American Association for Nuclear Cardiology, Inc.
Professionals Dedicated to Diagnostic Accuracy

August 17, 2009

Mr. James Caldwell
U.S. NRC, Region III
2443 Warrenville Rd., Ste. 210
Lisle, IL 60532-4352

Dear Mr. Caldwell,

In November, 2008, we notified you of a physician training program which provided content that was not appropriate for a physician's T&E requirements. In the interim, we estimate several hundred physicians have taken this questionable program.

Some agencies have taken the correct action when evaluating the program content; however, some have not exercised their responsibility to evaluate T&E content. We now provide you with a recent letter from the NRC (attached) that does address this issue. Please see Page 2 of that letter where we have "boxed" that reference.

If your agency is not investigating the purported "CONTENT" of programs and only looking at the potentially fraudulent "Attestation", you should be concerned. We recommend that not only new applicants be carefully examined, but that a sample of past approvals may reveal the necessity of investigating past approvals.

If you need clarification or assistance, please feel free to contact me.

Sincerely,

Charles H. Rose, MA, MSPH, D(ABSNM)
Executive Director

CHR:sn
Enc.

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 28, 2009

[redacted]
5660 Airport Boulevard, Suite 101
Boulder, CO 80301

SUBJECT: RESPONSE TO LETTER DATED JUNE 25, 2009

Dear [redacted]

I am responding to your June 25, 2009, letter addressed to Ms. Cindy Flannery, in which you describe proposals to change your program to incorporate several new options into your existing [redacted] training programs tailored for physicians seeking to become authorized users (AUs) and/or radiation safety officers (RSOs). You state further that each of these proposals is based on actual programs currently provided by other organizations. In addition, you provide different examples of classroom and laboratory training programs and ask whether the U.S. Nuclear Regulatory Commission (NRC) would accept these programs for the purpose of satisfying the training and experience (T&E) requirements specified in 10 CFR Part 35 for AUs. You also express your concern about how NRC becomes aware of training programs that do not meet NRC's standards if an attestation statement is provided and ask what actions NRC would take in the event of fraudulent attestations.

The NRC does not review or evaluate the training programs themselves, nor does NRC approve or accept the programs for purposes of the T&E requirements in 10 CFR Part 35. Rather, it is the documentation of T&E for each individual seeking to become an authorized individual (e.g., AU, RSO) under the alternate pathway that is reviewed to determine whether the individual meets the applicable T&E requirements in 10 CFR Part 35. If the T&E documentation demonstrates that the individual does meet the applicable T&E requirements, NRC approves the individual as an authorized individual, but does not approve the training program. As such, responses to your examples will be addressed by whether NRC would approve a proposed AU based on the documented amount of classroom and laboratory training that you provided in your examples, rather than by whether NRC would approve that training program.

In item 1A of your letter, you ask if NRC would accept an 80-hour training program that provides a certificate for 100 hours that includes take-home material, but no time tracking of that material. The NRC does not have any T&E regulations that require a minimum of 100 hours of classroom and laboratory training. However, if a course offers additional take-home material, a physician seeking to become an AU under the alternate pathway may apply that additional training toward the minimum number of hours of classroom and laboratory training requirement if the material relates to the topics identified in the applicable sections of 10 CFR Part 35. Since training program directors would only be able to provide estimates, rather than exact figures, on the number of hours expected for completion of additional take-home training; NRC expects that the actual time that a proposed AU spends on the training, rather than the estimated number of hours to complete training, would apply to required hours of classroom and laboratory training.

The documentation of the complete T&E is carefully reviewed on a case-by-case basis by NRC Regional license review staff, at the time that the licensee submits an application or amendment request, to ensure that the AU satisfies the specific clock hour requirements.

In item 1B of your letter, you ask if NRC would accept a 100-hour program taken again to meet a 200-hour classroom and laboratory requirement. The NRC would not approve an applicant's proposed AU who has taken a 100-hour program twice to meet a 200 hour classroom and laboratory requirement.

In item 1C of your letter, you ask if NRC would accept an 80-hour program where a significant portion of the curriculum is not applicable to the content specified by 10 CFR Part 35. Since the NRC does not approve training programs designed to meet the T&E requirements in 10 CFR Part 35, it is acceptable for training courses to spend some of the course time on topics other than those related to radiation safety and safe handling of byproduct material. However, a physician seeking to become an AU under the alternate pathway must provide evidence to the NRC that he or she has met the applicable T&E requirements by submitting information about the location, date and the number of hours of training for each of the topics listed under the classroom and laboratory training. In your example, if a proposed AU attends an 80-hour course that spends time on subject matter that is not related to radiation safety and safe handling of byproduct material, then the proposed AU would receive credit only for that portion of the 80-hour course that is directed at subject matter required by the T&E requirements. The documentation of the complete T&E is carefully reviewed on a case-by-case basis by NRC Regional license review staff to ensure that the AU satisfies the specific clock hour requirements with subject matter that relates to the topics identified in the applicable sections of 10 CFR Part 35.

In item 1D of your letter, you ask if NRC would accept an "on-line" program that attests that 80/100 hours may be completed in one to three days "on-line." NRC would not approve an applicant's proposed AU who documents that an 80 hour course, on-line or otherwise, was taken in one to three days.

In item 2 of your letter, you ask how NRC would recognize whether a program is inadequate or "potentially fraudulent" if NRC receives a signed preceptor attestation. Although the NRC relies on preceptor statements to determine if an individual has satisfactorily completed the T&E requirements and is competent to function independently as an AU, the NRC still performs a careful review of the documentation of T&E that the applicant is required to submit before listing an individual on a license as an AU. The NRC license reviewer may take additional measures or request additional information from the applicant if the license reviewer believes that the documentation of T&E originally submitted is inadequate (e.g., contacting the vendor providing the training, contacting the preceptor, or requesting a course syllabus).

In item 3 of your letter, you ask what action NRC would take if the NRC identified a fraudulent attestation. NRC regulations in 10 CFR 30.9(a) require, in part, that information provided to the Commission by a licensee or applicant for a license shall be complete and accurate in all material respects. It is the licensee's and applicant's responsibility to ensure the completeness and accuracy of all information it provides to the NRC. The licensee is also responsible for the

acts and omissions of its employees and therefore, should take reasonable steps to verify that the proposed AU actually received the T&E claimed before submitting the license amendment or application to the NRC.

Licensees and applicants for a license should consider contacting preceptors as well as training program directors and continuing medical education providers to verify that the T&E submitted by proposed AUs and proposed RSOs is accurate and commensurate with the T&E required by the applicable sections of 10 CFR Part 35.

Your question in item 3 of your letter regarding actions NRC would take if NRC identified a fraudulent attestation is addressed in Information Notice (IN) 2007-38 "Ensuring Complete and Accurate Information in the Documentation of Training and Experience for Individuals Seeking Approval as Medical Authorized Users" (http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/2007/index.html). This IN provides several cases in which licensees have submitted inaccurate information and describes the actions taken by the NRC against these licensees and applicants. NRC's position on this issue is stated in IN 2007-38 as follows:

> *Whether or not a licensee is aware of the incompleteness or inaccuracy of the information it submits to the NRC, a violation of 10 CFR 30.9, "Completeness and accuracy of information," occurs when inaccurate or incomplete information is submitted because licensees are responsible for the completeness and accuracy of the information they submit to the NRC. In addition, if the licensee willfully submits inaccurate or incomplete information to the NRC, or if inaccurate or incomplete information submitted to the NRC is determined to have been willfully supplied to the licensee by an employee, contractor, consultant, supplier, or subcontractor of the licensee, the licensee's violation of 10 CFR 30.9 may also be considered willful as the licensee is responsible for the conduct of its agents. Such violations will result in the consideration of escalated enforcement action against the licensee, including possible civil penalties. In addition, individuals who deliberately provide materially incomplete or inaccurate information to licensees or applicants for a license in connection with a submission to the NRC may be subject to NRC enforcement action under 10 CFR 30.10 and to criminal prosecution.*

For further information or for questions, please contact Ms. Cindy Flannery, Team Leader of the Division of Materials Safety and State Agreements' Medical Radiation Safety Team at (301) 415-0223, or via e-mail at cindy.flannery@nrc.gov.

Sincerely,

Christian Einberg, Chief
Radioactive Materials Safety Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs