

CRITERIA FOR MAINTAINING RTOG MEMBERSHIP

I. PATIENT ACCESSION REGISTRATION

<u>Membership Category</u>	<u>Minimum RTOG Credits (per year)</u>
Full	25 treatment and/or cancer control cases
Affiliate	5 treatment and/or cancer control cases
CCOP	10 cases (5 treatment cases, 5 cancer control cases)

II. QUALITY CONTROL

	<u>Acceptable Minimum %</u>
1) Eligibility & percent of patients evaluable	80%
2) Percent complete forms - no additional inquiries	80%
3) Timeliness of forms submission (including pathology & chemotherapy flow sheets)	80%
4) Submission of initial treatment planning data (received within 16 days)	80%
5) Responsiveness to additional inquiries	80%
6) Submission of treatment data on completed cases	80%
7) Initial medical oncology	80%
8) Pathology and surgery	80%
9) Intergroup Data (non-RTOG Forms)	80%

Overall Score must be > 80% or a Warning Letter will be issued.

EVALUATION PROCEDURES

The RTOG Membership Evaluation Committee will review all Full and Provisional members and the CCOP Membership Evaluation Committee will review all CCOP members using the following procedures. Headquarters review of the Affiliate members will utilize the same criteria:

- 1) Member institutions with a new principal investigator must reapply and be approved by the Membership Committee (6/79).
 - 2) Cases must be as follows:

Full Member	25
Provisional Member	See Paragraph #11
CCOP	10 cases; 5 treatment cases/year, 5 cancer control cases/year
Affiliate	5 treatment and/or cancer control cases
 - 3) New RTOG member institutions (Full, Affiliate or CCOP) will be sent a letter clearly stating the requirements for continued membership (6/79). A new Affiliate Member institution must choose its formal activation date. After the usual Headquarters review of its application, a new institution will receive an acceptance letter and an institutional number assignment, but will not be able to place patients on study until a copy of the OPRR assurance is on file at Headquarters and at least one protocol has been approved by the institution's IRB. It will then be necessary for the new institution to notify Headquarters when it is ready to "start the clock." As of that date, the institution will be required to place five treatment cases on study per year. When possible, all affiliates' accrual will be measured on a calendar year basis to facilitate oversight by Headquarters. (7/96)
 - 4) All members will be review annually in July based on the prior calendar year. Each institution will receive a statement regarding its performance. The statements will highlight one of the following categories: a) acceptable, b) letter of encouragement (minor deficiency - see #8 below), c) warning, d) probation, and e) request for resignation. The printouts used to evaluate an institution will be included with the letter and an institution will have 30 days to appeal the evaluation (6/03).
 - 5) An institution will be given a warning if its case accession falls below acceptable levels. If its performance has not improved, the institution will be placed on probation. An institution can remain on probation for one year, but if it continues to have unacceptable accrual, it will be asked to resign. If the institution's performance improves to acceptable levels for an entire year (a minimum of 12 months), it will be removed from probation. If an institution does not meet the accrual requirements for two consecutive calendar years, the institution will be asked to resign without a further warning or probationary period (1/88). However, if affiliation and improvement of last quarter accrual with good data is exhibited, then the institution should be allowed a six month extension to accrue 25 patients with good data quality (2/91).
 - 6) An institution with poor data quality will be given a warning. If data quality is still not acceptable at the time of their next evaluation, the institution will be placed on probation. If at the time of their next evaluation, the problem is still not corrected the institution will be asked to resign (7/98 Revised).
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- 7) Membership Evaluation Committee members must leave the room while their institution is being evaluated (1/80).
- 8) A minor deficiency category was created to call an institution's attention to areas in which performance is borderline. This will not replace the warning letter which will continue to be used for more serious problems (7/82).
- 9) The Principal Investigator (or co-PI at a CCOP member institution where the PI might not be a Radiation Oncologist) at any RTOG institution shall be certified in radiation oncology by the American Board of Radiology, the American Osteopathic Board of Radiology, or equivalent certification for participants from other continents. (7/95)

Additional Criteria for Full Members

- 10) An institution wishing to become a Full Member must first join as an Affiliate Member. After the facility has accrued 25 cases in one year, it may apply for Provisional Member status. This involves submitting a complete new application to the Committee, who will review it at their semi-annual meeting. If the application is in order, the institution will be site visited prior to the next Committee meeting, and if the site visitors' reports are then approved, the institution will be designated a Provisional member. Provisional Members may recruit affiliates. During the following year it must meet the requirements for Full Membership. If it meets these requirements, it will be awarded Full membership status. (6/03)
- 12) If an Affiliate Member facility achieves 25 cases in one year, it may apply for Provisional Membership. The Committee will, however, carry out a site visit to determine whether the institution is eligible for Full Membership. (6/03)
- 13) When an institution has been approved for a site visit, protocols and other pertinent information will be sent to the institution so that the study review process can be started (6/81).

Additional Criteria for CCOP Members

- 15) During the first six months of membership, each institution is required to complete any IRB details locally and complete the Research Associate Orientation. After 12 months of membership, the institution must have placed 50% of the yearly case requirement on study. Warning letters will be sent to all institutions not satisfying this standard. After 18 months, if tasks specified in warning letters are not fulfilled, the facility will be placed on six months probation with specific case accession tasks. After 24 months, the facilities on probation that do not fulfill their obligations will be asked to resign from RTOG.
 - 16) Institutions that participate in more than one Cooperative Group can receive credit toward fulfillment of their membership requirements for patients placed on joint protocols through another group. This credit cannot exceed one-quarter of the membership requirement (3 cases are allowed).
 - 17) A CCOP cannot be on probation more than once during a two-year period for the same deficiency. If, according to the Evaluation Criteria, an institution must be placed on probation for a second time the institution will be asked to resign.
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Definition of an Affiliate Member:

An affiliate member is an institution with its own professional and technical staff which has petitioned and been accepted as an affiliate of a full or provisional member, which is responsible for its affiliate's data management. Each affiliate will be expected to contribute a minimum of five treatment and/or cancer control cases per year. Affiliates intending to apply for Provisional membership must place 30 cases on study in one year (see #11 above). Contribution and compliance of affiliate members will be monitored by the central office of the RTOG.

If an affiliate is dropped for not meeting its accrual objectives and wishes to become active in the Group at a later date, then reinstatement will require consideration by the Membership Evaluation Committee. An explanation of why the institution's membership should be reinstated and endorsement of the proposed parent institution will be required.

Revised (07/01)
