NOTICE OF PROPOSED RULEMAKING
Title 17, California Code of Regulations

DPH-16-001 Source Material Distribution and General License Revisions
Published: December 21, 2018

PUBLIC PROCEEDINGS
The California Department of Public Health (Department) is conducting a 45-day written public proceeding during which time any interested person or such person’s duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in the Informative Digest/Policy Statement overview section of this notice.

PUBLIC HEARING
The Department has not scheduled a public hearing on this proposed action. However, the Department will hold a hearing if it receives a written request for a public hearing from any interested person, or his or her duly authorized representative, no later than 15 days prior to the close of the written comment period.

WRITTEN COMMENT PERIOD
Any written comments pertaining to these regulations, regardless of the method of transmittal, must be received by the Office of Regulations by 5 p.m. on February 4, 2019, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely. Persons wishing to use the California Relay Service may do so at no cost by dialing 711.

Written comments may be submitted as follows:

1. By email: regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier “DPH-16-001 Source Material Distribution and General License Revisions” in the subject line to facilitate timely identification and review of the comment;

2. By fax transmission: (916) 636-6220;

3. By Postal Service: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814;

All submitted comments should include the regulation package identifier, “DPH-16-001 Material Distribution and General License Revisions” author’s name and mailing address.

**INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW**
The California Department of Public Health (Department) proposes to amend, adopt, or repeal sections of title 17 of the California Code of Regulations (17 CCR) covering the following general topics addressing the regulation of source material (uranium and thorium). This action is taken to carry out California’s statutory duty as an Agreement State under federal law to maintain continued compatibility with the programs of the United States Nuclear Regulatory Commission (NRC) for the regulation of source material. This proposal addresses NRC’s amendments to title 10, Code of Federal Regulations, part 40 (10 CFR 40), Domestic Licensing of Source Material, and also amends existing regulations so they are consistent with corresponding NRC provisions found in 10 CFR 30 and 70. Nonsubstantial changes are also proposed.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Sections Affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exemption for persons to possess products containing very small amounts of source material.</td>
<td>Amend 30181.</td>
</tr>
<tr>
<td>General license for persons to possess small amounts of source material.</td>
<td>Amend 30191.</td>
</tr>
<tr>
<td>General license for persons to possess depleted uranium.</td>
<td>Amend 30192.6.</td>
</tr>
<tr>
<td>Specific license for persons to manufacture or distribute products or devices containing depleted uranium.</td>
<td>Adopt 30201.</td>
</tr>
<tr>
<td>Specific license for persons to distribute source material to general licensees.</td>
<td>Adopt 30202.</td>
</tr>
<tr>
<td>Reports required for persons to distribute source material to general licensees.</td>
<td>Adopt 30202.1.</td>
</tr>
<tr>
<td>Records required for licensees.</td>
<td>Amend 30293.</td>
</tr>
</tbody>
</table>
AUTHORITY AND REFERENCE
The Department proposes to adopt, amend, or repeal, as applicable, the sections identified in the above table, under the authority provided in sections 114975, 115000, and 131200 of the Health and Safety Code (HSC).

This proposal implements, interprets, and makes specific sections 114965, 114970, 114985(g), 115000, 115060, 115165, 115230, 115235, 131050, 131051, and 131052 of the HSC.

POLICY STATEMENT OVERVIEW
Problem Statement: Existing Department regulations that address source material fail to address NRC regulatory changes as required by California’s agreement specified in HSC sections 115230 and 115235. This failure could create undesirable public health consequences within California, and other Agreement States such as the States of Nevada, Oregon, and Washington, and inconsistent regulatory oversight of source material on a nationwide basis. Failure to address the NRC’s changes could also result in the NRC re-invoking federal authority over the possession and use of source material by any person or entity within California to protect the public health and safety. Existing regulations also contain provisions that are out of date, contain incorrect web addresses and inconsistencies, as well as grammatical and capitalization errors.

Objectives: The broad objectives of this proposed regulatory action are to:
- Ensure that the Department’s regulations are compatible with those of the NRC pursuant to the agreement.
- Provide for continuing a consistent and orderly regulatory pattern within the state, among the individual states, and between the federal government and the state, in accordance with legislative policy (HSC § 114965).
- Delete unnecessary regulations.

Benefits: Anticipated benefits from this proposed regulatory action are:
- Continued protection of the public health and safety, worker safety, and the environment, as provided for by the Legislature in the following provisions:
  - HSC sections 114705, 114740, 114755, 114965, 114970, 115000, 115230, and 115235.
- Standards and regulatory programs that are compatible with those of the NRC, in accordance with HSC sections 114965(a), 115000(b), and 115235, art. V.
- Regulatory programs that are consistent with those of other states, in accordance with HSC section 114965(c).
- Continued maintenance of a consistent and orderly regulatory pattern within the state, among the individual states, and between the federal government and the state, in accordance with HSC section 114965(b).
- Updated and clear regulations.
EVALUATION AS TO WHETHER THE PROPOSED REGULATIONS ARE INCONSISTENT OR INCOMPATIBLE WITH EXISTING STATE REGULATIONS

Based on the following evaluation, the Department determined that the proposed regulations are not inconsistent or incompatible with existing California regulations. This evaluation included a review of both the Department’s existing general regulations and those regulations specific to the regulatory control of products containing source material. Some inconsistencies in those specific regulations were found and are addressed in this proposal. An internet search of other California state agency regulations was also performed. It was determined that no other California regulation addressed the same subject matter.

PROGRAM BACKGROUND/AUTHORITY

Source material (uranium and thorium, as defined in HSC § 114985 (e)) is contained in ores, chemical mixtures, compounds, solutions, and alloys that are used in many consumer and industrial products, such as vacuum tubes, welding rods, electric lamps, rare earth metals, neutron dosimeters, glazed tableware, ceramics, glass, aircraft, missiles, bullets, optical devices, and photographic prints. Source material is regulated and controlled by both the NRC and the individual states.

The regulatory scheme is structured to allow possession of source material in three ways, as further described below; namely, hold a specific license; be subject to requirements under a particular general license; or, be exempt from both specific and general license requirements.

- Specific licenses: HSC section 114985(h) defines "specific license" as “a license, issued after application, to use, manufacture, produce, transfer, receive, acquire, own, or possess quantities of, or devices or equipment utilizing, byproduct, source, or special nuclear materials, or other radioactive material occurring naturally or produced artificially.”
- General licenses: HSC section 114985(g) defines “general license” as a “license, pursuant to regulations promulgated by the Department, effective without the filing of an application, to transfer, acquire, own, possess or use quantities of, or devices or equipment utilizing, byproduct, source, or special nuclear materials, or other radioactive material occurring naturally or produced artificially.” Title 17 CCR, sections 30190 – 30192.7 clarify and specify particular types of existing general licenses.
- Exempt products and concentrations: Specific types of products manufactured and distributed by authorized specific licensees may be possessed and used by persons without those persons being subject to regulatory requirements, provided the product is used as labeled. Exempt concentrations may be possessed by persons without those persons being subject to regulatory requirements, provided a certain amount is not exceeded or certain activities are not performed. Persons possessing exempt products and concentrations are commonly called “exempt persons.” Section 115060(c) of the HSC authorizes the Department to create such exemptions.
The Radiation Control Law (RCL) (HSC §§ 114960 - 115273) requires that the Department develop programs for licensing and regulating source materials. (HSC § 115000(b).) The Department is the successor of the California Department of Health Services and as such has the authority to license and regulate radioactive material under the California Public Health Act of 2006 (Stats. 2006, ch. 241).

In 1962, the State of California ratified and approved an agreement with the United States Atomic Energy Commission, the predecessor of the NRC, by which the federal agency discontinued its regulatory authority over certain radioactive materials. (HSC § 115230.) By such action, California became an “Agreement State.” California, as an Agreement State, has regulatory authority over the possession and use of source material by any person or entity subject to state jurisdiction.

A provision of the agreement between California and the NRC requires that the state “use its best efforts to maintain continuing compatibility between its program and the program of the [United States Atomic Energy] Commission for the regulation of like materials.” (HSC § 115235, art. V.) The NRC's stated policy is “to evaluate Agreement State programs established pursuant to Section 274 of the Atomic Energy Act (AEA) of 1954, as amended, to ensure they are adequate to protect public health and safety and compatible with the NRC's regulatory program.”

To determine a state's compatibility, the NRC uses Management Directive 5.9, Adequacy and Compatibility of Agreement State Programs, Handbook 5.9.¹ This handbook describes the specific criteria and processes that are used to determine which NRC program elements should be adopted and implemented by an Agreement State for purposes of maintaining compatibility, and which NRC program elements have a particular health and safety significance. The NRC rates the elements according to the degree of compatibility required. The NRC requires that some elements be adopted by the states in a form identical to the NRC's. Other elements need not be adopted in identical form, but are still required to meet the “essential objective” of the program element. The NRC’s overall determination of the adequacy and compatibility of an Agreement State’s program is made pursuant to Management Directive 5.6, The Integrated Materials Performance Evaluation Program (IMPEP).²

The NRC evaluates Agreement State programs every four years to determine if a state's radiation safety program meets the adequacy and compatibility criteria. If California fails to meet those criteria, the NRC may revoke California's status as an Agreement State and assume direct regulation and control of byproduct, source, and special nuclear material within California.

In conjunction with the NRC’s IMPEP review every four years, the NRC procedure

SA-200\(^3\) requires that Agreement States, when adopting regulations required for meeting the adequacy and compatibility determinations, submit proposed regulations to the NRC for review. The NRC then reviews the proposal to ensure that the proposed regulations meet the applicable NRC compatibility category, defined as follows:

**NRC Compatibility Categories**\(^4\) (underlined words are defined below)

**Category A:** Basic radiation protection standard, or related definitions, signs, labels or terms that are necessary for a common understanding of radiation protection principles. The state program element should be essentially identical to that of NRC.

**Category B:** Program element with significant direct transboundary implications. The state program element should be essentially identical to that of NRC.

**Category C:** Program element, the essential objectives of which should be adopted by the state to avoid conflicts, duplications, or gaps. The manner in which the essential objectives are addressed need not be the same as NRC, provided the essential objectives are met.

**Category D:** Not required for purposes of compatibility.

**Category NRC:** Not required for purposes of compatibility. These are NRC program elements that address areas of regulation that cannot be relinquished to Agreement States pursuant to the AEA or provisions of 10 CFR. The state should not adopt these program elements.

**Category Health & Safety (H&S):** Program elements identified as H&S are not required for purposes of compatibility; however, they do have particular health and safety significance. The state should adopt the essential objectives of such program elements in order to maintain an adequate program.

[ ] = A bracket around a category (e.g., [B]) means that the section may have been adopted elsewhere and it is not necessary to adopt it again. (Reference 3, p. 7.)

**Definitions**\(^5\)

**Conflict** means that the essential objectives of regulations or program elements are different and an undesirable consequence is likely to result in another jurisdiction or in the regulation of agreement material on a nationwide basis.

**Duplication** means that identical regulations or program elements apply to the

---

\(^3\) SA-200 is available at (https://scp.nrc.gov/procedures/sa200.pdf) (Reference 3).


\(^5\) Ibid, pg. 17.
same material at the same time. Note: this definition applies primarily to review of Agreement State regulations.

**Essential objective** of a regulation or program element means the action that is to be achieved, modified, or prevented by implementing and following the regulation or program element. In some instances, the essential objective may be a numerical value (e.g., restriction of exposures to a maximum value), or it may be a more general goal (e.g., access control to a restricted area).

**Essentially Identical** means the interpretation of the text must be the same, regardless of the version (NRC or Agreement State) that is read.

**Gap** means that the essential objectives of NRC regulations or program elements are absent from the Agreement State program, and an undesirable consequence is likely to result in another jurisdiction or in the regulation of agreement materials on a nationwide basis.

To ensure compliance with the NRC agreement and to maintain compatibility of state regulations, this proposal amends existing regulations relating to source material, and addresses those changes made by the NRC that were noted in the following volume of the Federal Register (FR): 78 FR 32310 (May 29, 2013).

The proposed changes are as follows:

**Amend Section 30181, Products Containing and Quantities of Source Material.** This section is amended to be compatible with 10 CFR 40.13.

**Amend Section 30191, General Licenses - Source Material.** This section is amended to be compatible with 10 CFR 40.22.

**Amend section 30192.6, General Licenses - Depleted Uranium.** This section is amended, without regulatory effect, for consistency and clarity with the proposed adoption of section 30201.

**Adopt section 30201, Requirements and Conditions for License to Manufacture or Distribute Products or Devices Containing Depleted Uranium.** This section is proposed to be adopted for compatibility with 10 CFR 40.34 and 10 CFR 40.35.

**Adopt section 30202, Requirements and Conditions for a License to Distribute Source Material to General Licensees.** This section is proposed to be adopted for compatibility with 10 CFR 40.54 and 10 CFR 40.55(a), (b) and (c).

**Adopt section 30202.1, Reports Required for Distributing Source Material to General Licensees.** This section is proposed to be adopted for compatibility with 10 CFR 40.55(d) and (e).

---

6 The citation format 78 FR 32310 (May 29, 2013) means the May 29, 2013 publication of Volume 78, commencing at page 32310, of the Federal Register.
Amend section 30293, Records. This section is amended to clarify when licensees are required to provide records of their activities and to maintain compatibility with equivalent provisions in 10 CFR parts 30, 40, and 70.

MANDATED BY FEDERAL LAW OR REGULATIONS
Not applicable.

DOCUMENTS INCORPORATED BY REFERENCE
None.

OTHER STATUTORY REQUIREMENTS
None.

BUSINESS REPORTING REQUIREMENT
The Department has determined that this proposed regulation would require businesses to submit a report, and that the report is necessary for the health, safety, and welfare of the people of this state.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE
The Department has made an initial determination that the proposed regulations would not have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

LOCAL MANDATE
The Department has determined that this regulatory action would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS
The Department is not aware of any cost impact that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

EFFECT OF HOUSING
The Department has determined that the regulations will have no impact on housing costs.

EFFECT ON SMALL BUSINESS
The Department has determined that there would be an effect on small businesses, because they will be legally required to comply with the regulation, and may incur a detriment from the enforcement of the regulation.

RESULTS OF THE ECONOMIC IMPACT ANALYSIS
The Department has determined that the proposed regulatory action would have no significant adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.
The Department has determined that the regulation would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code.

A. The creation or elimination of jobs within the State of California. The proposal will not impact the creation or elimination of jobs, because it only addresses compatibility with NRC regulations through restructuring, clarifying, and updating existing regulation, and making a number of nonsubstantial changes.

B. The creation of new businesses or the elimination of existing businesses within the State of California. The proposal will not impact the creation or elimination of businesses, because it only addresses compatibility with NRC regulations through restructuring, clarifying, and updating existing regulation, and making a number of nonsubstantial changes.

C. The expansion of businesses currently doing business within the State of California. The proposal will not impact the expansion of businesses, because it only addresses compatibility with NRC regulations through restructuring, clarifying, and updating existing regulation, and making a number of nonsubstantial changes.

D. The benefits of the regulation to the health and welfare of California residents, worker safety, and the state’s environment. The proposal increases and strengthens the health and welfare of California residents, worker safety, and protection of the state’s environment, because it addresses compatibility with NRC regulations through restructuring, clarifying, and updating existing regulation as intended by the Legislature as follows:

- Continues protection of the public health and safety, worker safety, and the environment, as established by the Legislature in HSC sections 114705, 114740, 114755, 114965, 114970, 115000, 115230, and 115235.
- Maintains compatibility with the standards and regulatory programs of the NRC, as specified in HSC sections 114965(a), 115000(b) and 115235 (article V).
- Maintains consistency with the regulatory programs of other states, as specified in HSC section 114965(c).
- Maintains an orderly regulatory pattern within the state, among the states, and between the federal government and the state, as specified in HSC section 114965(b).
- Initiates and administers programs of surveillance and control of those activities that could lead to the introduction of radioactive materials into the environment, as specified in HSC section 114705.
- Updates and clarifies existing regulations and deletes unnecessary regulations.
FISCAL IMPACT ESTIMATE

A. FISCAL IMPACT ON LOCAL GOVERNMENT: There will be an impact as described in item B.1 below.

B. FISCAL IMPACT ON STATE GOVERNMENT:
   1. State agencies that hire health physicists (HPs) and therapeutic medical physicists (TMPs) and pay for authorizations and renewals would be subject to the proposal. However, such payment is within the agencies’ discretion. The proposed application fee is $312 for HP or TMP authorization. The renewal fee is $267 payable every three years. Costs for continuing education (CE) credits widely range from $5 to $250 per credit. For 15 CEs every 3 years, the cost ranges from $75 to $3,750.

      2. The proposed application fee is $312 and the renewal fee is $267 payable every three years. Since the renewal fee of $267 is for a period of three years, the annualized renewal fee is $89 ($267 divided by 3 and rounded).

The applicant pool cannot be accurately estimated because it is unknown how many individuals will apply for authorization. The Department has previously approved 511 individuals. Therefore, 511 renewal applicants are assumed for the purpose of this estimate.

The Radiation Control Fund would receive an estimated one-time increase of $136,437 ($267 times 511) due to renewal fees (with a corresponding expenditure of $136,437), if all 511 previously approved individuals renew their authorization the first year of implementation, and $45,479 ($136,437 divided by 3) annually thereafter with corresponding expenditures of the same values for the subsequent fiscal years following implementation of this proposal. Estimated expenditures are: Fiscal Year (FY) 2019 – 2020 = $45,479; FY 2020 – 2021 = $45,479.

The fees covers workload increases to review and process applications and renewals, training staff, auditing continuing education credits, analyze laws, regulations and policies, conduct quality assurance, and correspond with customers, etc. as described in the Initial Statement of Reasons.

C. FISCAL IMPACTS ON FEDERAL FUNDING OF STATE PROGRAMS: None.

D. FISCAL IMPACT ON PRIVATE PERSONS OR BUSINESSES DIRECTLY AFFECTED: There will be a fiscal impact on private persons who wish to obtain the authorization. The cost for the one-time application fee is $312. The renewal fee is $267 payable every three years. The cost of complying with the CE requirement ranges widely from $5 to $250 per credit. For 15 CEs every 3 years, the cost ranges from $75 to $3,750.

E. MANDATE ON LOCAL AGENCIES OR SCHOOL DISTRICTS: None.
F. OTHER NON-DISCRETIONARY COSTS: None.

CONSIDERATION OF ALTERNATIVES
In accordance with Government Code section 11346.5, subdivision (a)(13), the Office must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Department invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations at the scheduled hearing or during the written comment period.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDIES, REPORTS OR DOCUMENTS RELIED UPON
Reference 1

Reference 2

Reference 3

Reference 4

Reference 4a
CONTACT PERSON
Inquiries regarding the subject matter in this notice may be directed to Phillip Scott, Department's Environmental Management Branch (916) 440-7978. Inquiries regarding the regulatory process described in this notice should be directed to Dawn Basciano, Office of Regulations, at (916) 440-7367, or to the designated backup contact person, Linda Cortez (916) 440-7807.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF REGULATIONS
The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, at the address noted above, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you, please call (916) 558-1710 (or the California Relay Service at 711), send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audocassette, or computer disk.

AVAILABILITY OF CHANGED OR MODIFIED TEXT
The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

FINAL STATEMENT OF REASONS
A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

INTERNET ACCESS
Materials regarding the action described in this notice (including this public notice, the regulation text, and the initial statement of reasons) that are available via the Internet may be accessed at the CDPH website, www.cdph.ca.gov.