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Subject: Comments - Draft Proposed Rule: 10 CFR Parts 20, 30, 31, 32, 35, 40, "Expend Definition of Byproduct Material"

Lydia Chang, Attached are our comments on NRC's Draft Proposed Rule: 10 CFR Parts 20, 30, 31, 32, 35, 40, "Expend Definition of Byproduct Material".

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Texas Department of State Health Services Comments on the US NRC's

draft proposal for

Requirements for Expanded Definition of Byproduct Material

NRC's draft proposed rule *Requirements for Expanded Definition of Byproduct Material* is acceptable overall. However, there are a number of specific concerns described in the following paragraphs, which the NRC could address before the rule is proposed by following the Energy Policy Act (EPAAct). It is recommended that NRC use "model State standards in existence on the date of enactment of this Act." (A quote from the EPAAct.)

Comment 1: The *Requirements for Expanded Definition of Byproduct Material* has several definitions specific to the NRC regulatory scheme (e.g., types of new byproduct material) that are in the draft proposed rule with a Category B compatibility level assigned. The Texas Department of State Health Services (DSHS) is confident that the NRC's State and Tribal Programs (STP) staff who have worked many years with the Conference of Radiation Control Program Directors' (CRCPD) Suggested State Regulations (SSR) system would agree that the States' use of the terms "radioactive material" and "particle accelerator" as defined in the SSRs already cover all the material that NRC has to add to its rules by use of these definitions. In most cases, the States do not need these definitions and adding them will only confuse readers of the States' statutes and regulations as the States have always used the term "radioactive material" rather than "byproduct material." It would be preferable if NRC clearly stated in writing that the States can continue to use "radioactive material" rather than revising the States' statutes and regulations to use "byproduct material" throughout the States regulations, and that the States do not have to add definitions of terms that the States do not use in the States regulations. For this rulemaking, the NRC should designate the definitions it is changing to bring its regulations in line with the EPAAct and the CRCPD's SSRs as compatibility Category C. The NRC is adding the terms not only because the EPAAct has the terms, but because its regulations use the term "byproduct material" generally and defining two more categories of radioactive material to be "byproduct material" efficiently resolves the NRC's regulatory issues. The States have used the term "byproduct material" typically only with reference to mill tailings and the term "radioactive material" for all that the NRC is proposing to define to be "byproduct material" except for mill tailings. As noted in the FRN on pages 31, 32 and 61 and in comment number 23, the States use of "radioactive material" has always included NARM and discrete radium as the NRC proposal defines these terms.

Comment 2: At the end of page 23 and continuing on page 24, the NRC requests comments "on the decommissioning of accelerator facilities, specifically addressing the extent to which accelerator components and facility building

materials may become activated, the need to remove and properly dispose of such activated material during decommissioning in order to meet the radiation dose limits in 10 CFR Part 20 Subpart E—Radiological Criteria for License Termination, the cost of the decommissioning and disposal, if required, and the need for financial assurance by accelerator facilities to guarantee sufficient funding for proper decommissioning.”

In the experience of the DSHS radiation staff, medical treatment accelerators (generally, linear accelerators referred to as linacs) and non-medical linacs (generally, industrial radiography use) have no real decommissioning issues regardless of the energy level because the induced radioactive is usually short lived and the machines are so valuable that older machines are traded in on newer machines or are refurbished by knowledgeable persons who know what components may be activated, how to measure the radiation level, and how to safely work with the “hot” components during the refurbishment process. The half-life of the “hot” components is so short that there is no “disposal” issue with regard to “low level radioactive waste” and there should be no export issues due to radioactivity. The NRC should clearly focus the application of its efforts on “production accelerators”—those used to produce radioactive materials for medical or other use. The States have licensed these types of accelerators, have required decommissioning cost estimates and, in some cases, have completed the decommissioning process for licensed accelerator facilities. Current information from one State that requires “Persons who use particle accelerators to manufacture radionuclides for distribution to other licensees or customers” to submit a reclamation plan and cost estimate for approval by the Agency; and, secure a financial arrangement in the amount specified on the Agency-approved cost estimate.” The Reclamation Plans outline the types of machines and activated hardware that must be disposed of and estimates the amount of concrete from the target vaults that require removal for disposal. These types of facilities reconfigure their operations from time to time based on product needs and changes. Sometimes the shielding material is reused. The number of vaults, targets, etc. drive the costs of decommissioning. For financial assurance cost estimating, most licensees plan on removing all of the concrete shielding.

Comment 3: On pages 30 and 31 the NRC indicates that it proposes to revise its rules to match the SSRs. We agree that this is the right way to go. For cases in which NRC is proposing a revision and a State has already adopted a comparable requirement that has stood the test of time; the States want a written statement by the NRC that the States do not have to revise the rule language to be like NRC even if it the NRC assigns a compatibility Category B or Category A.

For the column breakthrough limit (see page 31) DSHS recommends that the NRC state that the proposed criterion is from the US Pharmacopoeia, which is the criterion the States have used.

Comment 4: On page 33 and 34 there is a discussion under the title Definition of Discrete Sources that could be expanded to clearly state that residuals from treatment of water to meet drinking water criteria and residuals from treatment of waste water from public sewer treatment facilities are not discrete sources of radium regardless of the concentration of radium; however, some of these residuals may become licensable quantities of "source material" due to the concentration of uranium (and thorium).

Comment 5: On page 36 there is a discussion of the NRC's intent to accommodate existing products and materials that were previously regulated by the States under similar provisions. DSHS would like the NRC to clearly state that the wording in the States rules that covered this prior to the NRC receiving its new authority will not have to be revised because the NRC's phrases used to accomplish the same purpose may be different and the rule has compatibility Category B or Category A assigned by the NRC.

Comment 6: On the bottom of page 41, the NRC proposes to "accommodate generally licensed devices meeting the restrictions of the general license that were previously approved by the States under comparable provisions to 10 CFR 32.51." DSHS supports this approach. DSHS requests the NRC to clearly state that the States with provisions comparable to the NRC proposal, as evidenced by the fact that the rule was on the States' books and other States had not objected to it prior to this rulemaking by the NRC, will not have to revise the comparable provisions in order to be compatible with the NRC's new rule language even if the NRC rule is a compatibility Category B or Category A.

Comment 7: On page 44 is the term "revigartors" but a check of a device clearly showed the spelling to be "revigators" instead. Check the historical records and use correct term or, if both terms were used, then use both terms here and elsewhere in this FRN where the term is used. Also, the examples used were made of uranium ore rather than radium. This sentence could be deleted or new examples are needed. (See: <http://www.mtn.org/quack/devices/revig.htm> and <http://www.orau.org/ptp/collection/quackcures/revig30.htm>)

Much more importantly is the proposed new general license for certain items and self-luminous products containing radium, which makes sense with one possible exception: antiques. The experience of DSHS is that many of the antiques mentioned in the proposed Section 31.12(a) are held by members of the public or by organizations in private collections. These items are collected and thus no longer being used for their original purpose. Most, if not all, of these items have been considered as practically exempt from regulation by the States for decades. The transition from exempt to a general license may be problematic since a) many of the owners of these items are likely unaware of the radioactive content and thus unaware of regulatory requirements - current or future and b) we do not know the details of who has them - just the big picture. We are also unaware of any data that suggests these items pose significant enough risk to warrant regulation. The

NRC should consider including these antique items under an exemption, as has been the State practice for decades.

Comment 8: On page 45 at the center of the page, end of first full paragraph is a statement that persons possessing these devices under a general license are to respond to written requests for information from the NRC. It appears that this sentence should end with “from the NRC or the appropriate Agreement State.”

Comment 9: On page 58, at the center of the page, is a discussion regarding the potential for the existence of facilities currently contaminated from discrete sources of radium-226 and the NRC’s proposal to address these situations on a case-by-case basis as they are identified following promulgation of new requirements. The DSHS reminds NRC that radium-226 was once relatively common and unregulated. Therefore, NRC can reasonably expect radium-226 to turn up on a regular basis. NRC should be prepared to address voluminous situations requiring the NRC’s technical, public relations, and political resources.

Comment 10: On page 59 in the discussion of the transition plan, is specified “The statement of the Commission is subject to a certification provided by the Governor of the State to the Commission on the date of publication of the transition plan”... DSHS would like a clear statement that the date of publication of the transition plan will be provided well in advance so we can get the certifications provided on the exact date of publication of the plan.

Comment 12: On page 70 Section 35.2 Definitions, the proposed changes are because of the NRC’s use of the term “byproduct material” and the NRC should clearly state that States who use the term “radioactive material” as defined by CRCPD’s SSRs do not need to amend their definitions to be compatible even if the compatibility Category B or Category A is assigned because the States definitions already include what NRC is including with the proposed revision. Perhaps the NRC could designate the 11e(3) and 11e(4) additions to the definition as compatibility Category C to resolve the issue.

Comment 13: On page 81 at the top of the page is the statement “NRC specifically requests comments on the Compatibility designation. In particular, NRC request comments on whether the definition of *Discrete source* is correctly designated as Compatibility Category B, considering the procedures in Management Directive 5.9 and that Congress assigned NRC the task of defining *Discrete source* in the EPAct.” DSHS suggests that the FRN include a statement acknowledging that the CRCPD SSR and Agreement States term *Sealed source* is comparable and the Agreement States do not have to change their definitions to incorporate the definition of *Discrete source* or that the term is Category C.

Comment 14: On page 82 Section 30.4 Definitions of *Accelerator-produced radioactive material*, *Byproduct material*, *Positron Emission Tomography (PET)* and *Particle*

Accelerator, DSHS suggests that the FRN state that the NRC will accept as compatible regardless of the Compatibility Category the current Agreement States definitions of the terms as long as they are consistent with the current CRCPD's SSR. This statement applies to the other Sections where the same terms are defined.

Comment 15: On page 121 in footnote 2 the items named "revigarators" should be referred to as "revigators." This term was used in one or two other places of the FRN.

Comment 16: On pages 131 through 133 for Section 35.2 Definitions of *Authorized nuclear pharmacist*, *Authorized user* and *Positron Emission Tomography (PET)*, Any Agreement State that has rule language essentially the same as the current SSR provisions has should be considered to have compatible rules and should not have to revise those rules as a result of this NRC rulemaking regardless of the compatibility Category assigned by the NRC.