State of North Carolina
Department of Environment,
Health and Natural Resources
Division of Radiation Protection

James B. Hunt, Jr., Governor
Jonathan B. Howes, Secretary
Dayne H. Brown, Director

DEHNR

October 28, 1996

DRP INFORMATIONAL NOTICE 96-03

Memorandum

TO: All Group Medical and Accelerator Licensees

FROM: J. Aaron Padgett, Chief
Radioactive Material Section

SUBJECT: Adding Certified Physicians To a Group Medical or Accelerator License

The Agency has developed a new license condition that permits licensees to allow certified physicians to become users under a group medical or accelerator license. Historically all approvals of physicians to be added to a group medical or accelerator license were given through the Agency via a license amendment request. In order for a physician to be added to the license, qualifications were examined by the staff to determine if the physician met minimum qualifications using the qualifications as outlined in "Subpart J-Training and Experience Requirements" of 10 CFR 35 as guidance. In each section of Subpart J, one criteria for addition of a physician as an authorized user is that the user be certified by one of the organizations specified in that particular section. In an effort to eliminate any unnecessary work and reduce the paperwork generated by licensees and the Agency for these amendments, specified licensees can request, as part of their next license amendment, authority to approve users who are certified by an appropriate certifying organization.

A request will normally be approved from a group medical or accelerator licensee to be able to add physicians as authorized users of radioactive materials or accelerators under their license provided that **ALL** of the following conditions are **FULLY** met:

1. The licensee has established a Radiation Safety Committee as part of their license;
2. The physician to be authorized to work under the license has a certification issued by one of the certifying organizations listed in Attachment A appropriate to the work authorized;
3. The Radiation Safety Committee and the Radiation Safety Officer have reviewed the qualifications of the physician and given their approval **in writing prior to any authorized work being done by the physician**;
4. The physician is approved for a specific use or uses as described in Attachment A;

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3. Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific radioactive material license from the US Nuclear regulatory Commission.

4. Nothing in this policy relieves persons from complying with applicable FDA, other Federal and North Carolina requirements governing the receipt, administration, and use of drugs.

Please either write or call me if you have questions on the above policy.

Sincerely,

J. Aaron Padgett, Chief
Radioactive Materials Section

ATTACHMENT A TO DRP INFORMATION NOTICE 96-03

Listed below are the approved certifying organizations for which a certificate indicates that the prospective physician meets the qualifications set forth in the Regulations for being added to a license. The categories are those outlined in Subpart J of 10 CFR 35.

I. To add a user for uptake, dilution, excretion, imaging and localization studies, certification by one of the following organizations is required:
   A) American Board of Nuclear Medicine (in nuclear medicine); or,
   B) American Board of Radiology (in diagnostic radiology); or,
   C) American Osteopathic Board of Radiology (in diagnostic radiology or radiology).

II. To add a user for therapeutic use of radiopharmaceuticals, certification by one of the following organizations is required:
   A) American Board of Nuclear Medicine; or,
   B) American Board of Radiology (in radiology or therapeutic radiology).

III. To add a user for brachytherapy sources, certification by one of the following organizations is required:
   A) American Board of Radiology (in radiology or therapeutic radiology); or,
   B) American Osteopathic Board of Radiology (in radiation oncology); or,
   C) British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology" (radiology with a specialization in radiotherapy); or
   D) Canadian Royal College of Physicians and Surgeons (in therapeutic radiology).

IV. To add a user for teletherapy, certification by one of the following organizations is required:
   A) American Board of Radiology (in radiology or therapeutic radiology); or,
   B) American Osteopathic Board of Radiology (in radiation oncology); or,
   C) British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology" (radiology with a specialization in radiotherapy); or
   D) Canadian Royal College of Physicians and Surgeons (in therapeutic radiology).

V. To add a user for an accelerator, certification by one of the following organizations is required:
   Same organizations as for teletherapy.

5. A copy of the physicians certification is maintained as part of the written record of the approval;
6. The physician is licensed to practice medicine in the State of North Carolina; and,

7. The licensee must retain a record of the approval by the Radiation Safety Committee and Radiation Safety Officer for a minimum of two (2) years after the physician leaves the employ of the facility; or,

8. The physician has been identified on a North Carolina Division of Radiation Protection Radioactive Material or Accelerator License as an authorized user. The prospective Authorized User shall only perform those studies/procedures for which he was authorized on the previous license. A copy of the previous license shall be maintained as part of the written record.

The licensee will not be authorized to allow a user under their license who is certified by an organization named in items I-V of Attachment A for uses other than those that are allowed by that certification in Attachment A. For example, to be approved for teletherapy, the user would require certification by one of the four organizations listed in item IV of Attachment A.

If a licensee wishes a add an authorized user for work the physician is not certified to perform as described in Attachment A, the licensee must contact the N C Division of Radiation Protection, Radioactive Materials Section for a license amendment.