of use at the addresses identified in the application or on the license;
(d) The provisions of §35.14(a);
(e) The provisions of §35.14(b)(1) for an authorized user, an authorized
nuclear pharmacist, or an authorized medical physicist;
(f) The provisions of §35.14(b)(5).
(g) The provisions of §35.49(a).
[67 FR 20370, Apr. 24, 2002, as amended at 72
FR 55931, Oct. 1, 2007]

§ 35.18 License issuance.
(a) The Commission shall issue a li-
cense for the medical use of byproduct
material if—
(1) The applicant has filed NRC Form
313 "Application for Material License" in accordance with the instructions in
§35.12;
(2) The applicant has paid any appli-
cable fee as provided in Part 170 of this
chapter;
(3) The Commission finds the appli-
cant equipped and committed to ob-
serve the safety standards established
by the Commission in this Chapter for
the protection of the public health and
safety; and
(4) The applicant meets the require-
ments of Part 36 of this chapter.
(b) The Commission shall issue a li-
cense for mobile medical service if the
applicant:
(1) Meets the requirements in para-
graph (a) of this section; and
(2) Assures that individuals or human
research subjects to whom unsealed by-
product material or radiation from im-
plants containing byproduct material
will be administered may be released
following treatment in accordance with
§35.75.

§ 35.19 Specific exemptions.
The Commission may, upon applica-
tion of any interested person or upon
its own initiative, grant exemptions
from the regulations in this part that
it determines are authorized by law
and will not endanger life or property
or the common defense and security
and are otherwise in the public inter-
est.

Subpart B—General Administrative
Requirements

§ 35.24 Authority and responsibilities
for the radiation protection pro-
gram.
(a) In addition to the radiation pro-
tection program requirements of
§20.1101 of this chapter, a licensee’s
management shall approve in writing—
(1) Requests for a license application,
renewal, or amendment before sub-
mittal to the Commission;
(2) Any individual before allowing
that individual to work as an author-
ized user, authorized nuclear phar-
macist, or authorized medical physi-
cist; and
(3) Radiation protection program
changes that do not require a license
amendment and are permitted under
§35.26;
(b) A licensee’s management shall ap-
point a Radiation Safety Officer, who
agrees, in writing, to be responsible for
implementing the radiation protection
program. The licensee, through the Ra-
diation Safety Officer, shall ensure
that radiation safety activities are
being performed in accordance with li-
cense-approved procedures and regu-
latory requirements.
(c) For up to 60 days each year, a li-
censee may permit an authorized user
or an individual qualified to be a Radi-
ation Safety Officer, under §§35.50 and
35.59, to function as a temporary Radi-
ation Safety Officer and to perform the
functions of a Radiation Safety Officer,
as provided in paragraph (g) of this sec-
tion, if the licensee takes the actions
required in paragraphs (b), (e), (g), and
(h) of this section and notifies the
Commission in accordance with
§35.14(b).
(d) A licensee may simultaneously
appoint more than one temporary Ra-
diation Safety Officer in accordance
with paragraph (c) of this section, if
needed to ensure that the licensee has a
temporary Radiation Safety Officer
that satisfies the requirements to be a
Radiation Safety Officer for each of the
different types of uses of byproduct
material permitted by the license.
(e) A licensee shall establish the au-
thority, duties, and responsibilities of
the Radiation Safety Officer in writing.
§ 35.26 Radiation protection program changes.

(a) A licensee may revise its radiation protection program without Commission approval if—

(1) The revision does not require a license amendment under § 35.13;

(2) The revision is in compliance with the regulations and the license;

(3) The revision has been reviewed and approved by the Radiation Safety Officer and licensee management; and

(4) The affected individuals are instructed on the revised program before the changes are implemented.

(b) A licensee shall retain a record of each change in accordance with § 35.2026.

§ 35.27 Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user, as allowed by § 35.11(b)(1), shall—

(1) In addition to the requirements in §19.12 of this chapter, instruct the supervised individual in the licensee’s written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, regulations of this chapter, and license conditions with respect to the medical use of byproduct material.

(b) A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by § 35.11(b)(2), shall—

(1) In addition to the requirements in §19.12 of this chapter, instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to that individual’s involvement with byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter, and license conditions.

(c) A licensee that permits supervised activities under paragraphs (a) and (b) of this section is responsible for the acts and omissions of the supervised individual.

§ 35.40 Written directives.

(a) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

(1) If, because of the emergent nature of the patient’s condition, a delay in...