U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

§ 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.

(a) Except as provided in § 35.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who—

(1) Is an authorized user under § 35.390 for uses listed in § 35.390(b)(1)(ii)(G)(3), or equivalent Agreement State requirements; or

(2) Is an authorized user under § 35.490, § 35.690, or equivalent Agreement State requirements, and who meets the requirements in paragraph (b) of this section; or

(3) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under § 35.490 or § 35.690, and who meets the requirements in paragraph (b) of this section.

(b) The physician—

(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in § 35.390(b)(1)(ii)(G)(*3*). The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in § 35.57, § 35.390, § 35.396, or equivalent Agreement State requirements, in the parenteral administrations listed in § 35.390(b)(1)(ii)(G)(*3*). A supervising authorized user who meets the requirements in § 35.390, § 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve—

(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(v) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that include at least three cases of the parenteral administrations as specified in § 35.390(b)(1)(ii)(G)(*3*); and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in § 35.57, § 35.390, § 35.396, or equivalent Agreement State requirements. A preceptor authorized user who meets the requirements in § 35.390, § 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, § 35.390, § 35.396, or equivalent Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (b)(1) and (2) of this section.

[70 FR 16365, Mar. 30, 2005; 71 FR 15010. Mar. 27, 2006; 74 FR 33906, Jul. 14, 2009; 83 FR 33108, Jul. 16, 2018]

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Page Last Reviewed/Updated Wednesday, January 16, 2019

Gryglak, Magdalena

From: Gryglak, Magdalena
Sent: Thursday, August 15, 2019 12:29 PM
To: 'C. Kelly Stoneberg'
Subject: Request to add Irina Sparks, M.D. for 10 CFR 35.396 material use
Attachments: CN 613846 Request for Additional Information.pdf

Good afternoon Mr. Stoneberg,

I have reviewed you request to add Dr. Sparks for use of 10 CFR 35.396 material.

Please provide Dr. Spark's training and experience in accordance with 10 CFR 35.396 requirements. Please see the attached document for basis and guidance.

Please let me know if you have any questions.

Thank you

Magdalena R. Gryglak
US NRC Region III
630-829-9875