



RADIATION SAFETY COMMITTEES

PURPOSE

This Guideline document describes membership, function, meeting, and voting requirements for each of the Radiation Safety Committees.

SCOPE

This guideline applies to all Emory University employees, students and volunteers at any of the Emory College, Emory University School of Medicine, Emory University Hospital, The Emory Clinic, Emory University Hospital at Midtown, Emory University Orthopedic and Spine Hospital and Wesley Woods Geriatric Hospital facilities

RADIATION CONTROL COUNCIL (RCC)

Function

The RCC serves as the general policy-making and regulating body for activities at Emory University that involve the use of radiation and radioactive material. The Council delegates authority to the Radiation Safety Office for enforcement of Radiation Safety policies and procedures.

Approvals become effective when granted by the Radiation Safety Councils (RSCs) and are reported to the RCC at the next scheduled meeting.

Membership

The Radiation Control Council membership consists of:

- Representatives of each of the following areas under the broad license: Emory Hospital, Emory Clinic, Emory Midtown, Emory School of Medicine, and Emory College; and
- An authorized user of each type of use permitted by the license represented by Chairpersons of Committee 1, 2, 3 and the RDRC; the Radiation Safety Officer and Deputy Radiation Safety Officer; a representative of Nursing Services; and a representative of management who is neither an authorized user or the Radiation Safety Officer; and
- The Director of the Environmental Health and Safety Office serves as an ex-officio (non-voting) member of the Council.

Members serve terms of four years unless terminated earlier as provided below. Members are eligible for reappointment and may serve additional terms. The appointment year runs from September through August.

Members are appointed by, and serve at the discretion of, Emory's President (or his/her designee) and may be removed from membership by the President (or his/her designee) at any time by written notice from the President (or his/her designee).

Meetings

The Council will meet as often as needed to ensure that the Radiation Safety program is operating in compliance with the license, established procedures and the regulations- but not less than semi-annually.

RADIATION SAFETY COMMITTEES

Additional meetings may be called by the Council Chairperson at his/her discretion or at the request of one of the Committee Chairpersons and/or the Radiation Safety Officer.

To conduct business, a quorum consisting of more than fifty percent of the members must be present at the meetings, and each of the following representatives must be present: 1) the Chairperson (or his/her designee); 2) the Radiation Safety Officer or Deputy Radiation Safety Officer; and 3) the Executive Management representative (or his/her alternate).

For quorum purposes, alternate members may be counted if present and the respective primary member is absent or is an investigator on a study being discussed. If Council members are unable to be physically present at the meetings, attendance can be accomplished through teleconference or videoconference.

If a quorum cannot be reached or the representatives noted above are not available to participate, the meeting must be rescheduled.

Voting

Prior to the meeting, members may review protocol submissions, reports, and other materials of interest to the Council that are provided by electronic means and may comment electronically; provided however, that all discussion and voting take place at a convened meeting at which a quorum is present.

After discussion, a quorum of the Council members will vote to take one of the following actions:

- Approve with appropriate monitoring conditions;
- Approve pending minor changes or additional conditions which may be subsequently approved with review by the Radiation Safety Officer and Chair;
- Defer, requiring substantial changes or additional information which will be reviewed at a subsequent Council meeting; or
- Disapprove

RADIATION SAFETY COMMITTEE 1 (RSC1)

Function

Radiation Safety Committee I reviews applications and amendments for the human use of radioactive material with respect to user qualifications, types and quantities of materials requested, and uses of materials requested.

The Radiation Safety Office staff is empowered to administratively approve amendments to existing authorizations involving only supervised users changes or room changes. A summary of administrative approvals is submitted for consideration during the convened meetings.

New protocols or amendments to existing protocols involving diagnostic imaging within standard-of-care are registered with agreement by the Committee 1 Chair and the Radiation Safety Officer or their designees that the informed consent contains adequate information for participant protection. Such protocols may proceed upon registration.

Either the Chair or Radiation Safety Officer may recommend changes, corrections or full Committee review if the protocol is found to exceed standard-of-care.

Membership

The Committee consists of:

- Physicians specializing in Nuclear Cardiology, Nuclear Medicine and Radiation Oncology, and
- Other individuals with specialties in pathology, radiopharmaceuticals, nursing, hospital administration and radiation safety.

Members serve terms of four years unless terminated earlier as provided below. Members are eligible for reappointment and may serve additional terms. The appointment year runs from September through August.

Members are appointed by, and serve at the discretion of Emory's President (or his/her designee) and may be removed from membership by the President (or his/her designee) at any time by written notice from the President (or his/her designee).

Meetings

Committee I will meet at least quarterly. Special meetings may be called by the Chairperson or Radiation Safety Officer or at the request of some interested party.

To conduct business, a quorum consisting of more than fifty percent of the members and the Radiation Safety Officer or Deputy Radiation Safety Officer must be present at the meetings.

For quorum purposes, alternate members may be counted if present and the respective primary member is absent or is an investigator on a study being discussed. If Committee members are unable to be physically present at the meetings, attendance can be accomplished through teleconference or videoconference.

If a quorum cannot be reached or the representatives noted above are not available to participate, the meeting must be rescheduled.

Committee minutes are submitted to the RCC.

Voting

Prior to the meeting, members may review protocol submissions, reports and other materials of interest to the Committee that are provided by electronic means and may comment electronically; provided however, that all discussion and voting must take place at a convened meeting at which a quorum is present.

After discussion, a quorum of the Committee members will vote to take one of the following actions:

- Approve with appropriate monitoring conditions;
- Approve pending minor changes or additional conditions which may be subsequently approved with review by the Radiation Safety Officer and Chair;
- Defer, requiring substantial changes or additional information which will be reviewed at a subsequent Committee meeting; or
- Disapprove

No member may vote on a protocol in which he/she is an investigator.

RADIATION SAFETY COMMITTEE 2 (RSC2)

Function

Radiation Safety Committee 2 reviews applications and amendments for the non-human use of radioactive material and machine-produced radiation with respect to user qualifications, types and quantities of materials requested, and uses of materials requested.

The Radiation Safety Office staff is empowered to administratively approve amendments to existing authorizations involving only supervised users changes or room changes. A summary of administrative approvals is submitted for consideration during the convened meetings.

Membership

This Committee consists of:

- Qualified persons selected from various schools and departments working under the Broad License so as to represent those who are actively engaged in non-human work with radioactive materials through the College or the School of Medicine.

Members serve terms of four years unless terminated earlier as provided below. Members are eligible for reappointment and may serve additional terms. The appointment year runs from September through August.

Members are appointed by, and serve at the discretion of Emory's President (or his/her designee) and may be removed from membership by the President (or his/her designee) at any time by written notice from the President (or his/her designee).

Meetings

Committee II will meet at least semi-annually. Special meetings may be called by the Chairperson or Radiation Safety Officer or at the request of some interested party.

To conduct business, a quorum consisting of more than fifty percent of the members and the Radiation Safety Officer, Deputy Radiation Safety Officer or Associate Radiation Safety Officer must be present at the meetings.

For quorum purposes, alternate members may be counted if present and the respective primary member is absent or is an investigator on a study being discussed. If Committee members are unable to be physically present at the meetings, attendance can be accomplished through teleconference or videoconference.

If a quorum cannot be reached or the representatives noted above are not available to participate, the meeting must be rescheduled.

Committee minutes are submitted to the RCC.

Voting

Prior to the meeting, members may review protocol submissions, reports and other materials of interest to the Committee that are provided by electronic means and may comment electronically; provided however, that all discussion and voting take place at a convened meeting at which a quorum is present.

After discussion, a quorum of the Committee members will vote to take one of the following actions:

- Approve with appropriate monitoring conditions;
- Approve pending minor changes or additional conditions which may be subsequently approved with review by the Radiation Safety Officer and Chair;
- Defer, requiring substantial changes or additional information which will be reviewed at

a subsequent Committee meeting; or

- Disapprove

No member may vote on a protocol in which he/she is an investigator.

RADIATION SAFETY COMMITTEE 3 (RSC3)

Function

Radiation Safety Committee 3 reviews applications and amendments for the research use of machine-produced radiation on humans with respect to procedure, exposure to the subject, and risk information provided to the subject.

New protocols or amendments to existing protocols involving machine-produced radiation within standard-of-care or procedures delivering radiation dose less than or equal to average annual background (low-dose) procedures are registered with agreement by the Committee 3 Chair and the Radiation Safety Officer or their designees that the informed consent contains adequate information for participant protection. Such protocols may proceed upon registration.

Protocols that include radiation from nuclear medicine procedures as well as machine-produced radiation which are reviewed by RSC1 need not be reviewed by RSC3.

Either the Chair or Radiation Safety Officer may recommend changes, corrections or full Committee review if the protocol is found to exceed standard-of-care.

Membership

Radiation Safety Committee 3 consists of:

- Qualified persons selected from various departments working in the Emory system who are familiar with the use of machine-produced radiation on humans.

Members serve terms of four years unless terminated earlier as provided below. Members are eligible for reappointment and may serve additional terms. The appointment year runs from September through August.

Members are appointed by, and serve at the discretion of, Emory's President (or his/her designee) and may be removed from membership by the President (or his/her designee) at any time by written notice from the President (or his/her designee).

Meetings

Committee III will meet at least annually.

To conduct business, a quorum consisting of more than fifty percent of the members and the Radiation Safety Officer or Deputy Radiation Safety Officer must be present at the meetings.

For quorum purposes, alternate members may be counted if present and the respective primary member is absent or is an investigator on a study being discussed. If Committee members are unable to be physically present at the meetings, attendance can be accomplished through teleconference or videoconference.

If a quorum cannot be reached or the representatives noted above are not available to participate, the meeting must be rescheduled.

Committee minutes are submitted to the RCC.

Voting

Prior to the meeting, members may review protocol submissions, reports and other materials of interest to the Committee that are provided by electronic means and may comment electronically; provided however, that all discussion and voting must take place at a convened meeting at which a quorum is present.

After discussion, a quorum of the Committee members will vote to take one of the following actions:

- Approve with appropriate monitoring conditions;
- Approve pending minor changes or additional conditions which may be subsequently approved with review by the Radiation Safety Officer and Chair;
- Defer, requiring substantial changes or additional information which will be reviewed at a subsequent Committee meeting; or
- Disapprove

No member may vote on a protocol in which he/she is an investigator.

RADIOACTIVE DRUG RESEARCH COMMITTEE (RDRC#40)

The RDRC functions in accord with the FDA regulations, 21 CFR 361.1, as follows:

Function

The Radioactive Drug Research Committee (RDRC) is a subcommittee of the Emory University Radiation Safety Committee for Human Use (RSC-1). The RDRC reviews certain research protocols involving radioactive compounds as required by FDA regulations (21 CFR 361.1). RSC1 reviews all other human research protocols involving administration of radioactive materials or radiation from radioactive material to subjects solely as a result of participation in a research study.

A protocol submitted to the RDRC is also required to receive Institutional Review Board (IRB) approval. IRB approval is contingent upon RDRC review and approval.

Any revisions or modifications required by the RDRC must be incorporated into the protocol before final, full approval by the IRB will be granted. Communications between the RDRC and the IRB are described in greater detail in RDRC IRB Communication SOP (for additional information on the RDRC Function, see the RDRC Function SOP).

The Radiation Safety Office staff is allowed to administratively approve amendments to existing authorizations involving only supervised users changes or room changes. A summary of administrative approvals is submitted for consideration during the convened meetings.

The RDRC is required to report the following to the FDA:

- an annual summary of approved studies and membership;
- membership changes prior to the member assuming his/her duties; and
- immediately report to FDA any study involving more than thirty subjects or subjects less than 18 years of age or any adverse event probably attributable to the administration of the radioactive drug.

Membership

The RDRC must consist of at least five individuals. These five members must include:

1. A physician recognized as a specialist in nuclear medicine;
2. A person qualified by training and experience to formulate radioactive drugs;
3. A person with special competence in radiation safety and radiation dosimetry and
4. Individuals qualified in various disciplines pertinent to the field of nuclear medicine (e.g., radiology, internal medicine, clinical pathology, hematology, endocrinology, radiation therapy, radiation physics, radiation biophysics, radiopharmacy and clinical pharmacology).

Other considerations:

- Membership must be sufficiently diverse to permit expert review of technical and scientific aspects of protocols.
- Although one individual may have expertise in more than one category, an individual should only represent one category for the review of protocols.
- The addition of consultants in pertinent medical disciplines may help to provide oversight for specific studies (e.g., pediatric specialist).
- Administrative or management personnel may be included as non-voting members of the RDRC. These members should be listed in the “Non-Voting Members” section of Form FDA 2914.

Members serve terms of four years unless terminated earlier as provided below. Members are eligible for reappointment and may serve additional terms. The appointment year runs from September through August.

Members are appointed by, and serve at the discretion of Emory’s President (or his/her designee) and may be removed from membership by the President (or his/her designee) at any time by written notice from the President (or his/her designee).

For additional information on the RDRC Membership see the RDRC Membership SOP.

Meetings

The full committee will meet at least quarterly. Special meetings may be called by the Chairperson or Radiation Safety Officer or at the request of some interested party.

A quorum consisting of more than 50 percent of the members must be present at the meetings, and each of the following representatives must be present:

1. a physician recognized as a specialist in nuclear medicine;
2. a person qualified by training and experience to formulate radioactive drugs;
3. a person with special competence in radiation safety and radiation dosimetry;
and
4. Chairperson or delegate.

For quorum purposes, these specialties may be represented by the alternates listed for quorum purposes if one of the primary members is absent or is an investigator on a study being discussed.

If RDRC members are unable to be physically present at the meetings, attendance can be accomplished through teleconference or videoconference. Committee minutes are submitted to the RCC. For additional information on RDRC Meetings, see the RDRC Meeting SOP.

Committee minutes are submitted to the RCC.

Voting

Prior to the meeting, members may review protocol submissions, reports and other materials of interest to the Committee that are provided by electronic means and may comment electronically; provided however, that all discussion and voting must take place at a convened meeting at which a quorum is present.

After discussion, a quorum of the Committee members will vote to take one of the following actions:

- Approve with appropriate monitoring conditions;
- Approve pending minor changes or additional conditions which may be subsequently approved with review by the Radiation Safety Officer and Chair;
- Defer, requiring substantial changes or additional information which will be reviewed at a subsequent Committee meeting; or
- Disapprove

No member may vote on a protocol in which he/she is an investigator.

REFERENCES:

- State of Georgia Rules and Regulations on X-Ray, Chapter 290-5-22
- State of Georgia Rules and Regulations on Radioactive Material, Chapter 391-3-17
- FDA 21 CFR part 361.1, Radioactive Drugs for Certain Research Uses
- OSHA 29 CFR 1910.1096 Ionizing Radiation
- Emory University Broad Scope License, GA 153-1