

GUIDE FOR APPLYING THE ADDITIONAL REQUIREMENTS FOR INCREASED CONTROLS
ML063470434

Applicability—Immediately Effective Order [EA-05-090]

STEP ONE: DETERMINE WHETHER THE INCREASED CONTROLS ARE REQUIRED

The Order Imposing Increased Controls (EA-05-090), Attachment B, Table 1, “List of Radionuclides of Concern,” was incorporated into the modified licensing process that is described in NUREG-1556, Volume 20, Appendix C, “C.6—Checklist to Ensure that Risk Significant Quantities of Certain Radioactive Materials Will Be Used as Intended” (Checklist) (ML063480221) and the associated implementation guidance (ML063480256). Step 1 (Radioactive Materials and Quantities Requested) of the Checklist includes the Table of Risk Significant Quantities which contains the same values as EA-05-090, Attachment B, Table 1.

- A. For all licensing actions involving a new specific license or amendment or renewal of an existing specific license, complete Step 1 of the Checklist to determine whether additional requirements for increased controls are needed.
- B. If an applicant requests radionuclides listed in the Table and amounts that equal or exceed the Table values or requests an increase in the possession limit to equal or exceed the Table values, then proceed to STEP TWO. If the amounts requested do not exceed the Table values, then complete the action as usual.
- C. If an existing license does not specify the amounts per source or radionuclide and the total possession limits (see NOTES on next page) then proceed to STEP TWO. If an existing license already specifies the activity for individual sources or radionuclides and the total possession limit for multiple radionuclides or sources, then complete the action as usual.
- D. If an existing licensee requests to add radionuclides listed in the Table (e.g., add additional HDR units, GSR unit, etc.) and had previously received the Order but responded to NRC that they were not currently implementing the Order because the actual possession amounts would be maintained below the Table values (even though the license authorized amounts that equal or exceed the Table values), proceed to STEP TWO. If the request involves radionuclides that are not listed in the Table, then complete the action as usual.
- E. If the action involves an amendment or renewal request from a licensee that has already received the Order and is now requesting to reduce possession limits below the Table values, complete the action as usual and proceed to STEP THREE to send an email to Security_Orders@nrc.gov; SUBJECT: “Rescind IC Order.” Include the necessary information used as the basis for rescinding the Order.
- F. For all amendment or renewal actions, regardless of the request, in which the existing license authorizes radionuclides in the Table in amounts that equal or exceed the Table values and the licensee has already responded to implement the Order, proceed to STEP FOUR (modify the cover letter paragraph to delete the notification requirement) and complete the action as usual.

NOTES: All licenses will specify the possession limit per radionuclide or source, where applicable, and the total possession limit for multiple radionuclides or sources.

- ✓ Limited medical licenses authorized for 35.100 and 35.200 materials in quantities “as needed” are excepted because no radionuclide listed in the Table is currently used for diagnostic nuclear medicine.
- ✓ For sealed sources, the maximum possession limit will no longer indicate, “No single source to exceed the maximum activity specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State.” If multiple sources are requested, the activity per source will be indicated along with the total maximum possession limit for the sources. See the attached sample license formats.
- ✓ For all broad scope licenses, the “Atomic Nos. 1 - 83” grouping will not require additional requirements for increased controls for any of the radionuclides listed in the Table (i.e., Co-60, Cs-137, Gd-153, Ir-192, Pm-147, Se-75, Sr-90/Y-90, Tm-170, Yb-169) unless the radionuclide from the Table is listed separately. For the Atomic Nos. 1 - 83 grouping, the reviewer will authorize the smallest possession limits per radionuclide and total, in order to stay below the Table values and to ensure that the sum of the ratios is less than “one.” The reviewer will list a radionuclide from the Table separately to make it clear when additional requirements for increased controls apply to the radionuclide because the maximum possession limit for the radionuclide equals or exceeds the Table value. See the attached sample license formats.

STEP TWO: CONTACT THE LICENSEE

As appropriate, discuss maximum possession limits per source or radionuclide and total. Make the applicant aware that possession limits less than the Table value are preferred. You may use the following deficiency paragraph in a letter, email, or telephone call:

“Please be aware that the requested possession limits described in your <letter,application> dated <insert date> OR --as will now be listed on your license- will compel you to implement the requirements in the security order for increased controls (Order) 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 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 quantities that equal or exceed the Table values until you are in full compliance with the Increased Controls. If you have any question about the Order at the link provided above, please contact <insert regional point of contact and phone no.>”

If the licensee confirms that they will possess the radionuclides in the Table and submits the aforementioned schedule and confirmation, proceed to STEP THREE and STEP FOUR.

STEP THREE: COMPLETE NOTIFICATIONS

- A. Send an email to Security_Orders@nrc.gov and provide information required to update the licensee's implementation status in the Increased Controls database, i.e., 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.
- B. Notify the Materials Inspection Branch Chief.

STEP FOUR: COMPLETE A., B., AND C., BELOW, TO PREPARE THE LICENSE AND COVER (transmittal) LETTER

- A. Insert the following license condition on the license:

The licensee will comply with the requirements for "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern" (IC) (Accession No. ML053130364) published in the Federal Register (FR) on December 1, 2005 (70 FR 72128) as Attachment B to EA-05-090, "Order Imposing Increased Controls," (Accession No. ML053130218). The licensee will complete implementation of the IC requirements by the first day that radionuclides specified in Table 1, Radionuclides of Concern, (Accession No. ML053130250) of the IC are possessed at or above the limits specified in the table. Notwithstanding any provisions of the Commission's regulations to the contrary, all measures implemented or actions taken in response to the IC requirements shall be maintained until the Commission orders otherwise or until the Commission explicitly modifies its regulations to reflect increased controls, and states in modifying its regulations that the revisions are to supercede Order EA-05-090. The licensee shall notify the Director, Office of Federal and State Materials and Environmental Management Programs, USNRC, Washington, DC, 20555, in writing, within 25 days after it has completed the requirements of this condition. In addition, licensee responses applicable to this license condition shall be marked as "Withhold From Public disclosure Under 10 CFR 2.390."

- B. Insert the following paragraphs in the cover letter (transmittal letter):

Please note that by License Condition you are required to comply with the "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern" (IC) (ADAMS Accession No. ML053130364) published as "Attachment B" to the "*Orders Imposing Increased Controls*" (ML053130218) in the Federal Register on December 1, 2005 (70 FR 72128). This License Condition requires that you complete implementation of said requirements by the first day that radionuclides in quantities of concern are possessed at or above the limits specified in "Table 1: Radionuclides of Concern" found in the IC, and notify, in writing, the Director, Office of Federal and State

Materials and Environmental Management Programs, USNRC, Washington, DC, 20555, when you have completed the requirements of this License Condition. Your response must be marked as "Withhold from Public Disclosure Under 10 CFR 2.390".

The *Implementing Guidance for Licensees that Possess Radioactive Material Quantities of Concern and Q&A's* (ML053130233) and *Supplemental Q&A's* to the Implementing Guidance and IC's are located on the NRC website at the following links:

<http://www.nrc.gov/reading-rm/doc-collections/enforcement/security/2005/ml053130233.pdf>

<http://www.nrc.gov/reading-rm/doc-collections/enforcement/security/2006/ml060680221-a.pdf>

- C. Include the licensee's written response to STEP TWO (schedule and confirmation) in the tie-down condition of the license.

Suggested License Formats:

1. Research and Development

Example—Single radionuclide

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Carbon-14	A. Any	A. <u>XX</u> gigabecquerels (<u>YYY</u> millicuries), total
9. Authorized Use: A. Research and development as defined 30.4.		

2. Non-medical Sealed Sources or Devices

Example 1–Multiple sources

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cesium-137	A. Sealed Sources [insert name of manufacturer, Model Nos.]	A. <u>XX</u> gigabecquerels (GBq) [<u>YYY</u> millicuries] per source and <u>XXX</u> GBq [<u>YYYY</u> millicuries], total
<p>9. Authorized Use:</p> <p>A. For use in [specify type of device, e.g., portable or fixed gauges, industrial radiographic devices, etc.] in accordance with the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and which have been distributed in accordance with a Commission or Agreement State specific license authorizing distribution to persons specifically authorized by a Commission or Agreement State license to receive, possess, and use the devices.</p>		

- OR -

Example 2–Multiple sources

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cesium-137	A. Sealed sources registered either with NRC under 10 CFR 32.210 or with an Agreement State and incorporated in compatible devices as specified in item 9 of this license.	A. <u>XX</u> gigabecquerels (GBq) [<u>YYY</u> millicuries] per source and <u>XXX</u> GBq [<u>YYYY</u> millicuries], total
<p>9. Authorized Use:</p> <p>A. For use in [insert name of manufacturer] Model No. [insert model no.] for [insert authorized use, e.g., “measuring physical properties of materials”].</p>		

3. Medical- 35.400 Material

Example 1—Grouping radionuclides for manual brachytherapy use

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material permitted by 10 CFR 35.400	A. Sealed Sources (<u>insert name of manufacturer and model nos.</u>)	A. <u>XX</u> gigabecquerels (GBq) [<u>YYY</u> millicuries] per source and <u>XXX</u> GBq [<u>YYYY</u> millicuries], total
9. Authorized Use: A. Any manual brachytherapy use permitted by 10 CFR 35.400.		

** License reviewers have typically used a value of 2 curies for “Any byproduct material permitted by 10 CFR 35.400,” and may use the following expression in the future, e.g., “80 GBq [2.2 curies], total.” Several radionuclides in the Table are typically used for manual brachytherapy (e.g., Co-60, Cs-137, Ir-192, Sr-90/Y-90).

-OR-

Example 2—Individual radionuclides listed separately for manual brachytherapy

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material permitted by 10 CFR 35.400	A. Sealed Sources (<u>insert name of manufacturer and model nos.</u>)	A. <u>XX</u> gigabecquerels (GBq) [<u>YYY</u> millicuries] per source and <u>XXX</u> GBq [<u>YYYY</u> millicuries], total
B. [<u>insert name of radionuclide**</u>] permitted by 10 CFR 35.400	B. Sealed Sources (<u>insert name of manufacturer and model nos.</u>)	B. <u>XX</u> gigabecquerels (GBq) [<u>YYY</u> millicuries] per source and <u>XXX</u> GBq [<u>YYYY</u> millicuries], total
9. Authorized Use: A. and B. Any manual brachytherapy use permitted by 10 CFR 35.400.		

** License reviewers should list a radionuclide separately when the total amount requested for the radionuclide equals or exceeds 0.1 of the Table value (e.g., Cs-137, 100 GBq [2.7 curies], total).

4. Broad Scope

Example 1—Increased Controls are not required

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material with atomic numbers 1 through 83	A. Any	A. Not to exceed 0.15 terabecquerel (TBq) [4.08 curies] per radionuclide and 1.36 TBq [36.72 curies], total**
9. Authorized Use: A. Research and development as defined in 10 CFR 30.4.		

** A licensee can possess all the radionuclides listed in the Table within the group for Atomic Nos. 1 - 83 (i.e., Co-60, Cs-137, Gd-153, Ir-192, Pm-147, Se-75, Sr-90/Y-90, Tm-170, Yb-169) and the increased controls do not apply because 0.15 TBq is less than the most restrictive Table value (Co-60, 0.3 TBq) for radionuclides in the group and the sum of ratios is less than “one.”

-OR-

Example 2—Increased Controls are required

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material with atomic numbers 1 through 83, except Selenium-75 **	A. Any	A. Not to exceed 4 gigabecquerels (GBq) [104 millicuries] per radionuclide and 200 GBq [5.4 curies], total
B. Selenium-75	B. Any	B. 2 terabecquerels (TBq) [54 curies], total
9. Authorized Use: A and B. Research and development as defined in 10 CFR 30.4.		

** Se-75 is listed separately to indicate that the additional requirements for increased controls apply to Se-75, alone. The Atomic Nos. 1 - 83 grouping includes the other radionuclides listed in the Table that are also considered when determining applicability in STEP ONE of this guidance.