APPENDIX A

INSTRUCTIONS FOR THE PREPARATION OF A LICENSE APPLICATION MEDICAL PROGRAM

TRAINING AND EXPERIENCE REQUIREMENTS (See Title 12, Article 7)

I. GENERAL CRITERIA (Training must be within the last seven years if not active within the profession)

Any human use of radioactive material must be carried out by, or under the supervision of a person who is:

A. Licensed in Arizona to practice medicine; and

B. A citizen of the United States (A.R.S. §1-501).

An "authorized user" candidate can meet these requirements by providing the Agency a copy of State medical license, driver's license and social security number.

Note 1. A physician does not have to be on a radioactive material license to read nuclear medicine scans.

Note 2. The Agency continues to require that the training standards for authorized users meet the requirements in 10 CFR 35, which means there is now a separate preceptor statement (ARRA-2 Form Series) for each type of authorized user candidate. Included in this group of forms are a form for: radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, an authorized user of Groups 100, 200, and 500, an authorized user of Group 300, and an authorized user of Groups 400 and 600. **There is also a new guide, developed by the NRC, for assist in completing these ARRA-2 forms.**

The Agency will approve a medical license application to use radioactive material if it determines, among other things, that the radiation safety officer (RSO), physicist(s), nuclear pharmacist(s), and physician(s), all designated as authorized user(s), are adequately trained and experienced.
The requirements listed below for authorized users have been established by the Nuclear Regulatory Commission (NRC) in 10 CFR 35, and adopted by the Agency.

Use the correct ARRA-2 Form (Preceptor Statement) to document authorized user training and experience. The available forms are as follows:
ARRA-2 (RSO) - Radiation Safety Officer
ARRA-2 (AMP) - Authorized Medical Physicist
ARRA-2 (ANP) - Authorized Nuclear Pharmacist
ARRA-2 (AUD) - Authorized Physician (diagnostic)
ARRA-2 (AUT) - Authorized Physician (unsealed therapy)
ARRA-2 (AUS) - Authorized Physician (sealed therapy)
Licensing Guidance for using ARRA-3 Series Forms (January 2008)

Note 3. Board certification has been looked at very closely by the NRC. A Board certification will not be recognized in Arizona unless it is recognized by the NRC. In any case a preceptor statement will have to be submitted by each cndidate unless the candidate has been listed on a radioactice material license within the last seven years.

Note 4. The **Specialty Board(s) Certification Recognized by NRC Under 10 CFR Part 35** are available from the Agency or can be viewed on the NRC Medical License Toolbox web-page.

Note 5. The federal training standards can be found by using Google. Type in Code of Federal Regulations followed by clicking on Available CFR Titles on GPO Access.

II. RADIATION SAFETY OFFICER

The Agency will consider a candidate for RSO if the candidate is qualified through training and experience to meet the requirements in **R12-1-710,** which references the federal standards in 10 CFR 35.57 .

II. TRAINING FOR AUTHORIZED MEDICAL PHYSICISTS

The Agency will consider a candidate to be an authorized medical physicist and perform the many supportive duties to an authorized user treating patients with the radiation from sealed sources, if the candidate meets the requirements in **R12-1-711,** which references the federal standards in 10 CFR 35.51.

III. TRAINING FOR AUTHORIZED NUCLEAR PHARMACISTS

The Agency will consider a candidate to be an authorized nuclear pharmacist and perform the many radiopharmacy duties, if the candidate meets the requirements in **R12-1-712,** which references the federal standards in 10 CFR 35.55.

IV. TRAINING FOR GROUPS 100, 200, AND 500, AUTHORIZING UPTAKE, DILUTION AND EXCRETION STUDIES), AND IMAGING AND LOCALIZATION STUDIES NOT REQUIRING A WRITTEN DIRECTIVE

The Agency will consider a candidate for listing as an authorized user on a radioactive material license authorizing unsealed radioactive material in uptake, dilution, and excretion studies, if the candidate is qualified through training and experience to meet the requirements in **R12-1-719,** which incorporates by reference the federal standards in
10 CFR 190.

The Agency will consider a candidate for listing as an authorized user on a radioactive material license authorizing unsealed radioactive material inimaging and localization studies, not requiring a written directive, if the candidate is qualified through training and experience to meet the requirements in **R12-1-721(A),** which incorporates by reference the federal standards in 10 CFR 290. A candidate wishing to use PET radiopharmaceuticals to diagnose disease shall also meet the requirements in **R12-1-721(A)**. A candidate wishing to use radioactive material limited to the diagnosis of heart disease and cannot meet the training requirements in **R12-1-721(A).** shall meet the requirements in **R12-1-721(B),** which incorporates by reference the federal standards in 10 CFR 290(c).

The Agency will consider a candidate for listing as an authorized user on a radioactive material license authorizing sealed sources of radioactive material in imaging and localization studies, not requiring a written directive, if the candidate is qualified through training and experience to meet the requirements in **R12-1-728,** which incorporates by reference the federal standards in 10 CFR 590.

V. TRAINING FOR GROUP 300, AUTHORIZING THE USE OF UNSEALED RADIOACTIVE MATERIAL REQUIRING A WRITTEN DIRECTIVE, INCLUDING TREATMENT OF

HYPERTHYROIDISM, AND TREATMENT OF THYROID CARCINOMA

The Agency will consider a candidate for listing as an authorized user on a radioactive material license authorizing the treatment of human disease and requiring a written directive, if the candidate is qualified through training and experience to meet the requirements in **R12-1-723**. Depending on the requested authorization, the candidate will have to meet the federal standards incorporated by reference in 10 CFR 35.390, 392, and 394.

VI. TRAINING FOR GROUP 400 AND 600 AUTHORIZING THE USE OF MANUAL BRACHYTHERAPY SOURCES, THE USE OF STRONTIUM-90 SOURCES FOR TREATMENT OF OPHTHALMIC DISEASE, AND THE USE OF REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS0 IN THE TREATMENT OF HUMAN DISEASE

The Agency will consider a candidate for listing as an authorized user on a radioactive material license authorizing the treatment of human disease with brachytherapy sources, if the candidate is qualified through training and experience to meet the requirements in **R12-1-727(A),** which incorporates by reference the federal standards in 10 CFR 35 490. If a candidate will be limited to the authorized use of a Sr-90 eye applicator for the treatment of ophthalmic disease, the candidate shall meet only the requirements in **R12-1-727(B),** which incorporates by reference the federal standards in 10 CFR 35 491.

The Agency will consider a candidate for listing as an authorized user on a radioactive material license authorizing the use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units for treatment of human disease, if the candidate is qualified through training and experience to meet the requirements in **R12-1-744,** which incorporates by reference the federal standards in 10 CFR 35 690.

VII. RECENTNESS OF TRAINING, AND ADEQUATE SUPERVISED EXPERIENCE

The training and experience specified in this Appendix must have been obtained within the **seven years** preceding the date of license application or amendment requesting a candidate be authorized to use radioactive material, or the individual must have had related continuing education and experience since the candidate was last authorized to use radioactive material. The recentness of training is specified throughout the rules in Article 7 and the federal regulation10 CFR 35.59.

Candidates being considered for authorization on a radioactive material must participate in a minimum of **three cases** for each requested authorization if the authorization reuested requires the authorized user to function under a written director.

VIII. NUCLEAR MEDICINE TECHNOLOGISTS

As of January 2004 all persons functioning in the capacity of a nuclear medicine technologist shall be registered with the Medical Radiologic Technologist Board of Examiners (MRTBE). The Inspectors will be checking all personnel that handle radioactive material in the practice of nuclear medicine for a current MRTBE registration card. Registration of nuclear medicine technologists is required in **R12-2-501 and R12-2-502**.