

From: James Dwyer
To: Paul Early
Date: Fri, Oct 31, 2003 8:54 AM
Subject: Re: amendments

Paul:

I agree with a lot of what you say but I am trying to be consistent with what the other license reviewers in my Region are doing. This whole business of what is acceptable training and experience is the subject of a lot of discussion.

As you requested in another email, I am going to issue the amended license today without naming Dr. Anwar as an authorized user. I will fax you a copy of the amendment when it is completed. You can resubmit Dr. Anwar's credentials for re-consideration at any time.

jim

>>> "Paul Early" <pearly@digirad.com> 10/30/03 05:30PM >>>
Jim - During the 50 course that AMP gives in Cleveland (my old company) on Radiation Physics, all the other topics of instrumentation, radiation protection, math and chemistry and rad biology are certainly included. While this is not the AMP course, I would assume that this course is also designed so that these topics are covered also to meet the new requisites of Part 35. Certainly physics and instrumentation are included in a course with that name. And, even if they didn't include the other categories, certainly such topics as math (as much as he needs for Nuclear Cardiology in unit dosages) and chemistry (only two radiopharmaceuticals in Nuclear Cardiology) and radiation protection (as much as is necessary for unit dosages) are included in the work experience. And lets face it, all the doc really needs to know about radiation biology is that there is no diagnostic dosage that can create a problem. Do you really have to spend a lot of time on radiation biology only to tell them that none of these principles apply in the diagnostic dosages that we use in Nuclear Cardiology and therefore, you will never use this information? Forgive me if I sound caustic. I presume that this is the reason why the NRC did not put any hours on these items - and it especially holds true in Nuclear Cardiology. If the preceptor feels that his/her "preceptee" is trained sufficiently for the Nuclear Medicine job for which he/she is applying, then so be it.

Hope this helps.

Paul

----- Original Message -----

From: "James Dwyer" <JPD1@nrc.gov>

To: <pearly@digirad.com>

Sent: Thursday, October 30, 2003 2:04 PM

Subject: Re: amendments

Paul:

10 CFR 35.290(c)(1) requires 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies.

You have provided evidence that Dr. Burris and Dr. Anwar have both far exceeded the requirement for 700 hours. Again, we are no longer specifying a breakdown in how the hours were spent.

Furthermore, 10 CFR 35.290(c)(1) requires that the training and experience include:

(i) classroom and laboratory training in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of byproduct material for medical use, and radiation biology;

You provided for Dr. Burris a certificate of completion of a training course in radiation physics and instrumentation, radiation protection, mathematics pertaining to radioactivity, radiation biology and radiopharmaceutical chemistry. Dr. Burris' training meets the content requirements in 35.290(c)(1)(i).

For Dr. Anwar you provided a certificate of completion of a radiation physics course but nothing for the other subjects described in 35.290(c)(1)(i). Are you suggesting that the other subjects were handled by the authorized user while supervising the work experience required below in 35.290(c)(1)(ii)?

and

(ii) work experience, under the supervision of an authorized user, involving: ordering, receiving and unpacking of radioactive materials safely and performing the related radiation surveys; calibrating and checking instruments; calculating, measuring and safely preparing patient dosages; using administrative controls to prevent a medical event; spill procedures; administering dosages; and eluting generators.

Both Dr. Anwar and Dr. Burris meet the requirements described here in

35.290(c)(1)(ii). While I feel fairly certain neither has eluted a generator, I don't particularly care considering the number of generators I see anymore.

jim

>>> "Paul Early" <pearly@digirad.com> 10/30/03 01:06PM >>>

Jim - In both cases, they are applying under the new Part 35 regs that requires only 700 hours. In Dr. Burris' case, he has over 700 cases and its associated handling experience plus he has an additional 200 hours of didactic training, which, as the last sentence of the preceptor letter indicates that the total number of hours is not less than 1000 hours. In Dr. Anwar's case, he has over 500 cases and its associated handling experience plus he has an additional 50 hours of didactic training, which, as the last sentence of his preceptor letter indicates that the total number of hours is not less than 700 hours. Further, the preceptor in both cases included the competency statement.

As I read the new regs, both of these doctors satisfy the new Part 35 regs for licensure. Please advise.

Paul

----- Original Message -----

From: "James Dwyer" <JPD1@nrc.gov>

To: <pearly@digirad.com>

Sent: Wednesday, October 29, 2003 12:59 PM

Subject: amendments

Paul:

I am processing your amendment request to: (1) add Drs. Anwar and Burris; (2) close the Schererville facility; and (3) add the Egg Harbor Township. The only problem I have is that that 10 CFR 35.290(c)(1) requires, in part, classroom and laboratory training in: -A- Radiation physics and instrumentation; -B- Radiation protection; -C- Mathematics pertaining to the use and measurement of radioactivity; -D- Chemistry of byproduct material for medical use; and -E- Radiation biology. The only thing I have for Dr. Anwar that addresses this requirement is a certificate indicating successful completion of 50 hours training in the Principles of Radiation Physics. Did Dr. Anwar attend the other training programs?

jim