

# How to Submit a Regulation Review Package and Incorporation by Reference (IBR)

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# Why is this important?

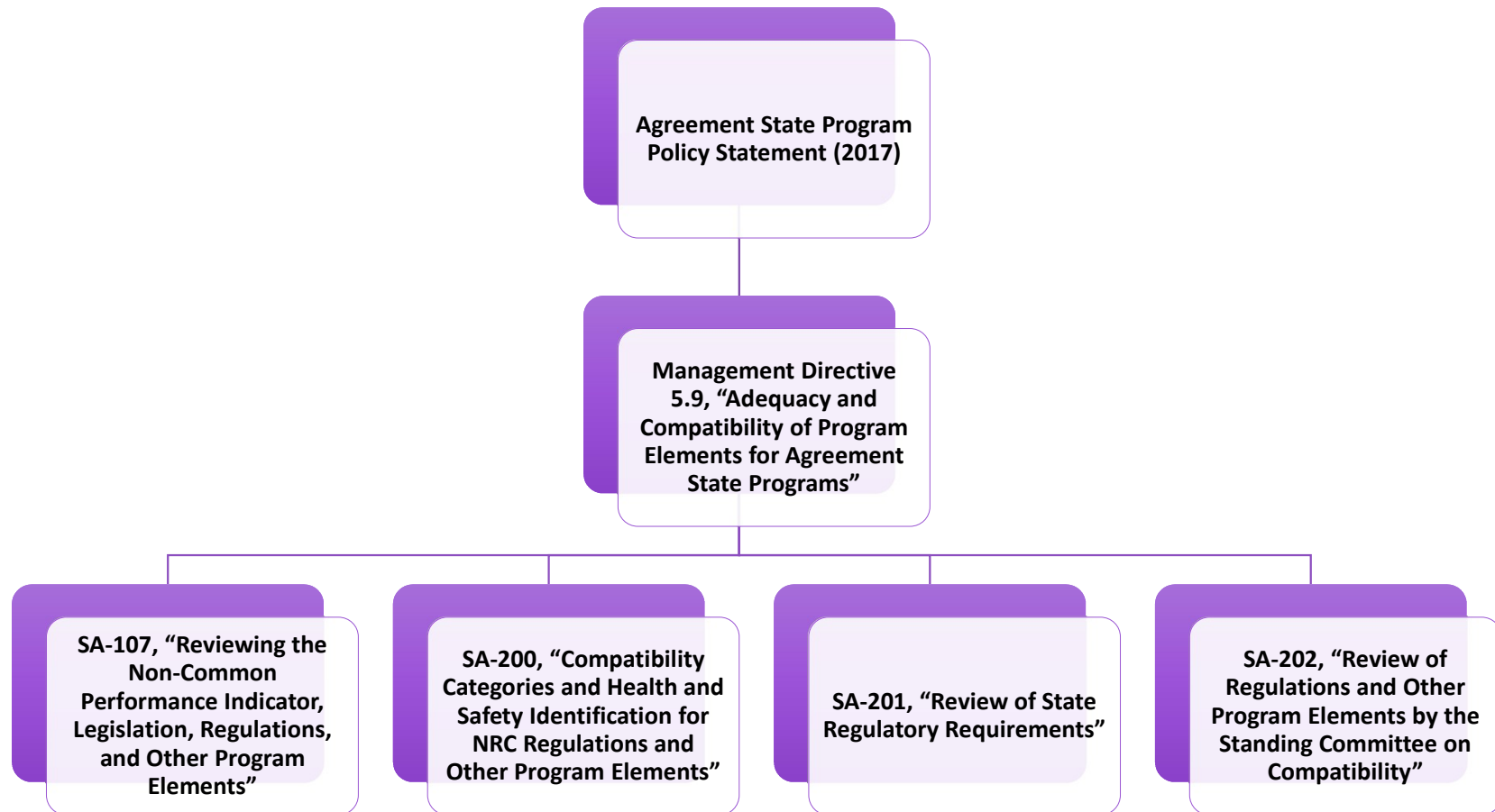
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- Compatibility and Adequacy
- In accordance with Section 274 of the AEA, any State that chooses to establish an Agreement State program must provide for an acceptable level of protection of public health and safety. This is the “adequacy” component. The Agreement State must also ensure that its program supports an overall nationwide program in radiation protection. This is the “compatibility” component.
- Applies to all aspects of a regulatory program: inspection, licensing, **regulations, legislation**, incident response, and staffing and training.

NRC and Agreement States



# Compatibility & Adequacy Guidance



# Regulatory Reviews and IMPEP: LROPE Guidance

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- Regulations & legally binding requirements (orders and license conditions)
  - Adopted within 3 years of effective date unless otherwise communicated.
  - Submitted to the NRC? Results of NRC review?
- Legislation
  - Adopted as soon as practicable.
  - Submitted to the NRC? Results of NRC review?
- Other application program elements
  - e.g., licensing guides, pre-licensing checklist, risk significant radioactive materials checklist, inspection procedures, NMED reporting procedures.
  - Adopted and implemented within 6 months of effective date unless otherwise communicated.



## **Office of Nuclear Material Safety and Safeguards Procedure Approval**

***Reviewing the Non-Common Performance Indicator,  
Legislation, Regulations, and Other Program Elements,  
State Agreements (SA) Procedure, SA-107***

<https://www.nrc.gov/materials/toolboxes/regulation.html>

## Agreement State Regulation Toolbox

*The Regulation Toolbox provides: information to assist the Agreement States when submitting legislation, regulations or legally binding requirements for a compatibility review; a flow diagram of the Regulation Review Process; tips and sample letters for use by the Agreement States and the NRC Reviewers; a list of resources; and contacts.*

- [Regulation Review Process](#) 
- [Tips for NRC Reviewers and State Reviewers](#)
- [Review Summary Sheets for Regulation Adoption for New Agreement States and Programs \(10 CFR\)](#)
- [Review Summary Sheets for Regulation Amendments \(RATS Identification\)](#)
- [Sample State and NRC Letters](#)
- [Sample State Regulation Status Sheet](#) 
- [Resources](#)
- [Contacts and Submission Information](#)
- [Incorporating NRC Regulations By Reference](#) 
- [Program Elements: Regulation and Non-Regulation](#)  (09/06/2022)
- [Program Element Table and associated Compatibility Categories as noted in SA-200](#) 
- [Review Summary Sheet for Suggested State Legislation](#) 
- [State Regulations Suggested by the Conference of Radiation Control Program Directors, Inc.](#)



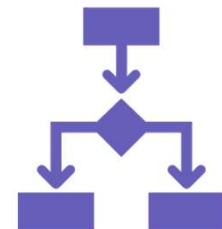
# Overall Review Process



Prepares package including redline  
strikeout and crosswalk.



State submits draft or final regulation,  
license condition, or legislation package  
to:  
[AgreementStateRegs.Resource@nrc.gov](mailto:AgreementStateRegs.Resource@nrc.gov)



The State Regulation Review  
Coordinator (SRRC) performs an  
acceptance review, assigns a reviewer,  
and notifies State of review.

# Overall Review Process



NRC reviews the package and prepares the draft letter including any comments.



SRRC, regulation reviewer, and OGC finalize comments and letter. OGC provides “No Legal Objection” NLO.



NRC letter (with comments as applicable) is sent to the State and posted on <https://www.nrc.gov/agreement-states.html>

## How does the NRC perform a review?

- Every regulation is assigned a “category” – there are 6 categories described in SA-200.
- The reviewer checks to make sure the State regulation meets its assigned category.

**A**

Essentially identical to NRC.

**B**

Essentially identical to NRC (has transboundary implications).

**C**

Some flexibility but needs to be at least as restrictive as NRC; Needs to embody essential objectives.

**D**

Not required for compatibility.

**NRC**

NRC only – State cannot adopt.

**H&S**

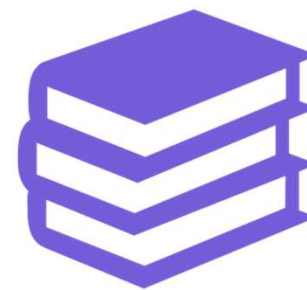
Required for adequacy. Some flexibility but needs to be as restrictive as NRC; Needs to embody essential objectives.

\*Please note these are not comprehensive definitions of the categories. Please see SA-200.

# Ways to adopt NRC Regulations



States drafts own version of NRC regulation



State incorporates NRC regulations by reference

## Drafting Example

10 CFR 35.51, “Training for an authorized medical physicist” is Compatibility Category B (essentially identical):

### **NRC**

Except as provided in § 35.57, the licensee shall require the authorized medical physicist to be an individual who—

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c) of this section. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC’s Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

### **State**

Other than provided in 123 STATE 7-026 the licensee must require the authorized medical physicist to be:

(A) An individual who is certified by a specialty board whose certification process has been recognized by the Department, the NRC or an Agreement State and who meets the requirements of 123 STATE 7-023(C). The names of board certifications that have been recognized by an Agreement State or the NRC are posted on the NRC’s Medical Uses Licensee Toolkit website. To have its certification process recognized, a specialty board must require all candidates for certification to:

## CRCPD Suggested State Regulations

<https://crcpd.org/ssrcrs/>

Categories	Number	Title
Suggested State Regulations (SSRCRs)		Part A – General Provisions
Suggested State Regulations (SSRCRs)		Part B – Registration of Radiation Machines, Facilities, and Services
Suggested State Regulations (SSRCRs)		Part C – Licensing of Radioactive Material
Suggested State Regulations (SSRCRs)		Part D – Standards for Protection Against Radiation
Suggested State Regulations (SSRCRs)		Part E – Radiation Safety Requirements for Industrial Radiographic Operations
Suggested State Regulations (SSRCRs)		Part F – Medical Diagnostic & Interventional X-ray & Imaging Systems
Suggested State Regulations (SSRCRs)		Part G – Use of Radionuclides in the Healing Arts
Suggested State Regulations (SSRCRs)		Part H – Radiation Safety Requirements for Non-Healing Arts Radiation Generating Device
Suggested State Regulations (SSRCRs)		Part I – Radiation Safety Requirements for Particle Accelerators



# Incorporating Regulations by Reference

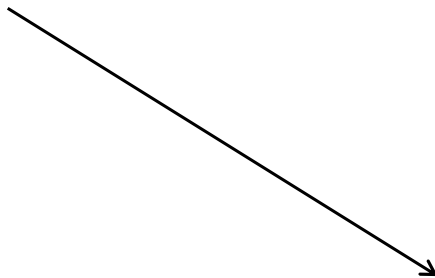
- “The regulations contained in 10 CFR 19, 20, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 61, 70, 71, 150, 170, and 171, as may be amended from time to time, are incorporated by reference with the exceptions set forth in Table 1.0 of this section.”
- With IBR, all A, B, C, D and H&S Categories could be incorporated with almost exact language as 10 CFR regs.
- Compatibility Category D could be excluded.
- Compatibility Category NRC should NOT be incorporated.

## NRC Review Summary Sheet

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
§40.13(c)(5)(iv)	Unimportant quantities of source material		NRC			

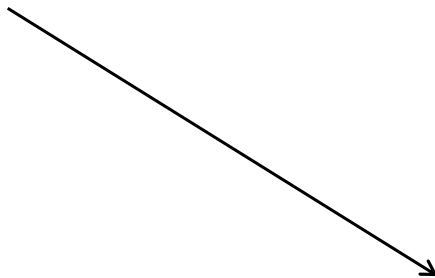
## IBR Regulations

10 CFR	Title	Exceptions
40	Domestic licensing of source material.	Sections 40.4 definitions of "Byproduct Material", "Commission", "Department", "Persons", "Foreign Obligations", "Reconciliation", "Source Material", and "Special Nuclear Material"; 40.6; 40.8; 40.12(b); 40.13(c)(5)(iv); 40.23; 40.27; 40.28; 40.31(j), (k), (l), (m); 40.32(d), (e) and (g); 40.33; 40.38; 40.41(d), (e)(1) and (e)(3), (g), and (h); 40.51(b)(6); 40.52; 40.53; 40.56; 40.64; 40.66; 40.67; 40.81; 40.82; and 10 CFR Part 40 Appendix A Criterion 11 A through F and Criterion 12 are not incorporated. Paragraph 2 of the definition of "commencement of construction" and paragraph 9(ii) of the definition of "construction" in section 40.4 are not incorporated.



## NRC Review Summary Sheet

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
§40.81	Violations		D	N/A		
§40.82	Criminal penalties		D	N/A		



## IBR Regulations

10 CFR	Title	Exceptions
40	Domestic licensing of source material.	Sections 40.4 definitions of "Byproduct Material", "Commission", "Department", "Persons", "Foreign Obligations", "Reconciliation", "Source Material", and "Special Nuclear Material"; 40.6; 40.8; 40.12(b); 40.13(c)(5)(iv); 40.23; 40.27; 40.28; 40.31(j), (k), (l), (m); 40.32(d), (e) and (g); 40.33; 40.38; 40.41(d), (e)(1) and (e)(3), (g), and (h); 40.51(b)(6); 40.52; 40.53; 40.56; 40.64; 40.66; 40.67; 40.81; 40.82; and 10 CFR Part 40 Appendix A Criterion 11 A through F and Criterion 12 are not incorporated. Paragraph 2 of the definition of "commencement of construction" and paragraph 9(ii) of the definition of "construction" in section 40.4 are not incorporated.




# Incorporating Regulations by Reference


- Previous mindset was to essentially incorporate the non-NRC compatibility category regs and make a few basic, across-the-board substitutions such as:
  - “NRC” means “[State]”.
  - “NRC and Agreement State” means “[State], NRC, and Agreement State”.
- Although for the most part these substitutions are correct, it cannot be done across all the 10 CFR regulations. Substitutions can be very complex.

# Example IBR Complexities

Some Agreement States refer to themselves as “Department” in their state regulations. Various places in 10 CFR define “Department” as DOE. These substitutions should not happen.



In some places, the Atomic Energy Act should be substituted with the Agreement State enabling legislation. In other places, it should not.



Some Agreement States have their own compatible definitions for various terms such as “byproduct material” and “person”. If these terms are already defined, they should not be incorporated by reference because then you have duplicate and potentially conflicting definitions.

# Example IBR Complexities

Agreement States have their own forms and contact information for notifications and reports. These should have substitutions to the States' forms and contact information.

- Not all contact or form information should be substituted (e.g., Advanced Notification list of governors)

Some NRC regulations are not required for compatibility such as 10 CFR 2 and 9. The IBR should have the appropriate Agreement State statutes substituted for these parts.

Some Compatibility Category D regulations become overly complex when IBR is applied which result in many substitutions. It may be better to simply exclude the regulation.

10 CFR	Title	Exceptions
40	Domestic licensing of source material.	<p>Sections 40.4 definitions of "Byproduct Material", "Commission", "Department", "Persons", "Foreign Obligations", "Reconciliation", "Source Material", and "Special Nuclear Material"; 40.6; 40.8; 40.12(b); 40.13(c)(5)(iv); 40.23; 40.27; 40.28; 40.31(j), (k), (l), (m); 40.32(d), (e) and (g); 40.33; 40.38; 40.41(d), (e)(1) and (e)(3), (g), and (h); 40.51(b)(6); 40.52; 40.53; 40.56; 40.64; 40.66; 40.67; 40.81; 40.82; and 10 CFR Part 40 Appendix A Criterion 11 A through F and Criterion 12 are not incorporated. Paragraph 2 of the definition of "commencement of construction" and paragraph 9(ii) of the definition of "construction" in section 40.4 are not incorporated.</p>

§ 150.20 Recognition of Agreement State licenses.

Purple highlights need to include NRC

(a)(1) Provided that the provisions of paragraph (b) of this section have been met, any person who holds a specific license from an Agreement State, where the licensee maintains an office for directing the licensed activity and retaining radiation safety records, is granted a general license to conduct the same activity in--

(i) Non-Agreement States;

(ii) Areas of exclusive Federal jurisdiction within Agreement States; and

(iii) Offshore waters.

Yellow highlights become the State Agency

(2) The provisions of paragraph (a)(1) of this section do not apply if the specific Agreement State license limits the authorized activity to a specific installation or location.

(b) Notwithstanding any provision to the contrary in any specific license issued by an Agreement State to a person engaging in activities in a non-Agreement State, in an area of exclusive Federal jurisdiction within an Agreement State, or in offshore waters under the general licenses provided in this section, the general licenses provided in this section are subject to all the provisions of the Act, now or hereafter in effect, and to all applicable rules, regulations, and orders of the Commission including the provisions of §§ 30.7(a) through (f), 30.9, 30.10, 30.34, 30.41, and 30.51 through (f), 40.9, 40.10, 40.41, 40.51, 40.61 through 40.63, 40.71, and 40.81 of this chapter; §§ 70.7(a) through (f), 70.9, 70.10, 70.32, 70.42, 70.51 through H of part 19 of this chapter; §§ 74.11, 74.15, and 74.19 of this chapter; and to the provisions of 10 CFR parts 19, 20 and 71 and subparts C through H of part 20 of this chapter. In addition, any person engaging in activities in non-Agreement States, in areas of exclusive Federal jurisdiction within Agreement States, or in offshore waters under the general licenses provided in this section...

“the Act” is the State Agency enabling legislation

Pink highlight needs to ensure regs are appropriately referenced

1) Shall, at least 3 days before engaging in each activity for the first time in a calendar year, file a submittal containing an NRC Form 241, "Report of Proposed Activities in Non-Agreement States" a copy of its Agreement State specific license, and the appropriate fee as prescribed in § 170.31 of this chapter with the Regional Administrator of the U.S. Nuclear Regulatory Commission Regional Office listed on the NRC Form 241 and in appendix D to part 20 of this chapter for the Region in which the Agreement State that issued the license is located. If a submittal cannot be filed 3 days before engaging in activities under reciprocity, because of an emergency or other reason, the Regional Administrator may waive the 3-day time requirement provided the licensee:

- (i) Informs the Region by telephone, facsimile, an NRC Form 241, or a letter of information submitted on the initial NRC Form 241;
- (ii) Receives oral or written authorization for the activity from the Region; and
- (iii) Within 3 days after the notification, files an NRC Form 241, a copy of the Agreement State license, and the fee payment.

Green highlights to be replaced with State Agency forms

(2) Shall file an amended NRC Form 241 or letter with the Regional Administrator to request approval for changes in work locations, radioactive material, or work activities different from the information contained on the initial NRC Form 241.

(3) Shall not, in any non-Agreement State, in an area of exclusive Federal jurisdiction within an Agreement State, or in offshore waters, transfer or dispose of radioactive material possessed or used under the general licenses provided in this section, except by transfer to a person who is specifically licensed by the Commission to receive this material.

(4) Shall not, under the general license concerning activities in non-Agreement States or in areas of exclusive Federal jurisdiction within Agreement States, possess or use radioactive materials, or engage in the activities authorized in paragraph (a) of this section, for more than 180 days in any calendar year, except that the general license in paragraph (a) of this section concerning activities in offshore waters authorizes that person to possess or use radioactive materials, or engage in the activities authorized, for an unlimited period of time.

(5) Shall comply with all terms and conditions of the specific license issued by an Agreement State except such terms or conditions as are contrary to the requirements of this section.

Purple highlights need to include NRC

Yellow highlights become the State Agency

Pink highlight needs to ensure regs are appropriately referenced

## EXAMPLE SUBSTITUTION LANGUAGE



In 10 CFR 150.20, where the words:

- (i) “non-agreement states”, “areas of exclusive federal jurisdiction within agreement states”, or “offshore waters” are used in (a)(1)(i), (ii), (iii), (b), (b)(3), and (b)(4), substitute the “[State Agency]”,
  - (ii) “agreement state license” are used, substitute “agreement state license or Nuclear Regulatory Commission license”,
  - (iii) “license issued by an agreement state” are used, substitute “license issued by an agreement state or the Nuclear Regulatory Commission”, and
  - (iv) “license from an agreement state” are used, substitute “license from an agreement state or the Nuclear Regulatory Commission.”
- In 10 CFR 150.20(b) reference to “the Act” means “[appropriate State Statutes]”.
  - Instructions in 10 CFR 150.20 to use forms of the NRC means to use forms of the [State agency], which will be available on the [State website] or available upon request from the [State agency address].

Questions?  
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