10A NCAC 15 .0213 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0213 ~~ADDITIONAL REQUIREMENTS: REGISTERED SERVICES~~ CLINICAL STUDIES, RESEARCH, AND SCREENING PROGRAM REQUIREMENTS

(a) ~~An applicant for registration of diagnostic area radiation survey, diagnostic radiation output measurements or therapeutic calibration services pursuant to Rule .0205 of this Section shall meet the following additional requirements:~~

~~(1) The applicant shall have adequate radiation survey and radiation measurement equipment appropriate to the services requested for authorization.~~

~~(2) The applicant shall ensure that the equipment in Subparagraph (a)(1) of this Rule is calibrated at least every 12 months by persons registered to provide such services pursuant to Rule .0205 of this Section, except as provided in Subparagraph (a)(3) of this Rule. The agency may approve less frequent calibration of equipment used for therapy calibration, provided the applicant satisfies the agency that the proposed frequency and procedures will provide equivalent or better assurance of proper calibration.~~

~~(3) The applicant may perform the equipment calibrations required in Subparagraph (a)(2) of this Rule provided that:~~

~~(A) such calibrations are currently traceable to the National Institute of Standards and Technology;~~

~~(B) the calibration procedures are approved by the agency;~~

~~(C) the radiation sources used for such calibration are licensed or registered as required by the rules in this Chapter; and~~

~~(D) the equipment is labeled to indicate the date of calibration and records of the calibration are maintained.~~

~~(4) The applicant shall submit:~~

~~(A) a description of the procedures that will be used in performing area radiation surveys including a list of all guides and references to the employed;~~

~~(B) a copy of all forms, reports and documents that will be supplied to customers;~~

~~(C) samples of three different types of surveys;~~

~~(D) samples of three reports of diagnostic radiation output measurements; and~~

~~(E) samples of three therapeutic calibration reports.~~

~~(b) An applicant for registration of services pursuant to Rule .0205 of this Section who proposes to provide diagnostic radiographic, fluoroscopic and therapeutic facility and shielding design services shall meet the following additional requirements:~~

~~(1) The applicant shall submit examples of the facility and shielding design which will be provided to clients.~~

~~(2) The applicant shall submit examples of the calculations which will be performed as part of the facility and shielding design along with any guides, occupancy factor rationales, and workload estimation rationales which will be used.~~

~~(3) The applicant shall ensure that the facility and shielding design services provided to licensees and registrants of the agency satisfy the applicable requirements in this Chapter.~~

(a) Persons proposing to conduct clinical studies, research, or screenings on humans may not initiate a program without receiving acknowledgment from the agency.

(b) A person shall provide to the agency a request to waive the requirements of Rule .0603(a)(1)(G) of this Chapter and receive an acknowledgment to initiate the program from the agency prior to conducting a clinical study, research, or screenings. Clinical studies and research programs that have received approval through an Institutional Review Board (IRB) are not exempt from meeting the requirements of this Section.

(c) A person requesting a waiver shall submit the following for agency review:

(1) Programs with an IRB approval:

(A) the study protocol submitted to the IRB;

(B) the IRB approval; and

(C) qualifications for radiation machine operators.

(2) Programs without an IRB approval:

(A) the registrant or applicant's business name, street address, city, state, and zip code;

(B) person(s) name proposing the research activity;

(C) a business address where all research activities will be conducted;

(D) contact name, telephone number, and e-mail address;

(E) copy of the informed consent provided to the subjects;

(F) machine model and serial number to be used;

(G) start and end date of the research program;

(H) description of the population to be examined in the program;

(I) purpose of the research program;

(J) diseases or conditions for which the examinations will be used in diagnosing;

(K) description of the X-ray procedure proposed in the program, the number of exposures, the number of procedures, total time involvement period for each subject;

(L) an evaluation of any known alternative methods not involving ionizing radiation that could achieve the goals of the screening program and reasons why these methods are not used instead of the x-ray examinations;

(M) name of the NC licensed practitioner who will supervise the program;

(N) name of the NC licensed practitioner(s) who will interpret images;

(O) qualifications for radiation machine operators;

(P) qualifications for the person who will supervise the radiation machine operators;

(Q) description of the methods used to advise the subjects and their physicians of the research program results;

(R) description of the quality control program;

(S) an evaluation by a medical physicist of the x-ray system to be used in the program. The evaluation by the medical physicist shall include a measurement of patient exposures from the x-ray examinations to be performed;

(T) description of the procedures for the retention or disposition of the images and other records pertaining to the X-ray exams; and

(U) plans for the radiation machine once the program is completed.

(d) After receiving the information in Paragraph (c) of this Rule, the agency will respond to the applicant in writing within 60 days. The agency may require additional information to complete the review.

(e) Nothing in this Rule relieves registrants from complying with the other requirements of this Chapter.

History Note: *Authority G.S. 104E-7;*
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