LICENSING GUIDE FOR BROAD SCOPE LICENSES

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I. INTRODUCTION

1.1 PURPOSE OF GUIDE

This guide outlines the type and extent of information needed by the Radioactive Materials Program staff to evaluate an application for a specific license of broad scope. Rule 391-3-17-.02(10) - "Special Requirements for Specific License of Broad Scope", provides for three distinct types of licenses of broad scope, i.e., Type A, Type B, and Type C, which are defined in Rule .02(10)(a). This guide is intended to provide you, the applicant and licensee, with information that will enable you to understand specific regulatory requirements and licensing policies as they apply to broad scope programs.

1.2 CONCEPT AND CONDITIONS OF BROAD SCOPE LICENSES

Broad scope licenses will be issued only to organizations that have:

1. Experience in a reasonable number of activities involving the use of radioactive materials under specific licenses of limited scope. Although the degree of experience is not specified in the regulations, an applicant has possessed a limited specific license for at least 5 years.

2. A good regulatory compliance performance record, based on the Radioactive Materials Program licensing and inspection of prior activities.

3. A radioactive materials utilization program of a scope that has involved a variety of radioactive materials and the operational flexibility to cover numerous uses and users.

4. An administrative structure, organization, and procedure adequate to ensure safe operations and to review and approve proposed uses, users, facilities, and procedures incorporated in the license.

A broad scope license is intended to accommodate organizations involved in an extensive radioactive materials program with a great variety of radionuclides and uses. Type A and B licenses are the most comprehensive issued and may be written to cover a wide range of radionuclides (e.g., all radionuclides with atomic numbers 1 through 83). The use of radioactive materials authorized in a Type A license must be controlled by a Radiation Safety Committee (RSC) and a qualified Radiation Safety Officer (RSO) and staff, whereas Types B and C licenses are controlled by an individual, i.e., a Radiation Safety Officer. Generally, the scope of authorization for Types B and C licenses is limited to the experience and knowledge of the Radiation Safety Officer and the range of intended uses. Types B and C licenses are not as diverse as Type A licenses.

Broad scope licenses may authorize the use of any radioactive material by anyone in accordance with review and approval procedures and criteria established by the RSC (Type A license) or the RSO (Types B and C licenses). Therefore, individuals are not specifically named on the license as users nor are the radionuclides limited to narrow, specific uses. Broad scope licenses are for licensees who cannot operate under a more limited specific license without seriously disrupting their programs.

Except for activities specifically excluded from broad scope licenses by Rule .02(10)(e)1, a broad scope license can include any licensed material the applicant needs and for which it qualifies. The exclusions

stated in Rule .02(10)(e)1. provide that, unless specifically authorized by other parts of the regulations, persons licensed under broad licenses will not:

1. Conduct tracer studies in the environment involving direct release of radioactive material.

2. Receive, acquire, own, possess, use, or transfer devices containing 100,000 Curies or more of radioactive material in sealed sources used for irradiation of materials.

3. Conduct activities for which a specific license issued by the Department under Rule .02(9) or (11) is required.

4. Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

1.3 MEDICAL INSTITUTION BROAD SCOPE LICENSES

Broad scope licenses that involve medical or nonmedical research using human subjects require establishing specialized subcommittees and using committees established in accordance with criteria promulgated by the U.S. Food and Drug Administration (FDA), e.g., Radioactive Drug Research Committees (RDRCs) or Institutional Review Boards (IRBs), when evaluating research requests.

Provided that broad scope medical licensees have staff qualified in radiopharmacy, radiochemistry, dosimetry, nuclear medicine, etc., they are exempted from the provisions of Rules .05(6)(m), .05(8)(a), .05(9)(a) and (b), .05(12)(a), .05(13)(a), and .05(14)(a). This exemption allows flexibility for broad scope licenses in preparing and processing radioactive material, but it does not affect the authorized uses identified on the license. Applicants must, of course, commit to possessing and using radioactive material for medical use in accordance with the prescriptive and performance criteria in other sections of Rule .05. Applicants should commit to instituting procedures at least equivalent to those described in "Licensing Guide for Medical Use Programs".

Medical use licensees, including broad scope Type A medical licensees, must establish and implement a written quality management program to provide high confidence that radioactive material or radiation from radioactive material will be administered as directed by the authorized user. See Appendix A "Quality Management Program" to assist applicants in the preparation of an acceptable program.

Broad scope medical licensees who want to approve physicians, dentists, or podiatrists to use radioactive material for medical purposes must commit to evaluating individuals using the criteria detailed in Rule .05(16). The mechanisms used to record the review of any individual's training and experience should be described.

1.4 APPLICABLE REGULATIONS

The following Georgia regulations apply and should be used in conjunction with this guide. The applicant or licensee should carefully read the applicable regulations since the guide does not substitute for an understanding of the regulations.

Rule 391-3-17-.01 "General Provisions, Amended."

Rule 391-3-17-.02	"Licensing of Radioactive Materials, Amended."
Rule 391-3-17-.03	"Standards for Protection Against Radiation, Amended."
Rule 391-3-17-.05	"Use of Radionuclides in the Healing Arts, Amended."
Rule 391-3-17-.07	"Notices, Instructions and Reports to Workers: Inspections, Amended."

1.5 AS LOW AS IS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Georgia Rule 391-3-17-.03(4)(b) states, "The licensee shall use to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)."

Applicants for broad scope licenses must address ALARA in all aspects of their programs. ALARA considerations, including establishing administrative action levels and monitoring programs, e.g., monitoring and controlling air and liquid effluents, need to be documented in the application.

Medical institutions applying for a license must incorporate ALARA provisions into their program. Appendix B, "Model Program for Maintaining Occupational Radiation Exposure at Medical Institutions ALARA," outlines criteria that are acceptable to the Program staff.

1.6 RADIOLOGICAL EMERGENCY PLAN

Applicants who request possession of radioactive materials in both unsealed and certain sealed forms in excess of specifically listed quantities in Rule .02(21)(e) must address the need for an Emergency Plan. Should this assessment support the need for an emergency plan, the plan must be submitted with your application.

1.7 FINANCIAL ASSURANCE AND RECORDKEEPING REQUIREMENTS

Rule .02(8)(g) outlines the technical and financial regulations for decommissioning of licensed facilities. The regulations address the planning needs, timing, funding methods, and the environmental review requirements for decommissioning public and private facilities holding a radioactive material license. The intent of the regulations is to ensure that the decommissioning of all licensed facilities will be accomplished in a safe and timely manner and that licensees will provide adequate funds to cover all costs associated with decommissioning.

1.8 DECOMMISSIONING PLAN REQUIREMENTS

A decommissioning plan as outlined in Rule .02(8)(g) shall be submitted with the license application. In particular, the licensee must submit a plan for completion of decommissioning if the procedures necessary to carry out decommissioning have not been approved by the Department and could increase potential health and safety impacts to workers or to the public.

1.9 PRELICENSING CONFERENCE

After an application for broad scope authority has been reviewed by the Department staff and found to be generally complete, a prelicensing visit will be scheduled by the Department at the facility. For renewal of broad scope licenses, a visit or conference may also be scheduled.

II. FILING AN APPLICATION

An applicant should apply for a license by completing the form "Application for Radioactive Material License". Broad scope medical license applicants should also complete the form "Application for Medical Radioactive Materials License". Additional information should be submitted on separate sheets given the limited space on the application. Please number all additional pages serially.

All items in the application should be completed in enough detail for the Department to determine that the proposed equipment, facilities, training and experience, and radiation safety program satisfy regulatory requirements and are adequate to protect health and minimize danger to life and property.

The application should be filed in duplicate, with one copy retained by the applicant.

III. CONTENTS OF AN APPLICATION

This portion of the guide explains, item by item, the information requested in "Application for Radioactive Materials License".

If you have questions, please contact the Radioactive Materials Program staff at (404) 362-2675. The Program's fax number is (404) 362-2653.

ITEM 1: LICENSE INFORMATION

For a new license, check subitem A, for an amendment to an existing license, check subitem B and give the license number, for renewal of an existing license check subitem C and give the license number.

ITEM 2: APPLICANT'S NAME AND MAILING ADDRESS

Applicants should be corporations or institutional entities. Because a broad scope licensee must have a Radiation Safety Committee (or RSO for Type B licensees), it is not appropriate for a private individual to apply for a broad scope license. The address specified here should be the mailing address for correspondence. In Items 5 through 11 of your application, describe the intended use and the facilities and equipment at each location.

ITEM 3: LOCATION(S) WHERE LICENSED MATERIAL WILL BE USED OR STORED

If radioactive material is to be used at more than one location then give the specific address of each location. In addition, identify facilities designed or established for special uses, e.g., panoramic dry or wet irradiators, waste storage facilities used for long-term storage, high-level laboratories (i.e., iodination laboratories processing quantities greater than 10 millicuries, alpha laboratories or individual laboratories processing radioactive material greater than 100 millicuries per single use, incinerators, waste compactors and animal facilities).

If radioactive material is to be used in field studies, the activities must be specifically identified and authorized on the license. Appendix C contains information required for field use of radioactive material.

ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Provide the name and telephone number of the person who knows your proposed program and can answer questions about your application. For a broad scope license this will usually be the Radiation Safety Officer.

ITEM 5. RADIOACTIVE MATERIAL TO BE POSSESSED

Describe the radioactive material you wish to possess by isotope, chemical or physical form, and quantity in curie, millicurie, etc. You should state the maximum quantity of each radioactive material you wish to possess at any one time and the total cumulative quantity for all materials. Your possession request should be categorized into general areas of use, e.g., research and development activities, routine gauging activities, self-contained irradiators, instrument calibrations, and medical applications, both routine and non-routine. The maximum quantity for each individual nuclide and total cumulative possession should be commensurate with your needs, facilities, procedures , and personnel. If certain nuclides will be needed in much larger quantities than others, they should be listed separately in Items 5a. 5b. and 5c. rather than increasing the quantity of all nuclides to include these larger quantities. A separate listing is also required in 5a. 5b. and 5c. for sealed sources needed in quantities larger than requested (e.g., bone mineral analyzers, brachytherapy after loaders, portable and non-portable gauging devices). Large activity sealed sources used in devices (e.g., self-contained irradiators, panoramic irradiators, instrument calibrators) should be described by manufacturer and model number under Item 5b.

If you desire to use an irradiator under a broad license, you should follow the guidance contained in the Regulatory Guide, "Guide for the Preparation of Applications for Licenses for the Use of Self-Contained Dry Source-Storage Gamma Irradiators". However, the regulations prohibit use of 100,000 curies or more of radioactive material in sealed sources for irradiation of material under a broad license. Similarly, if certain relatively more hazardous nuclides (e.g., strontium-90, americium-241) are needed only in smaller quantities, they should be listed separately. The maximum quantities of nuclides with atomic numbers above 83 also should be stated separately. When establishing both individual nuclide and total maximum quantities, all materials possessed under your license should be included, i.e., materials received awaiting use, materials in use/process, and that categorized as waste awaiting disposal.

ITEM 6: PURPOSE(S) FOR WHICH RADIOACTIVE MATERIAL WILL BE USED

Describe in general terms the purposes for which the licensed material will be used and explain why a broad scope license is needed rather than amendments to an existing specific license. The uses should be consistent with prior licensed activities. Although the Program staff only needs a general description of activities, sufficient information should be provided to enable the staff to have a clear understanding of each use.

Applicants who desire to perform field studies in which specifically licensed material is deliberately released to the environment must include the information outlined in Appendix C of this guide with their application and list other field studies that are currently authorized in their specific license.

ITEM 7: INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

7.1 SENIOR MANAGEMENT

A broad scope license is issued by the Department to accommodate institutions involved in an extensive radioactive materials program with a variety of radionuclides and uses. The Department grants significant latitude to licensee management to develop, implement, and maintain an appropriate radiation safety program. Consequently, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Applicants for Type A and Type B broad scope licenses are required to establish sufficient administrative controls and provisions relating to organization and management, including management review, as necessary to ensure safe operations.

Management responsibility and liability is often underemphasized in applications and often poorly understood by licensee employees and managers. Type A and medical broad scope licensees are required to establish an RSC that represents management when reviewing and approving safety evaluations. Therefore, senior management should delegate to the RSC and RSO in writing, sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding Department regulations and license provisions. The licensee retains the ultimate responsibility for the conduct of licensed activities. It is also essential that the institution devote sufficient resources (i.e., equipment, personnel, and materials) to support the radiation protection program.

A license application should discuss senior management oversight and mechanisms to be used by management to ensure adequate control over licensed broad scope activities. The Department expects senior management oversight to include regular meetings with the RSC, RSO, and support staff, along with annual audits of the program to assure safe operations and compliance with regulatory requirements. The audit program should include mechanisms to correct and resolve problems in an expeditious manner.

The application for a Type A license should include an organizational chart depicting the management structure, reporting paths, and flow of authority, including the statement empowering the RSC, outlining its authority to oversee the licensed program and responsibility for control and direction of the radiation safety program and the RSO.

The operational oversight for a Type B broad scope program is specified, in part, in Rule .02(10)(c), which states, "The appointment of a Radiation Safety Officer who is qualified by training and experience …" An application for a Type B license, as indicated above for the Type A license and RSC, should include an organizational chart and management statement describing the RSO's authority. Appendix D provides a sample certification that the RSO understands and accepts the responsibilities of the position and the management commits to support the RSO in ensuring that all licensed activities will be conducted in accordance with Department regulations and the specific terms of the license.

7.2 RADIATION SAFETY COMMITTEE (RSC)

For Type A and medical broad scope programs, the licensee is required to establish an RSC pursuant to Rule .02(10)(b). The RSC should be responsible for establishing appropriate policies and procedures to ensure control of the procurement and use of radioactive material, completion of safety evaluations of proposed uses and users, and the overall development and implementation of the radiation safety program.

The RSC should consist of the RSO; at least one representative of management; and at least one user authorized by the RSC, trained and experienced in the safe use of radioactive materials, from each of the departments, groups, or activities that will use radioactive materials under the broad scope license. For medical broad scope programs, the RSC should also include a representative of the nursing service and a physician authorized user for each type of medical use permitted by the license, as well as users authorized by the RSC for nonmedical use. The RSC chairperson should be named on the license application. A license amendment is required if the RSC chairperson changes. The other members need only be listed by title and qualifications, not by name.

The number of members constituting a quorum, as well as their names or fields of expertise, should be specified when a quorum of the RSC is empowered to act for the committee. The Program staff considers the minimum acceptable quorum would be the chairperson, RSO, management representative, committee members or members representing the department or area from which the radioactive material request originated, and any other committee member whose field of expertise is necessary to ensure all safety aspects have been addressed. To have a quorum and conduct business for medical broad scope programs, at least one-half of the Committee's membership representing medical use activities must be present, including the RSO and the management representative.

The RSO's role, as a member of the RSC, should be to provide technical expertise to the RSC. The Department does not recommend that the RSO and RSC chairperson be the same individual. The RSO is responsible for the day-to-day operations of the radiation safety program and may not realistically be able to manage the whole program and other assigned duties or responsibilities if he or she is also the chairperson.

An application should describe the frequency of RSC meetings and the criteria for selecting RSC members; it should include a specific and detailed description of the control functions of the RSC and the administrative procedures by which these functions are carried out. The RSC at a medical institution is required by Rule .05 to meet at least quarterly. Appendix E of this guide provides an outline of the duties and responsibilities of the RSC that are acceptable to the Program staff.

7.3 RADIATION SAFETY OFFICER (RSO)

Broad scope licensees are required to appoint an RSO pursuant to Rule .02(10). The RSO should be responsible for oversight of the day-to-day radiation protection program established by the RSC, should communicate with senior management and the RSC regarding program implementation and compliance status, and should be available to provide advice and assistance on radiological safety matters.

The RSO should have an academic degree in physical or biological science or engineering, specific training in radiation health sciences, and considerable professional experience (generally about 5 years) with a broad spectrum of radioactive materials. The RSO's professional experience should include the application of this training to the management and administration of a radiation safety program related to the types, quantities, and uses of the radioactive material to be used under this license. A previous background in program and staff management is also desirable.

The training and experience of the RSO in radiation protection and with radiation and radioactive materials should be listed and described. The RSO should report directly to senior management, have ready access to all levels of the organization, and have the authority to immediately terminate any activities that are found to be a threat to public health, safety, or property.

A statement should be included in the application delineating the RSO's duties, responsibilities, and authority for carrying out the radiation safety program. The extent of these responsibilities and duties will depend on the proposed broad scope license. Appendix F to this guide, which provides an outline of duties and responsibilities of the RSO under a broad scope license, are representative of those considered acceptable to the Program staff.

7.4 RADIATION SAFETY OFFICE STAFF (RSOS)

The RSO is supported by a staff of health physics professionals who assist in the maintenance and control of the licensee's program. The number and qualifications of these professionals will vary with the scope of the program. The application should include a description of the duties and responsibilities of the radiation safety office staff and an assessment of the staffing levels and qualifications of this support staff. The assessment should be sufficient to demonstrate that the technical staff is adequate to implement, support and oversee the proposed radiation protection program. If the current staffing is considered minimally acceptable, a projected timetable for achieving full staffing should be included. A projection of future needs would also be useful.

ITEM 8: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

You must establish and agree to follow written procedures for instructing individuals as required by Rule 391-3-17-.07(3), Instructions to Workers. As a minimum, these written procedures should require:

1. That individuals who work in or frequent restricted areas be instructed in the items specified in Rule 391-3-17-.07(3) at the time of initial employment and at least annually thereafter

2. That this instruction include all written procedures developed as a prerequisite for issuance of the license and other terms of the license pertinent to radiation safety.

3. That other individuals whose duties may require them to work in the immediate vicinity of licensed material be informed about radiation safety hazards and appropriate precautions at the time of their initial employment and at least annually thereafter.

4. Records of initial and refresher training shall be maintained.

Submit a copy of the personnel training program that you have established and agree to follow for instructing individuals as required in the above Rule.

ITEM 9: FACILITIES AND EQUIPMENT

Since broad scope licenses will be issued only to applicants who have had prior experience in the use of radioactive materials under other licenses, each applicant's facilities and equipment have already been described in previous license correspondence. However, these descriptions should be resubmitted as part of the license application. Any new or altered facilities and equipment that are essential to the license being sought should also be described. Facilities and equipment used for special applications should be specifically described if they might have a significant impact on workers or the public if radioactive material were accidentally released. These would include, room irradiators, specialized iodination or tritiation facilities, alpha laboratories, large-scale waste processing and storage facilities including decay-

in-storage locations, incinerators, compactors, and liquid reclamation processors, individual laboratories processing 100 millicuries or more of radioactive materials per experiment or process, nuclear pharmacies, and specifically designed therapy rooms or storage areas for radiopharmacueticals or sealed sources.

Administrative procedures for internal control of users under the broad license should include provisions for determining that facilities and equipment are adequate for all proposed uses. The application should include a laboratory or facility classification scheme that relates toxicity and quantity of radioactive materials to minimum facility and equipment requirements. The International Atomic Energy Agency (IAEA), as well as other health physics and industrial hygiene professional organizations, has developed classification schemes used in assessing minimum needs (for example, for equipment and facilities, user training, personnel monitoring, or surveys) in relation to the hazard and quantity of radioactive material to be used. The Program staff recommends that applicants consider developing such a classification scheme, since all aspects of the radiation safety program can be correlated to it. The IAEA document is not meant to be a model, but simply a reference. Each applicant's scheme should be based upon the types and quantities of radioactive materials that are anticipated to be needed. The criteria used to develop the classification scheme should be made into a manual and provided to each RSC member for use when evaluating requests to use licensed materials. A license application should describe the minimum facilities and equipment required for each laboratory classification.

ITEM 10. RADIATION SAFETY PROGRAM

The formal requirements for a radiation protection program under a broad license are contained in Rule .02(10). Applicants for a Type A license must have engaged in a reasonable number of activities involving the use of radioactive material. Applicants for both Types A, B and C licenses must have established administrative controls and provisions related to organization and management, procedures, recordkeeping, material control and accounting, and management review to ensure safe operations under the license. The radiation protection program description should be in narrative form and include the elements identified below. The requirement to develop, document, and implement a radiation protection program commensurate with the scope of the license request is contained in Rule .03(4); recordkeeping requirements related to the program are in Rule .03(13)(b).

10.1 PREVIOUS LICENSES

List the present and previous radioactive materials license for which this application requests a continuation or expansion of activities.

10.2 ADMINISTRATIVE PROCEDURES

The regulations require the establishment of appropriate administrative procedures to assure: (1) control of procurement and use of radioactive material; (2) completion of safety evaluations of proposed uses/users of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and operating or handling procedures. The Department recommends development of radiation safety manuals or other formal documents for informing your staff of safety criteria and good health physics practices, Department regulations and license commitments. Submit either a complete description of these administrative procedures or copies of formal documents you have issued (or will issue) to your staff.

10.2.1 CONTROL OF PROCUREMENT AND USE

The application should describe the administrative procedures you have established to ensure that all procurement, use, and users of radioactive material are properly authorized by the license and approved by the RSC. The Department recommends a procedure that centralizes all purchases or other procurement through an authorized purchasing agent in order to verify that the procurement and use are authorized under the license. If you do not use such centralized procedures, describe how your procedures prevent unauthorized procurement and use.

10.2.2 SAFETY EVALUATIONS OF PROPOSED USES/USERS

See Item 10.5 below.

10.2.3 EMERGENCY PROCEDURES

The application should describe the program in place for handling spills, fires, releases or loss of material, and accidental contamination of personnel. You should discuss provisions of immediate response and handling of such incidents including off-hours notification of your staff and the Radioactive Materials Program, when applicable. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, it should be clearly understood by your staff who they should contact and that only qualified and experienced individuals should conduct decontamination and recovery operations.

A copy of the emergency procedures should be posted in all restricted areas and address, at a minimum, the following:

a. Initial response actions and responsibilities, including immediate safety precautions for people and property.

b. Area and facility access control and security.

c. Internal and external notification mechanisms and responsibilities.

d. Provisions for medical and offsite agency assistance.

Consider the strategic placement of emergency spill kits at specified locations throughout your institution for use by authorized users and the radiation safety staff. These kits should be periodically inspected and replenished as necessary.

10.2.4 OPERATING AND HANDLING PROCEDURES

The application should include laboratory operating and handling procedures which describe radiation safety instructions necessary to ensure adequate external and internal exposure controls including contamination controls, waste disposal practices, personnel and area monitoring criteria, use of protective clothing and equipment, and prohibitions of specific unsafe practices, etc.

10.2.5 OTHER PROCEDURES

The application should include other administrative procedures as deemed necessary to guide, control and

ensure consistency in the implementation of the radiation protection program. You should consider, for example, standards operating procedures (SOPs) for routine health physics activities, including those conducted by the RSOS (e.g., radiation and contamination survey methods, smear analysis, source leak testing, air sampling, bioassays, etc.). The application should contain a commitment that certain changes to the radiation safety program must be approved by the RSC.

10.3 LICENSED MATERIAL INVENTORY AND ACCOUNTABILITY

A broad scope license authorizes possession and use of a vast array of radionuclides in relatively liberal quantities, typically for medical use, research, and research and development. These liberal possession limits, combined with a large number of individual users and locations of use can create material inventory and accountability problems, if not properly managed. Consequently, applicants should develop and maintain a strong inventory and accountability system. The institution should have the capability to continually track incoming shipments of licensed material, and account for material usage, decay, transfer, and disposal. A licensee's inventory and control system should have the capability to assure that licensed possession limits are not exceeded and that material is accountable throughout the institution at any given time. Sufficient staff and equipment should be devoted to the inventory and accountability control program.

The application must include a description of your inventory, control and accountability program for licensed material.

10.4. AUDITS AND APPRAISALS

The regulations require applicants to establish administrative controls and provisions relating to management review necessary to assure safe operations. The licensee must periodically (at least annually) review the radiation program content and implementation. The radiation safety program review and/or audits are the responsibility of management. Management must fulfill this responsibility either by having this audit conducted by the RSC or by contracting with an independent auditor to review the program. This auditor should be accompanied by management, the RSO, and available representatives of the RSC. The auditor's results of the program review should be submitted to the RSC for formal documented committee review and action. The licensee must maintain records of the radiation protection program including: 1) the provisions of the program, and 2) audits and other reviews of the program contents and implementation.

10.4.1 MANAGEMENT AND RADIATION SAFETY COMMITTEE AUDITS

The application should discuss senior management oversight and mechanisms used by senior management to ensure that they are aware of Department regulations, the provisions of the license, and compliance status of the institution's licensed program. This may include independent audits of the program, frequent meetings with the RSC and periodic tours of selected facility areas.

The RSC should be fully aware of the operations and activities of the Radiation Safety Office through frequent and routine meetings. The RSC should conduct periodic interactive management audits and evaluations of the Radiation Safety Office's performance, including the RSO's. Results of the RSC's audit and program reviews should be reported to senior management to allow for timely and aggressive remedial actions sufficient in scope to ensure compliance with Department regulations and license conditions. You should also consider establishment of RSC subcommittees to evaluate and audit those

areas of the program within their area of expertise.

10.4.2 RADIATION SAFETY OFFICER AND STAFF AUDITS

You should describe the audit mechanism implemented by the RSO and staff to determine compliance with the terms and conditions of the license, RSC approved permits and for adherence to good health physics practices. Your audit program should include routine unannounced inspections of each authorized user's laboratory and practices to supplement and audit the routine monitoring performed by authorized users. We recommend that the laboratory inspections include the following:

a. Review of user inventory and survey records.

b. Evaluation of user and technician training through discussion and observation of work practices.

c. Performance of independent surveys of user work areas.

d. Evaluation of compliance with RSC permit and safety manual requirements.

e. Provision for performance based instruction to users and technical level staff.

You should indicate the types and frequencies of monitoring performed by the RSO. The intervals of surveys and audits should be frequent enough to assure close communications and proper surveillance of individual radioactive material users. Type A broad scope licensees typically perform these surveys and audits at least quarterly. However, schedules of surveys and audits may be proposed based upon activity and use (e.g., high level laboratories, Type A (weekly), intermediate laboratories Type B (monthly), and low level laboratories, Type C (quarterly).

10.5 SAFETY EVALUATIONS OF PROPOSED USES AND USERS

The regulations require that Type A and Type B broad scope applicants, respectively, establish procedures to assure completion of safety evaluation of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures. The review and approval must be documented by the RSC prior to use of the radioactive material.

Your application should contain the criteria to be used by each committee member when evaluating the qualifications of users, facility and equipment adequacy and determining personnel monitoring and survey requirements.

Since your RSC will assume the responsibility for the review of users and uses of radioactive materials, your application must provide enough detail to assure the Program staff that the RSC evaluations are sufficient in scope and depth to satisfy the regulations. A copy of proposed user request and RSC approval forms or permits should be submitted for review with your application.

Broad licenses involving a wide range of uses should consider the development of a classification scheme of radionuclides according to relative toxicity per unit activity as discussed previously under Item 9. This classification scheme can be used to correlate standards of design for laboratories based upon toxicity and levels of activity used. The development of your classification scheme should be based upon the types

and uses anticipated at your institution. Once a classification scheme has been developed other required safety functions can be developed and incorporated into the criteria used by the individual committee members when reviewing applications, e.g., bioassays and frequencies, direct and removable contamination surveys, air sampling provisions, personnel monitoring. The submission of a classification scheme and criteria is intended to demonstrate to the Program staff the minimum standards which will be applied when approving uses. It is understood that certain permits issued by the RSC may deviate from the classification scheme due to unusual circumstances; however, it is expected that broad licensees will adhere to the classification scheme closely and when deviations occur, that justification and documentation of the deviation will be maintained for review by the Program inspection staff. Your safety evaluation procedures and criteria should include and describe how your RSC will evaluate and apply requirements for the following:

a. The proposed use of material considering the quantity and form requested, potential radiological hazards associated with such use and mechanisms for external and internal exposure control, contamination controls and waste disposal.

b. Training and experience for authorized users and individuals working under the supervision of an authorized user (e.g., technicians). Specialized training for certain users should also be included, (e.g., incinerator operators, waste compaction personnel, and animal handlers).

c. Facilities and equipment for each specific use.

d. Material handling and operating procedures including provisions for requiring users to conduct surveys to confirm that radiation levels and/or contamination levels are within specific guidelines. The type and frequency of surveys must take into consideration the amount and types of radioactive material used or being stored.

10.6 EXPOSURE CONTROL AND MONITORING

You should describe the procedures and mechanisms established to control and monitor both internal and external radiation exposure. The procedures should include general criteria for all intended radionuclides of use and specialized criteria to address control and monitoring when higher levels of radionuclide activity or toxicity are used.

10.6.1 External

Describe the type and frequency of radiation surveys that will be conducted in areas where radioactive materials are used or stored, and in adjacent unrestricted areas which are accessible to personnel. Surveys should be conducted by the authorized user and supplemented by radiation safety office surveys. Surveys conducted by authorized users should consist of both external radiation and contamination smear surveys in various laboratory use and storage areas, at frequencies commensurate with the quantity and form of radioactive material in use or storage (e.g., high-level laboratories (Type A), daily; intermediate laboratories (Type B), weekly; and low-level laboratories (Type C), monthly or quarterly). In addition, surveys of work areas should be performed throughout the day when radioactive materials are actively in use. The survey program should also include external radiation and contamination action or trigger levels for both restricted and unrestricted areas.

Explain which surveys are the responsibility of the authorized user and those which will be performed

as part of your radiation safety audit program. Characterize laboratories and facilities according to the radiological hazard and indicate the types and frequencies of monitoring and surveys performed by designated staff.

Provide information regarding the type tests (e.g., DOP, charcoal adsorption efficiency) and the frequency of tests to be performed on ventilation and filtration systems. This discussion should be separated by system, i.e., hood, glove boxes, filter systems (e.g., HEPA, charcoal), etc. If you use a recognized standard, indicate the reference or provide a copy.

Specify the criteria used to assign personnel monitoring devices; i.e., film/TLD whole body and extremity badges, direct reading dosimeters, and the frequency of device process for the various laboratory types. Indicate the supplier (required to be NVLAP approved) of your dosimetry system.

10.6.2 Internal

Describe the criteria used to determine the type and frequency of bioassay (both in-vivo and in-vitro) that will be performed to evaluate intakes.

Describe the criteria used to set the type and frequency at which routine surveys for airborne radioactive materials are performed, e.g., air sampling or breathing zones and general work areas, hood and room ventilation air flow rate measurement and stack effluent sampling. The air sampling criteria should be incorporated into your laboratory classification scheme and provide enough detail that the Program staff is assured that appropriate steps will be taken to manage and monitor such exposures.

ITEM 11: WASTE MANAGEMENT

Describe the methods used for disposal of radioactive waste. The application should include, as appropriate for the types of waste involved, provisions for monitoring and segregating waste materials (e.g., radioactive from nonradioactive, short from long half-life, liquid from solid waste). The following items should be considered and addressed in the application:

a. Transfers to an authorized recipient (usually a waste disposal service company or the original supplier) who is properly licensed to receive such waste. State the name and license number of the receiving company.

b. Storage of radioactive materials with half-lives greater than 65 days should be characterized regarding volume and anticipated time in residence at the facility prior to disposal. The Department does not consider storage as a final disposal of radioactive waste. Other than storage for radioactive decay, low-level radioactive waste should be stored only when disposal capacity is unavailable and for no longer than is necessary.

c. Describe the monitoring and control mechanisms in place to ensure compliance with the regulations regarding release of radioactive material into the air and water.

d. Disposal of radioactive waste by incineration may be performed only in the amounts and forms specified in Rule .03(12)(e). Specific approval for alternate procedures will be considered by the Department as outlined in Rule .03(12)(b).

e. Waste volume reduction operations which could create a radiological hazard to your employees or the general public must be described in detail in the application. For example, if you plan to use compactors to reduce volume, include the following:

1. A description of the compactor to demonstrate that it is adequately designed and manufactured to safely compact the type and quantity of waste generated in your operations (e.g., manufacturer's specifications, annotated sketches, photographs, etc.)

2. The type, quantities, and concentrations of waste to be compacted.

3. An analysis of the potential for airborne release of radioactive material during compaction activities.

4. The location of the compactor(s) within your waste processing area(s) as well as a description of the ventilation and filtering systems used in conjunction with the compactors. Include a description of your procedures for monitoring filter blockage and exchange.

5. Methods used to monitor worker breathing zones and/or exhaust systems.

6. The types and frequencies of surveys that will be performed for contamination control in the compactor area.

7. The instruction provided to compactor operators including instructions for protective clothing, checks for proper functioning of the equipment, method of handling uncompacted waste and examining for defects.

f. Disposals without regard to the radioactivity of hydrogen-3, carbon-14 and iodine-125 contained in scintillation counting media and in animal tissue in concentrations of 0.05 microcuries per gram, need not be described in the application.

An application should describe the ALARA considerations taken before disposal of radioactive materials. Discuss the potential for unmonitored or unanticipated release of radioactive materials to work areas and from release points, e.g., hoods and incinerator stacks. To be in compliance with the ALARA philosophy stated in Rule .03(4), radioactive waste stream concentrations should be a fraction of the limits specified in Table II of Appendix B of 10 CFR 20.1001-20.2401, effective January 1, 1994. Furthermore, because of the variability of inventory control programs for monitoring disposal and releases of radioactive material in use, a program for physically measuring releases should be in place whenever releases may exceed the specified ALARA action points.

ITEM 12; LICENSE FEES

See VIII for the license fees associated with a broad scope academic program.

ITEM 13: CERTIFICATION

The application should be dated and signed. The signature must be representative of an individual acting

in private capacity or a corporation or legal business entity who is authorized to sign official documents and to certify that the application contains information that is true and correct to the best of his or her knowledge. Failure to sign the application will result in the application being returned for proper signature, therefore delaying the review process.

IV. AMENDMENTS TO A LICENSE

After a license has been issued, licensees must conduct their programs in accordance with (1) the statements, representations, and procedures contained in the application, (2) the terms and conditions of the license, and (3) the Department's regulations.

It is the obligation of the licensee to keep the license current and to anticipate the need for a license amendment insofar as possible. If licensed activities change or require modification such that information provided in the application does not represent current operations, intended uses, or individual maximum uses, the license must be amended. An application for an amendment must be filed before initiating any such changes. Until approval of the amendment, the licensee must comply with the terms and conditions of the current license.

An application for a license amendment may be prepared either on the application form or in letter form and should be submitted in duplicate to the Radioactive Materials Program. The application should identify the existing license by number and clearly indicate the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph.

V. RENEWAL OF LICENSES

An application filed for renewal thirty (30) days or more before the expiration date assures that the existing license will not expire until the renewal application has been finally acted upon by the Department. Renewal applications should contain complete and up-to-date information concerning the applicant's current program.

To facilitate the review process, the application for renewal should be submitted without reference to previously submitted documents and information. If such references cannot be avoided, they should be clear and specific and should identify the pertinent information by date, page, and paragraph.

VI. RECORDS

Records shall be maintained in accordance with the requirements set forth in Georgia "Rules and Regulations for Radioactive Materials, Chapter 391-3-17.

VII. CONFIDENTIALITY

Licensees should remember that all documents submitted to the State of Georgia will be made available to the public, with certain exceptions. These exceptions include classified data, trade secrets, and personnel and medical files, the disclosure of which would clearly constitute an unwarranted invasion of privacy.

The State of Georgia recommends that the licensee not include in any submittal trade secrets or personal information about your employees, unless the information is directly related to radiation safety or specifically required by the State of Georgia. For example (1) information submitted on training and experience of employees should be limited to training related to radiation safety; (2) home addresses and home telephone numbers should be submitted only if they are part of the emergency procedures; and (3) dates of birth, social security numbers, and radiation dose information should be submitted only as specifically required by the State of Georgia.

If you submit trade secrets, proprietary information, or personnel information that you want withheld from public disclosure, you must request withholding in accordance with procedures specified in the Georgia Open Records Law. Failure to follow this procedure may result in disclosure of the information to the public and/or substantial delays in processing your submittals. Using labels such as "confidential" or "restricted" will not guarantee that your documents will be withheld.

VIII. FEES

The license fee for a broad scope academic program is in a fee category D.1 with the following fees:

Annual Fee	$2100	Non-routine Inspection Fee	$1200
Application Fee	$2300	Renewal Fee	$2000
Amendment Fee	$500	Routine Inspection Fee	$930

Checks for the fees should be made payable to **Department of Natural Resources, Radioactive Materials Program,** and mailed to the following address:

Radioactive Materials Fees
P. O. Box 101161
Atlanta, Georgia 30392

Mail license applications, amendment, and renewal requests the same day as the check to the following address:

Radioactive Materials Program
4244 International Parkway, Suite 114
Atlanta, Georgia 30354

APPENDIX A

QUALITY MANAGEMENT PROGRAM

An applicant for licensure for the use of radioactive material in the healing arts is required to establish a written quality management program (QMP) to provide documentation that radioactive material or radiation therefrom is administered as directed by the authorized user.

The administration of radioactive material or radiation therefrom can involve a number of modalities, e.g., radiopharmaceutical therapy, teletherapy, brachytherapy, or gamma stereotactic radiosurgery. Specific policies and procedures shall be established for each modality to ensure that the objectives of the QMP as outlined in Rule .05(6)(h) are met.

In general, we recommend that licensees have:

- Policies to have an authorized user date and sign a written directive prior to the administration,
- Procedures to identify the patient by more than one method,
- Procedures to ensure that the plans of treatment are in accordance with the written directive,
- Procedures to confirm that, prior to administration, the person responsible for the treatment modality will check the specific details of the written directive (e.g., in radiopharmaceutical therapy, verify the radiopharmaceutical, dosage, and route of administration, or in oncology, verify the treatment site, total dose, dose per fraction, and overall treatment period).
- Procedures to record the radiopharmaceutical dosage or radiation dose actually administered.

The QMP should contain the essential elements of the policies and procedures listed in the following sections.

1.0. **Suggested Policies and Procedures for Certain Radiopharmaceutical Uses**

1.1. The licensee should establish a policy to have an authorized user date and sign a written directive prior to the administration of any therapeutic dosage of a radiopharmaceutical or any dosage of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131.

1.2. Before administering a radiopharmaceutical dosage, the licensee should establish a procedure to verify by more than one method the identity of the patient as the individual named in the written directive. The procedure used to identify the patient should be to ask the patient's name and confirm the name and at least one of the following by comparison with corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, or the name on the patient's medical insurance card.

1.3. The licensee should establish a procedure to verify, before administering the radioactive material, that the specific details of the administration are in accordance with the written directive. The radiopharmaceutical, dosage, and route of administration should be confirmed by the person administering the radiopharmaceutical to verify agreement with the written directive, that is, the

dosage should be measured in the dose calibrator and the results compared with the prescribed dosage in the written directive.

1.4. The licensee should establish a policy for all workers to seek guidance if they do not understand how to carry out the written directive. That is, workers should ask if they have any questions about what to do or how it should be done rather continuing the procedure when there is any doubt.

1.5. The licensee should establish a procedure to have an authorized user or a qualified person under the supervision of an authorized user (e.g., a nuclear medicine physician, physicist, or technologist), after administering a radiopharmaceutical, make, date and sign or initial a written record that documents the administered dosage in the patient's chart or other appropriate record.

1.6. The licensee should establish procedures to perform periodic reviews of the radiopharmaceutical Quality Management Program.

2.0. Suggested Policies and Procedures for Teletherapy

2.1. The licensee should establish a policy to have an authorized user date and sign a written directive prior to the administration of any teletherapy dose.

2.2. Before administering a teletherapy dose, the licensee should establish a written procedure to verify by more than one method the identity of the patient as the individual named in the written directive. The procedure used to identify the patient should be to ask the patient's name and confirm the name and at least one of the following by comparison with the corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, the name on the patient's medical insurance card, or the photograph of the patient's face.

2.3. The licensee should establish a policy to have an authorized user approve a plan of treatment that provides sufficient information and direction to meet the objectives of the written directive. Suggested guidelines for information to be included in the plan of treatment may be obtained from the American College of Radiology.

2.4. The licensee should establish a procedure to verify, before administering each teletherapy dose, that the specific details of the administration are in accordance with the written directive and plan of treatment. In particular, the treatment site and the dose per fraction should be confirmed by the person administering the teletherapy treatment to verify agreement with the written directive and plan of treatment.

2.5. The licensee should establish a policy for all workers to seek guidance if they do not understand how to carry out the written directive. That is, workers should ask if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.

2.6. The licensee should establish a procedure to have a qualified person under the supervision of an authorized user (e.g., an oncology physician, radiation therapy physicist, dosimetrist, or radiation

therapy technologist), after administering a teletherapy dose fraction, make, date, and sign or initial a written record in the patient's chart or in another appropriate record that contains, for each treatment field, the treatment time, dose administered, and the cumulative dose administered.

2.7. The licensee should establish a procedure to have a weekly chart check performed by a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, dosimetrist, oncology physician, or radiation therapy technologist) to detect mistakes (e.g., arithmetic errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative teletherapy dose administrations from all treatment fields or in connection with any changes in the written directive or plan of treatment.

2.8. If the prescribed dose is to be administered in more than three fractions, the licensee should establish a procedure to check the dose calculations within three working days after administering the first teletherapy fractional dose. An authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), who whenever possible did not make the original calculations, should check the dose calculations. If the prescribed dose is to be administered in three fractions or less, a procedure for checking dose calculations as described in this paragraph should be performed before administering the first teletherapy fractional dose.

Manual dose calculations should be checked for:

(1) Arithmetic errors,

(2) Appropriate transfer of data from the written directive, plan of treatment, tables, and graphs,

(3) Appropriate use of nomagrams (when applicable), and

(4) Appropriate use of all pertinent data in the calculations.

Computer generated dose calculations should be checked by examining the computer printout to verify that the correct data for the patient were used in the calculations (e.g., patient contour, patient thickness at the central ray, depth of target, depth dose factors, treatment distance, portal arrangement, field sizes, or beam-modifying factors). Alternatively, the dose should be manually calculated to a single key point and the results compared to the computer-generated dose calculations.

If the manual dose calculations are performed using computer-generated outputs or vice versa, particular emphasis should be placed on verifying the correct output from one type of dose calculation (e.g., computer) to be used as an input in another type of dose calculation (e.g., manual). Parameters such as the transmission factors for wedges and the source strength of the sealed source used in the dose calculations should be checked.

2.9. The licensee should establish a procedure for independently checking certain full calibration measurements as follows:

After full calibration measurements that resulted from replacement of the source, or

whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last calibration corrected mathematically for radioactive decay, an independent check of the output for a single specified set of exposure conditions should be performed. The independent check should be performed within 30 days following such full calibration measurements.

The independent check should be performed by either:

(1) An individual who did not perform the full calibration (the individual should meet the requirements specified in Rule .05(16)(j)) using a dosimetry system other than the one that was used during the full calibration (the dosimetry system should meet the requirements specified in Rule .05(15)(i)), or

(2) A teletherapy physicist (or an oncology physician, dosimetrist, or radiation therapy technologist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming teletherapy doses and that is accurate within 5 percent.

2.10. The licensee should establish a procedure to have full calibration measurements include the determination of transmission factors for trays and wedges. Transmission factors for other beam-modifying devices (e.g., nonrecastable blocks, recastable block material, bolus and compensator materials, and split-beam blocking devices) should be determined before the first medical use of the beam-modifying device and after replacement of the source.

2.11. The licensee should establish a procedure to have a physical measurement of the teletherapy output made under applicable conditions prior to administration of the first teletherapy fractional dose if the patient's plan of treatment includes (1) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration or (2) transmission factors for beam-modifying devices (except nonrecastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.

2.12. If the authorized user determines that delaying treatment to perform the checks of (1) dose calculations for a prescribed dose that is administered in three fractions or less or (2) teletherapy output would jeopardize the patient's health because of the emergent nature of the patient's medical condition, the prescribed treatment may be provided without first performing the checks of dose calculations or physical measurements. The authorized user should make a notation of this determination in the records of the calculated administered dose. The checks of the calculations should be performed within two working days of completion of the treatment.

2.13. The licensee should establish a procedure for performing acceptance testing by a qualified person (e.g., a teletherapy physicist) on each treatment planning or dose calculating computer program that could be used for teletherapy dose calculations. Acceptance testing should be performed before the first use of a treatment planning or dose calculating computer program for teletherapy dose calculations. Acceptance testing should also be performed after full calibration measurements when the calibration was performed (1) before the first medical use of the teletherapy unit, (2) after replacement of the source, or (3) when spot-check measurements indicated that the output differed by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay. Computer-generated beam data should be compared to

measured beam data from the teletherapy unit. The licensee should assess each treatment planning or dose calculating computer program based on the licensee's specific needs and applications.

2.14. The licensee should establish procedures to perform periodic reviews of the teletherapy QMP.

3.0. **Suggested Policies and Procedures for Brachytherapy**

3.1. High-Dose-Rate Remote Afterloading Devices

Similar licensee policies and procedures for low and medium-dose-rate remote afterloading devices would be equally helpful.

3.1.1. The licensee should establish a policy to have an authorized user date and sign a written directive prior to the administration of any brachytherapy dose from a high-dose-rate remote afterloading device. See Section 5 for procedures for oral directives and revisions to written directives.

3.1.2. Before administering a brachytherapy treatment, the licensee should establish a procedure to verify by more than one method the identity of the patient as the individual named in the written directive. Identifying the patient by more than one method is required by Rule. 05(6)(k). The procedure used to identify the patient should be to ask the patient's name and confirm the name and at least one of the following by comparison with the corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, the name on the patient's medical insurance card or the photograph of the patient's face.

3.1.3. The licensee should establish a procedure to verify, before administering the brachytherapy dose, that the specific details of the brachytherapy administration are in accordance with the written directive and plan of treatment. The prescribed radioisotope, treatment site, and total dose should be confirmed by the person administering the brachytherapy treatment to verify agreement with the written directive and plan of treatment.

3.1.4. The licensee should establish a policy for all workers to seek guidance if they do not understand how to carry out the written directive. That is, workers should ask if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.

3.1.5. The licensee should establish a procedure for using radiographs or other comparable images (e.g., computerized tomography) as the basis for verifying the position of the nonradioactive "dummy" sources and calculating the administered brachytherapy dose before inserting the sealed sources. The term sealed sources includes wires and encapsulated sources.

3.1.6. The licensee should establish a procedure to check the dose calculations before administering the prescribed brachytherapy dose. An authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), who whenever possible did not make the original calculations, should check the dose calculations. The responsibilities and conditions of "supervision" are contained in Rule .05(6)(e). Suggested methods for checking the calculations include the following:

- Computer-generated dose calculations should be checked by examining the computer printout to verify that correct input data for the patient were used in calculations (e.g., source strength and positions).

- The computer-generated dose calculations for input into the brachytherapy afterloading device should be checked to verify correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times).

3.1.7. The licensee should establish a procedure to have an authorized user, after administering the brachytherapy treatment, date and sign or initial a written record of the calculated administered dose in the patient's chart or in another appropriate record.

3.1.8. If the authorized user determines that delaying treatment in order to perform the checks of dose calculations would jeopardize the patient's health because of the emergent nature of the patient's medical condition, the checks of the calculations should be performed within two working days of the treatment.

3.1.9. The licensee should establish a procedure for performing acceptance testing by a qualified person (e.g., a teletherapy physicist) on each treatment planning or dose calculating computer program that could be used for brachytherapy dose calculations when using high-dose-rate remote afterloading devices. Acceptance testing should be performed before the first use of a treatment planning or dose calculating computer program for brachytherapy dose calculations when using high-dose-rate remote afterloading devices. The licensee should assess each treatment planning or dose calculating computer program based on the licensee's specific needs and applications.

3.1.10. The licensee should establish procedures to perform periodic reviews of the brachytherapy QMP for using the high-dose-rate remote afterloading device.

3.2. **All Other Brachytherapy Applications**

3.2.1. The licensee should establish a policy to have an authorized user date and sign a written directive prior to the administration of any brachytherapy dose. A written directive is required by Rule .05(6)(k). See Section 5 for procedures for oral directives and revisions to written directives.

3.2.2. Before administering a brachytherapy dose, the licensee should establish a procedure to verify by more than one method the identity of the patient as the individual named in the written directive. The procedure used to identify the patient should be to ask the patient's name and at least one of the following by comparison with the corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, the name on the patient's medical insurance card, or the photograph of the patient's face.

3.2.3. The licensee should establish a procedure to verify, before administering the brachytherapy dose, that the specific details of the brachytherapy administration are in accordance with the written directive and plan of treatment. In particular, the radioisotope, number of sources, and source strengths should be confirmed to verify agreement with the written directive and plan of treatment.

3.2.4. The licensee should establish a policy for all workers to seek guidance if they do not understand how to carry out the written directive. That is, workers should ask if they have any questions

about what to do or how it should be done rather than continuing a procedure when there is any doubt.

3.2.5. The licensee should establish a procedure to have an authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist) verify that the radioisotope, number of sources, source strengths, and, if applicable, loading sequence of the sources to be used are in agreement with the written directive and plan of treatment before implanting the radioactive sealed sources. The term sealed sources includes wires and encapsulated sources. The licensee may use any appropriate verification method, such as checking the serial number of the sealed sources behind an appropriate shield, using a radiation detector, using a dose calibrator, using color-coded sealed sources, or using clearly marked storage locations, i. e., one location for each source strength.

3.2.6. For temporary brachytherapy implants, the licensee shall establish a procedure for using radiographs or other comparable images (e.g. computerized tomography) of brachytherapy radioactive sources or nonradioactive "dummy" sources in place as the basis for verifying the position of the sources and calculating the exposure time (or, equivalently, the total dose). Whenever possible, nonradioactive "dummy" sources should be used before inserting the radioactive sealed sources (e.g., cesium-137 sealed sources used for intracavitary applications). However, some brachytherapy procedures may require the use of various fixed geometry applicators (e.g., appliances or templates) to establish the location of the temporary sources and calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary provided the position of the sources is known prior to inserting the radioactive sources and calculating the exposure time (or, equivalently, the total dose).

3.2.7. For permanent brachytherapy implants, the licensee should establish a procedure for using radiographs or other comparable images (e.g., computerized tomography) of brachytherapy radioactive sources in place as the basis for verifying the position of the sources and calculating the total dose, if applicable, after inserting the sources (e.g., iodine-125 sealed sources used for interstitial applications). However, some brachytherapy procedures may require the use of various fixed geometry applicators (e.g., templates) to establish the location of the sources and calculate the total dose, if applicable. In these cases, radiographs or other comparable images may not be necessary.

3.2.8. After insertion of the temporary implant brachytherapy sources, the licensee should establish a procedure to have an authorized user promptly record the actual loading sequence of the radioactive sources implanted (e.g., location of each sealed source in a tube, tandem or cylinder) and sign or initial the patient's chart or other appropriate record.

3.2.9. After insertion of the permanent implant brachytherapy sources, the licensee should establish a procedure to have an authorized user promptly record the actual number of radioactive sources implanted and sign or initial the patient's chart or other appropriate record.

3.2.10. The licensee should establish a procedure to check the dose calculations before the total prescribed brachytherapy dose has been administered. An authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), who whenever possible did not make the original

calculations, should check the dose calculations. Manual dose calculations should be checked for:

- Arithmetic errors,
- Appropriate transfer of data from the written directive, plan of treatment, tables, and graphs,
- Appropriate use of nomograms (when applicable), and
- Appropriate use of all pertinent data in the calculations.

Computer-generated dose calculations should be checked by examining the computer printout to verify that the correct data for the patient were used in the calculations (e.g., position of the applicator or sealed sources, number of sources, total source strength, or source loading sequence). Alternatively, the brachytherapy dose should be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), particular emphasis should be placed on verifying the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual).

3.2.11. The licensee should establish a procedure to have an authorized user date and sign or initial a written record in the patient's chart or in another appropriate record after insertion of the brachytherapy sources but prior to completion of the procedure. The written record should include the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

3.2.12. If the authorized user determines that delaying treatment in order to perform the checks of dose calculations would jeopardize the patient's health because of the emergent nature of the patient's medical condition, the checks of the calculations should be performed within two working days of completion of the brachytherapy treatment.

3.2.13. The licensee should establish a procedure for performing acceptance testing by a qualified person (e.g., a teletherapy physicist) on each treatment planning or dose calculating computer program that could be used for brachytherapy dose calculations. Acceptance testing should be performed before the first use of a treatment planning or dose calculation computer program for brachytherapy dose calculations. The licensee should assess each treatment planning or dose calculating computer program based on the licensee's specific needs and application.

3.2.14. The licensee should establish procedures to perform periodic reviews of the brachytherapy QMP.

4.0. **Suggested Policies and Procedures for Gamma Stereotactic Radiosurgery**

4.1. The licensee should establish a policy to have an authorized user date and sign a written directive before administering treatment. A written directive is required by Rule .05(6)(k).

4.2. Before administering treatment, the licensee should establish a procedure to verify by more than one method the identity of the patient as the individual named in the written directive. Identifying the patient by more than one method is required by Rule .05(6)(h). The procedure used to identify

the patient should be to ask the patient's name and confirm the name and at least one of the following by comparison with the corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, the name on the patient's medical insurance card, or the photograph of the patient's face.

4.3. The licensee should establish a procedure to have the neurosurgeon, the oncology physician, and the radiation therapy physicist date and sign a plan of treatment that includes, for each target point, the coordinates, the plug pattern, the collimator size, the exposure time, the target date, and the total dose before administering treatment.

4.4. The licensee should establish a policy for all workers to seek guidance if they do not understand how to carry out the written directive. That is, workers should ask if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.

4.5. The licensee should establish a procedure to verify, before administering each treatment, that the specific details of the administration are in accordance with the written directive and plan of treatment. The verification should be performed by at least one qualified person (e.g., an oncology physician, radiation therapy physician, or radiation therapy technologist) other than the individuals who dated and signed the written directive and plan of treatment. Particular emphasis should be directed toward verifying that the stereotactic frame coordinates on the patient's skull match those of the plan of treatment.

4.6. The licensee should establish a procedure to check the computer-generated dose calculations by examining the computer printout to verify that correct data for the patient were used in the calculations.

4.7. The licensee should establish a procedure to check that the computer-generated dose calculations were correctly input to the gamma stereotactic radiosurgery unit.

4.8. The licensee should establish a procedure to have the neurosurgeon or the oncology physician, after administering the treatment, date and sign or initial a written record of the calculated administered dose in the patient's chart or in another appropriate record.

4.9. If the authorized user determines that delaying treatment in order to perform the checks of the dose calculations would jeopardize the patient's health because of the emergent nature of the patient's medical condition, the checks of the calculations should be performed within two working days of the treatment.

4.10. The licensee should establish a procedure for performing acceptance testing by a qualified person (e.g., a teletherapy physicist) on each treatment planning or dose calculating computer program that could be used for gamma stereotactic radiosurgery dose calculations. Acceptance testing should be performed before the first use of a treatment planning or dose calculating computer program for gamma stereotactic radiosurgery dose calculations. The licensee should assess each treatment planning or dose calculating computer program based on the licensee's specific needs and applications.

4.11. The licensee should establish procedures to perform reviews of the gamma stereotactic radiosurgery QMP.

5.0. Oral Directives and Revisions to Written Directives

The following concerns oral directives and revisions to written directives.

If, because of the patient's medical condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is dated and signed by the authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

If, because of the emergent nature of the patient's medical condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

6.0. Periodic Reviews

The licensee should establish written procedures to conduct periodic reviews of each applicable program area, e.g., radiopharmaceuticals, teletherapy, brachytherapy, and gamma stereotactic radiosurgery. The review should include, from the previous 12 months (or since the last review), a representative sample of patient administrations, all recordable events, and all misadministrations. The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each treatment modality performed in the institution, e.g., radiopharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery.

These periodic reviews could be conducted weekly, monthly, or quarterly if one of these periods is more compatible with the licensee's operations.

If feasible, the persons conducting the review should not review their own work. If this is not possible, two people should work together as a team to conduct the review of that work. The licensee or designee should regularly review the findings of the periodic reviews to ensure that the QMP is effective.

For each patient case reviewed, the licensee should determine whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the written directive or plan of treatment as applicable. For example, were the following correct:

- For radiopharmaceutical therapy: the radiopharmaceutical, dosage, and route of administration;

- For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;

- For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose;

- For all other brachytherapy prior to implantation: the radioisotope, number of sources, and source strengths; after implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, total dose);

- For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose.

For each patient case reviewed, the licensee should identify deviations from the written directive, the cause of each deviation, and the action required to prevent reoccurrence. The actions may include new or revised policies, new or revised procedures, additional training, or increased supervisory review of work. The licensee should reevaluate the QMP policies and procedures after each annual review to determine whether the program is still effective or to identify actions required to make the program more effective.

Program review results should be documented and should be available for Radioactive Materials Program inspectors. To obtain the maximum results from the lessons learned from each review, the program review reports should be distributed within the institution to appropriate management and departments. Corrective actions for deficient conditions should be implemented within a reasonable time after identification of the deficiency.

APPENDIX B

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

1. MANAGEMENT COMMITMENT

(a) The management of this facility is committed to the program described in this document for keeping exposures (individual and collective) as low as reasonably achievable (ALARA). We have developed an administrative organization for radiation safety and have and will develop and update the necessary written policy, procedures, and instructions to foster the ALARA concept within our organization. The organization will include a Radiation Safety Officer (RSO) and a Radiation Safety Committee (RSC)[1].

(b) We will perform a formal annual review of the radiation safety program, including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

(c) Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to show, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. We will be prepared to describe the reasons for not carrying out all of the recommendations.

(d) The sum of the doses received by all exposed individuals will be maintained at the lowest practicable level. It is not desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit. Especially if this involves exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. RADIATION SAFETY OFFICER (RSO)

(a) Annual and Monthly Review

(1) The RSO will conduct an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.

(2) The RSO will review a monthly review of the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of this program.

(3) The RSO will review radiation level surveys of unrestricted and restricted areas to decide if they were at ALARA levels during the previous quarter.

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[1] Only medical institutions have an RSC.

(b) Education Responsibilities for ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy. These persons will also be informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

(c) Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be encouraged to participate in deciding the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

(d) Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will find out the cause(s). When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

(e) Reporting to Management

The RSO will brief management annually on the radiation safety program.

3. RADIATION SAFETY COMMITTEE (RSC)[2]

(a) Review of Proposed Users and Uses

(1) The RSC will thoroughly review each applicant's qualifications with respect to the types and quantities of materials and uses for which he has applied. This will ensure that the applicant can act appropriately to maintain exposure ALARA.

(2) When considering a new use of radioactive material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA and shall have incorporated the use of special equipment which may be necessary to support the new use of material. If necessary, the special equipment will be in addition to equipment already required to maintain exposures ALARA.

(3) The RSC will ensure that the user justifies his procedures and that doses will be ALARA (individual and collective).

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[2] The RSO for other than medical institutions will assume the responsibilities of the RSC outlined in this Section.

(b) Delegation of Authority

(The careful delegation of RSC authority is essential to the enforcement of an ALARA program.)

(1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

(2) The RSC will support the RSO in those instances where it is necessary for the RSO to assert his/her authority. Where the RSO has been overruled, the RSC will record the basis for its action in the minutes of the quarterly committee meeting.

(c) Review of ALARA Program

(1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to carry out the ALARA concept.

(2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigation Levels in Table K-1 in this document are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigation Levels are exceeded (see Section 5).[3]

(3) The RSC will evaluate the combined efforts of the RSO, authorized users, workers and those of management to maintain the ALARA concept.

4. PERSONS WHO RECEIVE OCCUPATIONAL RADIATION EXPOSURE

(a) Workers will be instructed in the ALARA concept and its relationship to work procedures and conditions.

(b) Workers will be instructed about what recourse is available if they feel that ALARA is not being promoted on the job.

5. ESTABLISHMENT OF INVESTIGATION LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION EXPOSURES

This organization establishes the following Investigation Levels for occupational external radiation exposures that, when exceeded, will initiate review or investigation by the RSC and/or the RSO. We have adopted the Investigation Levels listed in Table K-1. These levels apply to the exposure of individual workers.

Emphasis on the Investigation Levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify further investigations.

TABLE K-1

	Investigation Levels (mrem per calendar quarter)	
	Level I	Level II
1. Total Effective Dose Equivalent (TEDE)	125	375
2. Sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye	1875	5625
3. Shallow dose equivalent to the skin or any extremity	1875	5625
4. Eye dose equivalent to the lens of the eye	750	2250

The Radiation Safety Officer will review and record results of personnel monitoring not less than once in any calendar quarter. We will take the following actions for the Investigation Levels as stated in Table K-1:

(a) Quarterly exposure of individuals to less than Investigation Level I.

No action will be taken in those cases where an individual's exposure is less than Table K-1 values for Investigation Level I, unless the RSO finds reason to question the exposure.

(b) Personnel exposures equal to or greater than Investigation Level I, but less than Investigation Level II.

The RSO will review the exposure of individuals whose quarterly exposures equal or exceed Investigation Level I. The results are reported at the first RSC meeting following the quarter of the recorded exposure. The RSC will compare the exposure with those of others performing similar tasks as an index of ALARA program quality. The RSC may take actions to prevent similar exposures in the future. Their review and recommended actions will be recorded in the RSC minutes.

(c) Exposure equal to or greater than Investigation Level II.

The RSO will quickly investigate the cause(s) of all personnel exposures equaling or exceeding Investigation Level II. The RSO will take appropriate action based on the outcome of the investigation. A report of the investigation, actions taken, and a copy of the individual's radiation exposure record will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes. The RSC minutes will be made available to Georgia Department of Natural Resources, Radioactive Materials Program for review during their inspection.

(d) Reestablishment of an individual occupational worker's Investigation Level II to a level above that listed in Table K-1.

If a worker's or a group of worker's exposures need to exceed Investigation Level II, a new, higher Investigation Level II may be established. The new, higher level will be consistent with good ALARA practices for that individual or group. Justification for a new Investigation Level II will be documented.

The RSC will review the justification for, and will approve, all revisions of Investigation Level II. In such cases, when the exposure equals or exceeds the newly established Investigation Level II, those actions listed in 5.c. above will be followed.

7. SIGNATURE OF CERTIFYING OFFICIAL[4]

I hereby certify that this institution (or private practice) has implemented the ALARA Program set forth above.

Signature:_____

Name (print or type):_____

Title:_____

Licensee Name and Address:

Name:_____

Address:_____

City:_____ State:_____ Zip: _____

[4] The person who is authorized to make commitments for the administration of the organization (i.e., president, owner, hospital administrator, president, owner).

APPENDIX C

INFORMATION REQUIRED FOR FIELD USE OF RADIOACTIVE MATERIAL

1. A complete license application describing the type and amount of material to be used, the location of use, and training and experience of the individual using the material.

2. A complete experimental protocol.

3. A description of the amount of radioactive material to be released in the field, decontamination procedures at the conclusion of the experiment, if appropriate, and procedures for minimizing releases.

4. A description of the expected radiation dose to humans.

5. A description of the proposed methods of disposal of radioactive waste generated during the field use of radioactive material.

6. The written permission of the property owner to use radioactive materials at the proposed site.

APPENDIX D

RADIATION SAFETY OFFICER CERTIFICATION

We certify that the individual to be named on this license to perform the function of Radiation Safety Officer:

1. Has read and understands the Department regulations applicable to this license and the specific conditions in the license,

2. Has sufficient technical knowledge to perform the duties of a Radiation Safety Officer,

3. Has and will continue to have sufficient time to perform the duties of the Radiation Safety Officer,

4. Has and will continue to get sufficient resources to accomplish the tasks of the Radiation Safety Officer,

5. Is completely willing to perform the functions of the Radiation Safety Officer, and

6. Has and will continue to receive the support of the management of this licensee in ensuring that all licensed activities will be conducted in accordance with Department regulations and the specific terms of the license.

Radiation Safety Officer Applicant _____
Date _____

Corporate Officer\Certifying Official _____
Date _____

APPENDIX E

DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY COMMITTEE (RSC)

1. Meet as often as necessary to conduct business but not less than quarterly.

2. Conduct periodic reviews and audits of the Radiation Safety Program and devote sufficient time, along with the Radiation Safety Officer and the Radiation Safety Office staff, to reviewing records, reports from the RSO, results of Department inspections, and written safety procedures, along with observing audits performed by the RSO and the Radiation Safety Office staff to ensure the adequacy of the institution's management control systems. These reviews may be conducted by an independent auditor, but this does not relieve the RSC of the responsibility to ensure that the reviews are conducted in accordance with the regulations. Examples of program reviews include, but are not limited to, the following:

   A. Periodic review of protocol or user permits issued by the RSC (e.g., review of each user authorization at 1 to 2 year intervals).

   B. Review of letters of agreement with offsite emergency response agencies as appropriate.

   C. Review of procedures for controlling and maintaining inventories, procurement of radioactive material, individual user and institutional cumulative possession limits, transfer of radioactive materials within the institution, and transfer of radioactive material to other persons or licensees.

   D. Review of audit findings (of RSC-approved users and facilities) by the Radiation Safety Office staff.

   E. Conduct radiation safety evaluations of proposed users and uses.

   F. Develop procedures and criteria for training and testing each category of worker.

   G. Establish methods for maintaining records of the committee's proceedings and radiation safety evaluations of proposed users and uses of radioactive materials.

   H. Develop radiation safety manuals as necessary to ensure proper program implementation and good health physics practices.

   I. Maintain a list of current committee members and their appropriate training and experience.

APPENDIX F

DUTIES AND RESPONSIBILITIES OF A BROAD SCOPE RADIATION SAFETY OFFICER

1. Maintain surveillance of overall activities involving radioactive material, including monitoring and surveys of all areas in which radioactive material is used.

2. Determine compliance with rules and regulations, license conditions, and the conditions of project approvals authorized by the Radiation Safety Committee.

3. Monitor and maintain absolute and other special filter systems associated with the use, storage, or disposal of radioactive material.

4. Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility.

5. Oversee proper delivery, receipt, and conduct of radiation surveys of all shipments of radioactive material arriving at or leaving from the institution, as well as packaging and labeling all radioactive material leaving the institution.

6. Distribute and process personnel radiation monitoring equipment, determine the need for and evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching maximum permissible amounts, and recommend appropriate remedial action.

7. Conduct training programs and otherwise instruct personnel in the proper procedures for the use of radioactive material prior to use, at periodic intervals (refresher training), and as required by changes in procedures, equipment, regulations, etc.

8. Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records.

9. Store radioactive materials not in current use, including wastes.

10. Perform or arrange for leak testing on all sealed sources and calibration of radiation survey instruments.

11. Maintain an inventory of all radioisotopes at the institution and limit the quantity of radionuclides at the institution to the amounts authorized by the license.

12. Immediately terminate any activity that is found to be a threat to public health and safety or property.

13. Supervise decontamination and recovery operations.

14. Maintain other records not specifically designated above.

15. Hold periodic meetings with and provide reports to licensee management, the Radiation Safety Committee Chairman and the Radiation Safety Committee.

Georgia Department of Natural Resources
Environmental Protection Division
Radioactive Materials Program

APPLICATION FOR RADIOACTIVE MATERIALS LICENSE

INSTRUCTIONS - Complete Items 1 through 13 if this is an initial application or renewal of a license. Use supplemental sheets where necessary. Item 13 on the application must be completed and signed. Retain one copy for your records. Submit original application to: Georgia Department of Natural Resources, Radioactive Materials Program, 4244 International Parkway, Suite 114, Atlanta, Georgia, 30354. Upon approval of this application, the applicant will receive a Georgia Radioactive Materials License. Georgia Radioactive Materials Licenses are issued in accordance with the general requirements contained in the Georgia Department of Natural Resources Rules and Regulations, Chapter 391-3-17. **The Department can be reached via the Internet. The address is rad_materials @ mail.dnr.state.ga.us.**

1.This is an Application for: (Check appropriate item) A.☐ New License B. ☐ Amendment to License C. ☐ Renewal of License
If B or C , Please indicate GA. License Number _____

2.a. Name and Mailing Address of Applicant Name: Address: City, State, Zip Code: County: Telephone Number ( ) _____ -_____ Internet Address:	2.b. Address where licensed material will be stored and/or used (Street Address) A. Permanent B. Coordinates 1. Latitude: 2. Longitude: C. Temporary sites throughout Georgia? Yes _____ No_____
3. Person to Contact Regarding this Application Name: Title: Telephone Number ( ) _____ - _____	4. Locations where records will be kept:
SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.	
5. RADIOACTIVE MATERIAL a. Element and mass number, b. Chemical and/or physical form; and c.. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS
9. FACILITIES AND EQUIPMENT	10. RADIATION SAFETY PROGRAM
11. WASTE MANAGEMENT	12. LICENSEE FEES (SEE DEPARTMENT'S FEE SCHEDULE) FEE CATEGORY : AMOUNT ENCLOSED $ CHECK MAILED ☐ PLEASE INVOICE ☐
MAKE CHECKS PAYABLE TO: DEPARTMENT OF NATURAL RESOURCES RADIOACTIVE MATERIALS PROGRAM	**MAIL FEES TO: RADIOACTIVE MATERIALS PROGRAM, P.O. BOX 101161 ATLANTA, GEORGIA 30392**

13. CERTIFICATION (Must be completed by the applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH GEORGIA DEPARTMENT OF NATURAL RESOURCES RULES AND REGULATIONS, DESIGNATED CHAPTER 391-3-17 AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

CERTIFYING OFFICER -- TYPED PRINTED NAME AND TITLE	SIGNATURE	DATE

FOR DEPARTMENT USE ONLY

TYPE OF FEE	FEE CATEGORY	AMOUNT RECEIVED	INVOICE DATE	COMMENTS

APPROVED BY DATE:

APPENDIX H

GEORGIA DEPARTMENT OF NATURAL RESOURCES
RADIOACTIVE MATERIALS PROGRAM
REQUEST TO TERMINATE RADIOACTIVE MATERIAL LICENSE

1. Licensee Name _____ 2. License Number _____

3. Address _____
No. Street/P. O. Box No. City, State Zip code

4. Contact Person _____ 5. Telephone Number _____

6. Request is hereby made that the Radioactive Material License described above be terminated for the following reason:

_____

_____

7. Radioactive Material possessed under this license has been disposed of as indicated below:

☐ No materials have been possessed or procured by the licensee under this licensee.

☐ All material was used for the licensed purposes, none remains.

☐ All material was leased, and has been returned to lessor.

Name of lessor: _____ License No. _____

☐ Lessor acknowledgment of receipt attached.

☐ Material has been transferred to the following licensee:

Licensee Name _____ License No. _____

Address _____
No. Street/P.O. Box No. City, State Zip code

Date of transfer: _____ ☐ Transferee acknowledgment of receipt attached.

☐ Material has been disposed of in the following manner:

_____

_____

☐ A radiation survey was conducted to confirm the absence of radioactive material and to determine whether any contamination remains at the facility covered by the license.

☐ Copy of survey results attached.

8. Management Official or Radiation Safety Officer

_____ _____
Signature of certifying officer Date

_____ _____
Print name Title

Keep one copy for your records and send original to:

GEORGIA DEPARTMENT OF NATURAL RESOURCES
RADIOACTIVE MATERIALS PROGRAM
4244 INTERNATIONAL PARKWAY, SUITE 114
ATLANTA, GEORGIA 30354