orders simultaneously (e.g., within 5 days of the issuance of the license).

- b. Complete Step 3, Item B, to notify SSSB without delay after making the decision to apply or void the additional requirements for increased controls. SSSB will update the National Source Interim Inventory or, in the future, the National Source Tracking System to comport with the licensing action. The increased controls are based on Step 1, Table of Risk Significant Quantities. The instructions to apply the additional requirements for increased controls are available elsewhere and should be implemented separately from the C.6 Checklist. When using the Table of Risk Significant Quantities, complete the calculation for the Total Activity if a single radionuclide is requested or the Unity Rule if multiple radionuclides are requested. If an amendment of an existing license is being requested the calculations shall include the previously authorized quantities for the radionuclide(s) involved.

C.6-03 SPECIFIC GUIDANCE FOR COMPLETING THE C.6 CHECKLIST

03.01 Step 1–Radioactive Materials and Quantities Requested.

The purpose of Step 1 is to determine whether an additional safety and security evaluation is needed because the applicant is an unknown entity that has never had a license (new applicant) or a licensee transferring control to a new applicant or the applicant is requesting risk significant quantities of certain radioactive materials. Complete the “applicant information” at the beginning of the form (e.g., name, location, control no., type of request, program codes, license no. docket no.) then mark Item A and Item B, as appropriate. Specific guidance for Item A and Item B is below. Sign, date, and place the completed Step 1 form in ADAMS as the OAR (profiled as Sensitive and Non-Publicly Available unless all responses are “NO” the profile will be Non-Sensitive and Non-Publicly Available). Alternatively, when all responses for Step 1 are “NO,” a notation may be placed on a licensing action summary sheet in lieu of completing the form for Step 1.

- a. Step 1, Item A, “The applicant is an entity or a licensee transferring control to an entity that has never had a license or is unknown.” Indicate “YES” for Step 1, Item A, if the applicant is an entity requesting a license for the first time or a licensee requesting to transfer control to an entity that has never had a license or is unknown to the licensing agency. In such a case, the reviewer will complete Step 2. Even if the unknown entity is requesting a type of use and quantity that are low risk the reviewer will complete the additional review in Step 2. The transfer of control aspect will be reviewed as per the appropriate program-specific guidance in the NUREG-1556 series. Each volume in the series addresses timely notification of transfer of control. The NUREG-1556 series is available on the NRC web site at the following location:
<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556>

Indicate “NO” for Step 1, Item A, if the applicant is a licensee requesting a new Radiation Safety Officer or a new user whom NRC or an Agreement State has never encountered. In such a case, the reviewer will evaluate the individual’s credentials by

using the health and safety criteria in the appropriate licensing guide that is consistent with the type of use. The reviewer will not complete an additional review under Step 2 because the licensee is responsible for the radiation safety program and the regulatory agency has already determined that the licensee has adequate equipment, facilities, and procedures. Similarly, if a current or former licensee is starting a new company and applies for a new license then Step 1, Item A, is “NO.” A current or former licensee is not a new applicant. The reviewer will consider the enforcement and inspection history that may be available for a current or former licensee.

- b. Step 1, Item B, “The applicant is requesting certain radionuclides and quantities that equal or exceed the Risk-Significant Quantity (TBq) value in the table, below, as 'highlighted' by the reviewer **and** has not been subject to a security order or the additional requirements for increased controls.” It is not necessary to complete Step 2 if the applicant is a licensee that has already implemented the additional compensatory measures in a security order or the additional requirements for increased controls. In such a case, indicate, “NO,” for Step 1, Item B.

As background information about the Table of Risk Significant Quantities, the NRC supports the use of the source categorization methodology as described in the International Atomic Energy Agency (IAEA), Safety Guide No. RS-G-1.9, “Categorization of Radioactive Sources,” (August 2005–STI/PUB/1227) http://www-pub.iaea.org/MTCD/publications/PDF/Pub1227_web.pdf and as endorsed by the “IAEA Code of Conduct for the Safety and Security of Radioactive Sources” (January 2004) http://www-pub.iaea.org/MTCD/publications/PDF/Code-2004_web.pdf. The Code of Conduct used the source categorization methodology to derive a three-tiered structure which is related to Step 1, Item B, Table of Risk Significant Quantities, as follows.

Category 1	Category 2	Category 3
100 X Category 2	Risk-Significant Quantity (TBq) value indicated in the table, Step 1	0.1 X Category 2

IAEA, Safety Guide No. RS-G-1.9, Appendix II, provides a plain language description of the relative radiation hazards for both individual sources and radioactive material that is dispersed by an explosion or fire. Category 1 sources are potentially the most dangerous. The following excerpt from Appendix II provides context for this issue.

“II.2. If a radioactive source were to become separated from the system of control or the radioactive material from the source were to become dispersed as a result of an accident or a malevolent act, people could be exposed to radiation at dangerous levels. For the purposes of this Safety Guide, and in accordance with the Safety Requirements for emergency preparedness and response [25] and the Code of Conduct [19], a radioactive source is considered dangerous if its misuse could be life threatening or could cause a permanent injury that would reduce the quality of life of the person exposed. Possible permanent injuries include burns requiring surgery and debilitating injuries to the hands. Temporary injuries such as reddening and irritation of the skin or temporary changes to the composition of the blood are not considered dangerous. The extent of any such injuries will depend on many factors, including: the activity of the radioactive source; how close a person is to the source and for how long; whether the source is shielded; and whether or not its radioactive material has been dispersed, thus leading to contamination of the skin or inhalation or ingestion. For the purposes of categorization, any possible harm from delayed effects of radiation — such as radiation induced cancer developing later in life in any persons who are exposed — is treated as a secondary consideration to the paramount need to protect against the dangerous consequences described above.”

When completing Step 1, Item B, "highlight" the radionuclide(s) and the corresponding value in the Table of Risk Significant Quantities that corresponds to the applicant's request. Always assume that the requested possession limits for all materials are co-located to a single site without a physical separation of the requested materials so that the Total Activity or the Unity Rule is calculated for all materials authorized by a specific license.

If the requested possession limit in curies (Ci) is close to the Ci-value listed in the table, the reviewer will calculate the activity in terabecquerels (TBq) to determine whether an additional review in Step 2 will be completed and Step 3 will be completed to notify SSSB to initiate preparation of a Security Order.

The conversion factor from Ci to TBq is 27 Ci/TBq, e.g., "X" Ci ÷ 27 Ci/TBq = "Y" TBq.

1. Total Activity: (Applies to multiple forms of a single radionuclide). If multiple forms of a single radionuclide are requested then the sum of the activities for the radionuclide will be compared to the Risk-Significant Quantity (TBq) value for the radionuclide that is listed in the Table in Step 1. If an amendment is being requested for an existing license, the Total Activity will include the previously authorized quantities for the radionuclide. If the sum is less than the table value then no further review is needed. In such a case, indicate "NO" for Step 1, Item B.

If the sum equals or exceeds the table value then the reviewer will also complete Step 2 (Screening Criteria) and Step 3 (Notify NRC Headquarters [SSSB]), Item A or Item B, as appropriate. In such a case, indicate "YES" for Step 1, Item B.

See Attachment 1 for examples of the calculation of Total Activity.

2. Unity Rule: (Applies to a single request for multiple radionuclides). If multiple radionuclides are requested then the reviewer will apply the unity rule which is the sum of the ratios of the Total Activity for each radionuclide to its value listed in the Table in Step 1. If an amendment is being requested for an existing license, the calculation will include the previously authorized quantities for the radionuclides. If the sum of the ratios is less than "one" then no further review is needed. In such a case, indicate "NO" for Step 1, Item B.

If the sum of the ratios equals or exceeds "one" then the reviewer will also complete Step 2 (Screening Criteria) and Step 3 (Notify NRC Headquarters [SSSB]), Item A or Item B, as appropriate. In such a case, indicate "YES" for Step 1, Item B.

See Attachment 1 for examples of the Unity Rule calculation.

03.02 Step 2–Screening Criteria.

The purpose of Step 2 is to complete an additional review by comparing publicly available information about the applicant with the information in the application to reasonably assure that the radioactive materials will be used as intended. The reviewer will sign, date, and place the completed Step 2 form in ADAMS as the OAR (profiled as Sensitive and Non-Publicly Available).

- a. Complete Step 2 for any application that yielded a “YES” response for Step 1, Item A. or Item B. Use the safety information in the application as well as sources of information that are outside of the application to identify obvious inconsistencies which may indicate a potential security risk. Document the additional review of each screening criterion in the Step 2 form.
- b. For each screening criterion, provide a preliminary indication as to whether an additional evaluation is needed to reasonably assure that the requested materials will be used as intended. Indicate “YES” or “NO” in the last column for each of the screening criterion in the Step 2 form. If a particular screening criterion is “not applicable” for the review of a particular application, indicate “NA” instead of leaving the last column blank for the criterion. Attachment 2 contains examples of questions and sources of information that may be used to review the screening criteria in the Step 2 form. Review each screening criterion by using some of the examples from Attachment 2. An Agreement State may obtain from the Regional State Agreements Officer a copy of the Office of Enforcement list of escalated enforcement actions against individuals or organizations that are or have been prohibited from licensed activities. Reviewers are encouraged to develop effective and efficient methods to locate meaningful public information to assure that materials will be used as intended and should not be constrained to use only the examples in Attachment 2. Reviewers may explore any area that is appropriate to reasonably assure that an applicant will use the licensed material as intended.
- c. NUREG-1556, Volume 20, Section 4.9 indicates a licensing site visit is needed for certain types of use, e.g., (1) Type A licenses of broad scope, (2) panoramic irradiators greater than 10,000 curies, (3) manufacturers or distributors using unsealed radioactive material or significant quantities of sealed material, (4) radioactive waste brokers, (5) radioactive waste incinerators, (6) commercial nuclear laundries, and (7) any other application that, in the judgment of the regional staff, involves complex technical issues, complex safety questions, or unprecedented issues. If the reviewer is completing a licensing site visit as per Section 4.9 then incorporate Step 2 into the plan for the site visit, unless the reviewer is suspicious of the applicant to the point of requesting SSSB to complete an additional evaluation for a potential security risk. For example, a reviewer may be suspicious of an applicant who provided false information indicated in Attachment 3. In such a case, cease further licensing contacts with the applicant until further notice from SSSB. Reviewers should be careful at this point in the process when dealing with the applicant. In particular, do not go to the site if the concern was turned over to SSSB. In such a case, indicate “YES” for Step 2, Item K.
- d. Review the findings of the additional review within the context of the entire set of screening criteria and indicate at the bottom of the table in Step 2 whether the reviewer and cognizant supervisor are reasonably assured that the requested radioactive materials will be used as intended or if an additional evaluation of a potential security risk is needed. If “YES” is indicated, the reviewer will provide specific comments to explain the rationale to support the decision (e.g., based on a preponderance of inconsistent information, the reviewer was not reasonably assured that radioactive material will be used as intended) and Step 3, Item C, will be completed without delay and will include the completed form for Step 2. If “NO” is indicated, the reviewer will indicate “NA” for the rationale. Sign, date, and place the completed Step 2 form in ADAMS as the OAR (profiled as Sensitive and Non-Publicly Available).

03.03 Step 3–Notify NRC Headquarters at FSME/DMSSA (SSSB):

Complete the Step 3 form if the applicant requested a type of use that is subject to Orders for additional security measures, compensatory measures, or the additional requirements for increased controls for risk significant quantities of certain radioactive materials or if the reviewer concluded in Step 2 that support information could not be obtained to reasonably assure that the requested radioactive materials will be used as intended. Sign, date, and place the completed Step 3 form in ADAMS as the OAR (profiled as Sensitive and Non-Publicly Available). Supervisors will notify SSSB without delay after the decision is made.

- a. Step 3, Item A, Security Orders. The security orders for certain types of use (panoramic and underwater irradiators, manufacturer and distributors, or transportation of RAMQC) are indicated on the NRC web site at the following location, <http://www.nrc.gov/reading-rm/doc-collections/enforcement/security/index.html>. If the reviewer determines that an Order is required for the type of use requested by the applicant then the supervisor will complete Step 3, Item A, without delay. There are two phases for Security Orders that involve Safeguards Information (SGI). First, SGI initial access authorization will be established for the applicant, and secondly, the actual Security Orders that will be issued simultaneously (e.g., within 5 days) by SSSB when the specific license is issued by the reviewer.

NOTE–Reviewers will make the applicant aware that SSSB will contact the applicant to initiate the process for initial access authorization and to obtain additional information for the SGI Security Orders. Following is a template paragraph for a letter or email from a reviewer to an applicant:

“Please be aware that the requested possession limits described in your application/letter dated **<insert date>** will require the NRC to issue you a Security Order. When authorized to possess **<insert radionuclide>** you will be required to comply with the NRC Security Order before the date that you possess the material. SSSB will be contacting you regarding this matter. If you have any questions regarding the issuance of the Security Orders, please contact **<insert point of contact information for MSIB>**.”

Also, the supervisor will send an e-mail to SECURITY_ORDERS@NRC.GOV. Following is a template paragraph for the e-mail. Remember, DO NOT send SGI via email.

“We have a licensing action that requires issuance of a Security Order. The applicant **<insert name, license no. docket no., control no., ADAMS accession no.>** has requested **<insert radionuclide>** to be used for **<insert type of use>** **<insert, as appropriate, 'and which equals or exceeds the amounts in the Step 1, Table of Risk Significant Quantities'>**. Following is the applicant point of contact information for your use: **<insert name, mail address, phone, FAX, email>**.”

- b. Step 3, Item B, Increased Controls. The instructions to apply or void the additional requirements for increased controls are available elsewhere and should be implemented separately from the C.6 Checklist. As appropriate, the reviewer will ask the applicant about the possibility of reducing the requested maximum possession limits to values that are less than the values in the Table of Risk Significant Quantities in Step 1. If Step 1, Item B, is "NO" then a notification of SSSB is not needed. If "YES" then the supervisor

will notify SSSB. If a licensee requests to reduce the possession limits to less than the Table values or to terminate the license the supervisor will notify SSSB to remove the licensee's information from the National Source Interim Inventory or in the future the National Source Tracking System database. The supervisor will send an appropriate email without delay to SECURITY_ORDERS@NRC.GOV after deciding to apply or void the additional requirements for increased controls. Following is a template paragraph for the email:

"We have a pending action to **<insert 'apply' or 'void', as appropriate>** the additional requirements for increased controls. The update information is: **<insert the license number, docket number, license name, address (city, state, and zip code), main contact name, title of contact, phone number, email address (if available), date the license condition is effective, ADAMS accession number.>**. Please modify the National Source Inventory database to reflect this licensing action."

If an applicant indicates that risk significant quantities are needed then the reviewer will notify the applicant to implement the additional requirements for increased controls. Following is a template paragraph to be included in a deficiency letter or email:

"Please be aware that the requested possession limits described in your application dated **<insert date>** will compel you to implement the requirements in the security order for increased controls as indicated in the NRC web site at the following location, <http://www.nrc.gov/reading-rm/doc-collections/enforcement/security/index.html>. When authorized to possess **<insert radionuclide>** you will be required to comply with the additional requirements for increased controls before the date that you possess the material. Please submit your schedule for implementing the increased controls and provide confirmation that you will not take possession of the additional radioactive materials in risk significant quantities until you are in full compliance with the Increased Controls. If you have any question about the Security Orders at the link provided above, please contact **<insert regional point of contact and phone no.>**

- c. Step 3, Item C, Request for additional evaluation of the applicant. If a reviewer suspects that some information provided by the applicant may be false or misleading then discuss the matter with the cognizant supervisor and follow the allegation process to engage the assistance of the Office of Investigations. NUREG-1556, Volume 20, Section 4.11, Criteria for Denying Applications—Material Licenses, contains guidance for unusual cases. Any question about an applicant's suitability, integrity, ability, or commitment to comply with NRC requirements will be coordinated with FSME.

Attachment 3 contains examples of suspicious information from an applicant that warrant further consideration, e.g., involving the Office of Investigations and/or the allegation process and/or completing Step 3, Item C, to submit a technical assistance request for an additional evaluation of a potential security risk.

If a reviewer cannot determine or has some doubt that the requested radioactive material will be used as intended then notify SSSB to complete an additional evaluation of a potential security risk. The reviewer will initiate the process described in NUREG-1556, Volume 20, Section 4.14, Technical Assistance Request—Materials Licensees and complete the Regional Technical Assistance Request (TAR) Form in Appendix B.

Reviewers in the Agreement States will follow Management Directive 5.7, "Technical Assistance for Agreement States," (revised November 19, 2004) and submit a routine request for an additional evaluation of an applicant. An example of a completed TAR form is in Attachment 3. Additional instructions about the TAR Form are provided below.

1. The "Problem or Issue" field on the form will detail the reason for requesting an additional review. The completed form for Step 2 will be included in the TAR package.
2. The "Action Request" field will state, e.g., "An additional review is requested from SSSB because there is concern that the applicant may not use the requested radioactive material as intended." Such a statement will identify to SSSB that the TAR is requesting the evaluation of a potential security risk.
3. Send the TAR Form to SSSB for coordination with the Office of Nuclear Security and Incident Response (NSIR) so that a security specialist may conduct the additional evaluation of the applicant. A TAR Panel will not be convened.
4. SSSB and NSIR will close out the TAR within 60 days of receipt of same and will contact the reviewer's organization, accordingly.

Attachment 1

**Step 1, Item B
Sample Calculations**

NOTE—If an amendment of an existing license is being requested, the calculations shall include the previously authorized quantities for the radionuclide(s).

Total Activity

Radionuclide	Number of Sources	Source Strength (TBq)	Total Source Strength (TBq)	Total for Radionuclide (TBq)	Table 1 Risk-Significant Quantity (TBq)	Complete Step 2 and Step 3?
Example 1. Am-241	4	0.0185 (0.5 Ci)	0.074	0.629	0.6	YES ($0.6 \geq 0.6$)
	5	0.074 (2 Ci)	0.37			
	1	0.185 (5 Ci)	0.185			
Example 2. Ir-192	1	0.48 (13 Ci)	0.48	0.743	0.8	NO ($0.7 < 0.8$)
	1	0.17 (4.5 Ci)	0.17			
	1	0.093 (2.5 Ci)	0.093			

Unity Rule

The ratio for the radionuclide in column 4, below, is equal to the total activity (column 2) divided by the Risk-Significant Quantity value from Table 1 (column 3).

	Radionuclide	Total Activity (TBq)	Table 1 Value (TBq)	Ratio for Radionuclide	Sum of the Ratios	Compare to Unity	Complete Step 2 and Step 3?
	1	2	3	$4 = 2 \div 3$	5	6	7
Example 1	Co-60	0.259 (7.0 Ci)	0.3	0.86	$0.86 + 0.67 = 1.5$	$1.5 > 1.0$	YES
	Cs-137	0.667 (18.0 Ci)	1	0.67			
Example 2	Co-60	0.122 (3.3 Ci)	0.3	0.41	$0.41 + 0.52 = 0.93$	$0.9 < 1.0$	NO
	Ra-226	0.207 (5.6 Ci)	0.4	0.52			

Attachment 2

**Step 2, Screening Criteria
Additional Review for Inconsistent Information**

The table below contains examples that a reviewer may use to identify obvious inconsistencies between the safety information in the application and other publicly available information about the applicant. The reviewer will evaluate each screening criteria by using some of the examples in the table below to obtain additional information about the applicant. If a particular screening criterion is “not applicable” for the review of a particular application then indicate “NA” for the criterion in the last column of the Step 2 form. Reviewers should not feel constrained to use only these criteria and are encouraged to explore any area they feel is appropriate to confirm that the applicant will use the licensed material as intended.

If the information for a particular screening criteria yields a preponderance of “YES” responses for the screening criteria then the reviewer may also provide a preliminary indication of “YES” for the screening criteria on the Step 2 form. After all the screening criteria have been evaluated, the reviewer will summarize the preliminary indicators on the form and decide whether to request an additional evaluation by SSSB for a potential security risk. For example, one or two screening criteria alone may not be sufficient to request an additional evaluation; however, within the context of the entire set of screening criteria the reviewer and cognizant supervisor may identify contributing factors which may be sufficient to request an additional evaluation of a potential security risk. The decision will be documented at the bottom of the form for Step 2 and endorsed by the reviewer and cognizant supervisor.

Screening Criteria	Questions and Sources of Information to Evaluate the Screening Criteria
A. Request for materials	<ol style="list-style-type: none"> 1. Is the applicant asking for a large amount of material - more than normally required for the type of use? 2. Is the applicant asking for a radionuclide not normally used for the requested purpose? 3. Are there inconsistencies between the Sealed Source and Device Registration Certificate(s) and the requested source model(s) and activity or activities?
B. Former licensee or authorized user	<ul style="list-style-type: none"> • Is this the applicant’s initial attempt to obtain a specific license? Check for a previous license if the current license no. is, e.g., XX-YYYY-02, or there is an additional docket no. or reference no. listed in Item 5 on the current or a previous license • Is this the initial attempt to list the individual as an authorized user? Check for another license that authorized the individual (Agreement State or NRC). • Is there a record of poor performance for the applicant or individual? Ask the Regional State Agreements Officer to contact the Agreement State (or vice versa) to ensure there was no prior poor performance.
C. Ownership or senior management	<ul style="list-style-type: none"> • Is the applicant or individual on OE’s list to prohibit involvement in a licensed activity http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/individuals • Is the applicant concealing their previous identity? Perform an internet search for the applicant’s website. Is there a name change or change of ownership posted that is inconsistent with the application? Use www.google.com or www.addresses.com or www.yellowpages.com or www.superpages.com • Does the internet search show business activities that are not consistent with the request? • Check the last employment and training history of owner/senior management
D. Radiation Safety Officer (RSO)	<ul style="list-style-type: none"> • Is this the initial request to be the authorized RSO on a specific license? • Is the applicant or individual on OE’s list to prohibit involvement in a licensed activity http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/individuals • Are there deficiencies in the training & experience to perform as an RSO? • Is the training certificate altered or counterfeit? • Did the internet search reveal inconsistencies with the previous places of employment or educational institutions and academic degrees? • Did the internet search reveal authored publications which are inconsistent with prior places of employment or educational institutions and academic degrees?

Screening Criteria	Questions and Sources of Information to Evaluate the Screening Criteria
E. Authorized User (AU)	<ul style="list-style-type: none"> • Is this the initial request to be named as an AU on a specific license? • Is the information in the application inconsistent with the request for authorization to use radioactive material? • Is the applicant or individual on OE's list to prohibit involvement in a licensed activity http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/individuals • Are there deficiencies in the training & experience to perform as an AU? • Is the training certificate altered or counterfeit? • Does an internet search list publications which are inconsistent with prior training and experience, educational institutions, etc.? • Does an internet search contradict the individual's stated association with previous places of employment or university programs?
F. Fee payment	<ul style="list-style-type: none"> • Call or email your CFO point of contact for Fees. Was payment in cash or off-shore account or other suspicious method?
G. Financial assurance (FA)	<ul style="list-style-type: none"> • Questions about FA are unusually deficient and cannot be resolved or reconciled. • Is an off-shore or international bank account being used? • Are the FA documents other than original or un-notarized? • Are the business names different on the FA documents and the application?
H. Deficiency correspondence	<ul style="list-style-type: none"> • Was the deficiency correspondence (e.g., letter, FAX, or email) undeliverable? • Was the applicant's response inadequate or evasive? • Is the applicant's reply inconsistent with the type of use they are requesting? • Does the letterhead used by the applicant indicate a business name and address other than the business name and address that is in the application?
I. Contacts to the applicant	<ul style="list-style-type: none"> • Were you unable to contact the applicant by telephone? • Unresponsive applicant?
J. Publicly available web sites	<ul style="list-style-type: none"> • Perform an internet search using the applicant's name, owner or senior officer's name, or other available data to confirm that the company appears to be a legitimate business that would need a specific license. Use www.google.com or www.addresses.com or www.yellowpages.com or www.superpages.com • Check with the local state agency (e.g., the Secretary of State) and inquire if the applicant has been registered as a legitimate business entity in that state • If the website listed an email address, did the email "bounce back?"
K. Licensing Site Visit (Section 4.9)	<ul style="list-style-type: none"> • Is the facility an abandoned building or vacant lot? • Is the applicant unfamiliar with NRC, the type of use requested, and other pertinent details of the application? • Is the facility atypical for the type of use requested in the application?
L. Security	<ul style="list-style-type: none"> • Is the applicant unfamiliar with control of access to licensed material, e.g, constant surveillance for material not in storage? • Does the applicant's facility or program allow for unsecured material or unauthorized removal or access to stored material?

Attachment 3

Step 3, Item C
Examples of Suspicious Information from an Applicant
and an Example of a Completed TAR Form

The table below contains examples of information and scenarios that a reviewer may consider to be false or misleading and should, if possible, defer a licensing site visit. The reviewer and cognizant supervisor will discuss such information when completing Step 3, Item C, to submit a TAR package requesting an additional evaluation of a potential security risk. The supervisor may consider other alternatives for dealing with the applicant, e.g., involving the Office of Investigations or the allegation process. If possible, a reviewer should defer a licensing site visit described in NUREG-1556, Volume 20, Section 4.9, until SSSB has determined whether a potential security risk exists.

Type of Information	Examples of Suspicious Information from an Applicant
Identification	<ul style="list-style-type: none"> • The training certificate appears to be forged (e.g., wrong title, wrong signature, wrong course dates—future date) and the certificate is different from certificates that we usually receive from the certifying organization • The internet search for the applicant’s name reveals a totally different line of business • The applicant provides a copy of an Agreement State license and the reviewer’s contact of the State reveals no such licensee • The applicant or radiation safety officer or authorized user is listed in Escalated Enforcement Action for Individuals on the Office of Enforcement web page • The internet search for the applicant’s name reveals that the person has or had affiliations with explosives, bomb-making, etc.
Materials	<ul style="list-style-type: none"> • The activity requested is ~ 100 times higher than the usual and customary request for this type of use • The applicant requests an authorization for incompatible types of use, e.g., industrial radiography, gauges, and a broad scope license. It appears the applicant is trying to accumulate radioactive sources of various types.
Location	<ul style="list-style-type: none"> • The deficiency correspondence is undeliverable, e.g., email is blocked or letter is returned with an address unknown or person not at this address • The reviewer’s telephone contact to the applicant reveals no such person is or has ever been working at that location or the telephone service was disconnected • The reviewer attempts a licensing site visit and determined that the address is an empty lot • The reviewer discovers another business at the location and no one is familiar with the applicant • The reviewer is expecting, e.g., an industrial facility but the applicant is actually located in an office park or a medical therapy clinic and the applicant is actually located in an isolated building near a landfill • The applicant indicates they will be moving but does not provide a location of use, only a P.O. Box. After repeated requests for the new street address, the applicant provides an address in another country, e.g. an overseas address
Fees	<ul style="list-style-type: none"> • Financial assurance is provided in cash or from an off-shore account • The fee contact reveals that the payment arrived in an unusual container and included extra cash which appears to be a bribe
Urgency	<ul style="list-style-type: none"> • A request for an expedited licensing action in combination with any of the examples listed above should heighten a reviewer’s suspicion of an applicant, however, a request for expedited action, alone, will not cast suspicion on an applicant

Example of a Completed TAR Form

[NOTE--the italicized text is an example of information provided by a reviewer who completed C.6 Checklist, Step1 and Step 2.]

REGION TECHNICAL ASSISTANCE REQUEST				
Date:	ADAMS Package Accession No.			
To:	_____, Director Division of Materials Safety and State Agreements, FSME [cc to DMSSA Adm. Asst.] [cc to RPDC clerk]			
From:	_____, Director Division of Nuclear Materials Safety			
Original signed by:				
Licensee: <i>New Applicant is XYZ, Incorporated</i>				
License No.	Docket No.	Control No.		
Letter Dated:	ADAMS Accession No.			
Enforcement Action being held in abeyance:	<input type="checkbox"/>	YES	<input type="checkbox"/>	No
Problem or Issue: <i>Based on the completion of the C.6 Checklist to Ensure that Radioactive Materials Will Be Used as Intended, Step 2 (Screening Criteria), the license reviewer could not determine or has some doubt that radioactive material will be used as intended. Specifically, the publicly available information is inconsistent with the applicant's information as indicated in the 7 items listed below:</i> <i>Item A. The applicant is requesting <insert activity> of <insert radionuclide> to be used for the purpose of <insert purpose>. However, based on our experience, the activity is 100x the norm for this type of use OR this nuclide is typically not used for this stated purpose.</i> <i>Item A. The applicant is requesting radioactive material for the purpose of <insert purpose>. However, the company's web page <insert URL address> shows their business interest to be in <insert type of business> and not <insert typical type of use for requested materials></i> <i>Item D. The listed RSO indicated that he/she had experience in working with radioactive materials and provided a list of publications. However an internet search could not locate any publications by this person.</i>				

Item E. The internet search lists publications which are not consistent with the applicant's prior training and experience/educational institutions, as per the application.

Item E. The applicant's stated association with previous places of employment or university programs is not consistent with the internet search.

Item G. The financial assurance mechanism used by the applicant was issued by a foreign bank account.

Item K. During the site visit, the reviewer noted that the applicant could not provide adequate security for licensed material.

Action Requested *Coordinate with NSIR for an additional evaluation of a potential security risk.*

Recommended Action and Alternatives Accept XXX Reject

The application should be denied as per NUREG-1556, Volume 20, Section 4.11.

TARs addressing similar issues (subject, date and location):

None

Background Documents (Include date and ADAMS Accession Number):

1. *Completed form for Step 1*
2. *Completed form for Step 2 indicating links to inconsistent information.*
3. *NRC Form 313 dated **<insert date>** and pertinent portions thereof.*
4. *Conversation Records with the applicant revealed the following details:
<insert date for each record and give the pertinent details>*
5. *Site Visit Report dated **<insert date>***

Remarks:

Alert the Regional Offices and the Agreement States to determine if multiple applications have been submitted to regulatory agencies by the applicant.

Reviewer: () - Reviewer Code:

Needed by (date, 60-day milestone):