

# ASTRO'S APEX - ACCREDITATION PROGRAM FOR EXCELLENCE®



## Accreditation Procedures

# Overview

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ASTRO's APEX - Accreditation Program for Excellence<sup>®</sup> evaluates radiation oncology practices (ROPs) by objectively assessing the facility, radiation oncology care team, and their policies and procedures. APEX uses nationally recognized standards to support quality improvement in all aspects of radiation oncology. ROPs accredited by APEX must:

- Undergo an objective, external review of radiation oncology practices, policies and processes by professional peers;
- Demonstrate respect for protecting the rights of patients and being responsive to patient needs and concerns; and
- Adopt procedures to encourage safety and quality of care.

APEX reviews the treatment modalities and equipment in operation at the time of the accreditation application and facility visit.

Applicants must also meet applicable state and federal licensure and certification requirements, including those of the Nuclear Regulatory Commission, and requirements of professional practice organizations. APEX Standards identify systematic quality and safety approaches that build on the regulatory framework to add value for clinicians and patients.

## Eligibility

For purposes of APEX, an ROP is defined as a medical practice offering radiation therapy services, using the services of interdisciplinary professionals under the direction of a board-certified radiation oncologist. Currently, only practices located in the U.S. or in a U.S. territory are eligible to apply for accreditation. An ROP may be either a single facility or a multi-facility practice. A multi-facility practice is comprised of a main location and one or more satellites. Multi-facility APEX applications will have their determination assessed as a single practice. This will result in one accreditation determination that will apply to all the facilities in the group.

To qualify as a multi-facility practice, all facilities in the application must have:

- Shared policies and procedures for key evidence indicators;
- An individual or committee from within radiation oncology practice leadership responsible for overseeing the operations of all locations of the multi-facility practice, including the culture of safety;
- a radiation oncologist medical director responsible for each facility; and
- all satellite facilities within a 50-mile radius of the main facility\*.

*\*ASTRO will allow a multi-facility practice application to include a satellite facility located between 50 to 150 miles from the main location if the facility meets all other requirements. If approved, the satellite facilities would be subject to an additional fee. Satellites outside of the 150-mile radius of the main facility may not be included in the same application but may apply as a single facility.*

## Length of Accreditation Cycle

Practices applying for APEX have a choice between a 3- and 4-year accreditation cycle.

In order to avoid a lapse in APEX accreditation status, the ROP should receive a reaccreditation determination before its current accreditation expires. Extensions of an ROP's accreditation status, valid until a new determination is given, will be granted when:

- the facility visit is scheduled prior to the expiration date, and
- the facility visit occurs within 90 days of the expiration date.

Example: If an ROP's accreditation is set to expire on March 31, it will receive an extension if a facility visit is finalized prior to March 31 and occurs before June 29.

## APEX Process

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### Application

The APEX application is housed on [www.ASTRO.org](http://www.ASTRO.org), where basic information about your practice is entered, legal agreements are signed and payment is made. Signing into the APEX Portal through ASTRO's website allows for single sign on, using your ASTRO login information.

ROPs in the APEX Portal are expected to be actively working on their applications. Prior to payment, applicants that fail to make timely progress on their applications may be removed from the system. ASTRO will provide a notification prior to this occurring. After the application is complete, ROPs will be required to meet the deadlines included in the facility agreement to ensure the information is current.

An application must be prepared with the degree of thoroughness that will satisfy an in-depth and detailed review. ASTRO expects facilities applying for accreditation to comply with all aspects of the Facility Agreement, these Accreditation Procedures and any applicable APEX or ASTRO policies and procedures (together, "APEX Policies and Procedures"). The ROP will gain access to the APEX Portal and resources after all application steps are completed.

### Self-Assessment

Practices assess their compliance with APEX Standards by completing the Self-Assessment. This phase of the program includes medical record reviews, uploaded policies and procedures and a physics checklist to help prepare for the facility visit. All sections of the Self-Assessment occur within the APEX Portal. For multi-facility ROPs, only the main facility completes the Self-Assessment.

The ROP will have access to feedback that identifies compliance with each of the APEX evaluation criteria and may indicate deficiencies that should be addressed before the facility visit. This feedback, maintained in the APEX Portal, will only be shared as specified in the APEX Policies and Procedures or as required by law. Feedback obtained during the Self-Assessment process is a preliminary indication of readiness and does not guarantee accreditation.

## Facility Visit

The facility visit is an on-site or virtual assessment by an APEX Surveyor(s). The facility visit consists of four sections: Medical Record Review, Physicist Interview, Team Interview and Verification. For multi-facility applications, all facilities have individual facility visits.

The surveyor team assigned to a single location practice or the main campus of a multi-facility practice consists of two surveyors, one medical physicist and one radiation oncologist. The surveyors will conduct an in-depth review at the main location that may last one business day. An additional surveyor will conduct an expedited review of any satellite facilities on the same day that the main location is reviewed. Survey team visits of the main and any satellite facilities are expected to be completed on the same business day.

Before accepting a facility visit assignment, ROPs will be provided with potential surveyors' name, location, and place of employment for review of conflicts of interest with each facility and its leadership. ROPs are expected to circulate this information to facility leadership and relevant personnel, and alert ASTRO to any financial, contractual, fiduciary, personal or professional relationships between leadership and the surveyors that could compromise the impartiality of the facility visit.

## Withdrawal from Accreditation Process

An ROP may withdraw from the accreditation process without prejudice, except that it shall forfeit its application fees, at any time after acceptance of the application but before the Practice Accreditation Subcommittee (PAS) takes final action to grant or deny accreditation. The decision to withdraw must be communicated to ASTRO by an executive-level staff person.

# Determinations

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An ROP's final determination is issued by ASTRO based on the recommendation of the PAS and in its sole discretion. The PAS reviews the blinded results of the Self-Assessment, facility visit, and other relevant materials to make an educated and objective decision. The accreditation decision is communicated to the ROP, via the APEX Portal, no later than six weeks after the facility visit. The ROP also receives a statement of the factual basis for the determination and, in the case of an adverse decision, a listing of the standards the ROP did not meet. ASTRO may provide the ROP with process improvement recommendations.

## Accreditation Decisions

An ROP will receive one of the following accreditation decisions:

**Full Accreditation:** Full accreditation will be granted to an ROP that meets the APEX Standards.

**Provisional Accreditation:** Provisional accreditation will be granted to an ROP that does not meet the requirements for full accreditation, but for which the PAS believes there is a reasonable expectation that they can be met within a short period of time. These ROPs will be required to complete a Corrective Action Plan (CAP) within an established time frame to be granted full accreditation. In limited circumstances, the PAS will consider extending provisional accreditation beyond the initial time frame to allow an ROP additional time to meet the specifications in its CAP. Provisionally accredited ROPs that receive neither full accreditation nor continued provisional accreditation will receive a denial of accreditation.

**Denial of Accreditation:** ROPs that do not meet the requirements of the APEX Standards are denied accreditation. This includes provisionally accredited ROPs that do not satisfy the specifications of their CAP within the specified timeframe. Applicants may reapply after one year or other such period as ASTRO shall identify in its sole discretion. If an ROP is denied accreditation because of submission of false information or other conduct that demonstrates bad faith and/or substantial lack of commitment to the APEX Standards, ASTRO may decide not to allow the ROP to reapply in perpetuity.

Awards or denials of accreditation are effective as of the date of the ROP's determination letter. Listings of accredited ROPs are published on the ASTRO website and publicized in the ASTROgram and social media channels.

*Quorum:* Two-thirds of the members of the PAS shall constitute a quorum for the purpose of making a determination. The accreditation decision requires a 75% vote of the PAS members in favor of the determination.

An ROP's accreditation status can be changed in the following ways:

**Deferral of Accreditation:** An ROP that is denied accreditation by the PAS has the opportunity to apply for a deferred determination to allow for additional quality improvement. ROPs who apply for this opportunity must meet all eligibility requirements. The ROP would be required to submit an improvement plan and submit to a second site visit for an additional fee.

**Probation:** An ROP may be placed on probation if ASTRO learns that it is not in satisfactory compliance with the APEX Standards or does not cooperate in a complaint investigation. Probationary status continues for such period until ASTRO determines that the full accreditation status should be resumed or revoked. An ROP placed on probation will be removed from the public listing of accredited facilities on the ASTRO website until the PAS decides. Probation is a clear warning that the ROP will have its accreditation revoked at the end of the probationary period if it does not substantially correct the deficiencies noted by the PAS. In such a case, ASTRO may require ROPs to file a periodic report with ASTRO during the accreditation period to provide evidence of the ROP's continued compliance with the APEX standards. If each report is acceptable to ASTRO, the ROP's current accreditation status will be reaffirmed. If it is not, ASTRO may request additional information or an additional facility visit.

**Revocation:** ASTRO, in its sole discretion, has the authority to revoke accreditation, with or without first placing the ROP on probation, when a persistent or significant lapse in safety impacts its compliance with one or more of the APEX Standards, it is discovered to have falsified information provided to ASTRO, or the ROP has materially changed its form (e.g., through a change of ownership) to the extent that it is no longer eligible for or compliant with ASTRO's accreditation requirements. The ROP may reapply for accreditation without prejudice in ASTRO's sole discretion.

**Voluntary Withdrawal from Accredited Status:** The ROP may request termination of accreditation and removal from the published list of accredited facilities. Requests must be made in writing by an executive-level staff person with authority to make such a decision and sent to [APExSupport@astro.org](mailto:APExSupport@astro.org). ASTRO will comply with that request and delete the ROP from its published lists. The ROP may reapply for accreditation without prejudice at a subsequent time.

## Impact on Publication of APEX Accreditation Status

In the event an ROP withdraws from accredited status, accreditation is revoked, or it is placed on probation, the ROP must immediately remove all references to APEX accreditation on the ROP's website, its signage and other materials.

## Ongoing Accreditation

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ROPs are expected to maintain compliance with the APEX Standards throughout their accreditation term.

### Reporting of Changes to the Accredited Practice

An accredited ROP must notify ASTRO within 30 days of name changes, address changes, changes in ownership or control, bankruptcy, or other significant changes to the ROP, including any material changes to content submitted during the Application process. The information must be sent in writing by an executive-level staff person to [APExSupport@astro.org](mailto:APExSupport@astro.org). ASTRO will evaluate the change(s) and determine whether such change(s) will have an impact on the ROP's accreditation status after receipt of such notification. A fee may be charged in connection with ASTRO's processing of changes.

### Reporting of Patient Safety Incidents

ROPs must comply with federal, state and local requirements for reportable patient safety incidents.

### Reaccreditation

APEX accredited practices may start the reaccreditation process 12 months before the expiration of their current accreditation to avoid a lapse in accreditation status. The practice will begin by reviewing and submitting their application, legal agreements, and payment to ASTRO. Once this is complete, the practice will gain access to the Self-Assessment and program resources. Each main facility must successfully complete the Self-Assessment to be deemed ready to schedule a facility visit.

### Synchronization of Accreditation

APEX includes a satellite synchronization process that allows APEX-accredited practices on a 4-year accreditation cycle to add new facilities that meet all criteria for a Multi-Facility Practice to their current accreditation cycle for an additional fee. Any new satellites will be assessed on their compliance with the APEX standards, going through the same rigorous process as the previous affiliated practices. This process is only open within the first three years of an ROP's 4-year cycle.

## Appeals

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An ROP may appeal any of the accreditation decisions listed below within 30 days of the date of written notice of the determination. ROPs wishing to file an appeal should contact [APExSupport@astro.org](mailto:APExSupport@astro.org) for specific instructions. The email must specify the grounds on which the appeal is made and authorize sharing of information with the appeal panel, the ASTRO Board of Directors, and as otherwise necessary for ASTRO to conduct the review. The burden of presenting the argument initially, and persuading the appeals body, rests with the ROP filing the appeal.

## Appealable Decisions

Only the following decisions of the PAS may be appealed:

1. A denial of accreditation.
2. Provisional accreditation instead of full accreditation.
3. A denial of full accreditation after provisional or revocation of provisional accreditation.
4. A decision to revoke the practice's full accreditation.
5. A decision to revoke accreditation for facilities on probation.

## Formation of Ad Hoc Appeal Panel

The Chair of the Board of Directors of ASTRO will refer the matter to a three-member Ad Hoc Appeal Panel ("Appeal Panel") with three alternates, none of whom shall have had affiliation with the ROP, within 30 days of receipt of the appeal. ASTRO staff shall notify the ROP of the names of the three members. If the ROP shows good cause why a named member is unacceptable, an alternate shall be selected. The co-chairs of the PAS shall designate a representative to appear before the Appeal Panel to support the determination and to respond to questions of the Appeal Panel.

## Ad Hoc Appeal Panel Meeting

The Appeal Panel will meet within 90 days from the date on which the ROP is notified of the adverse decision by the PAS or on a date mutually acceptable to the ROP, the Appeal Panel, the PAS representative and ASTRO. The ROP may have one or more representatives appear before the Appeal Panel to make an oral and/or written presentation and to respond to questions. The Appeal Panel may request the assistance of counsel to provide guidance in the interpretation and resolution of legal or procedural problems that may arise in the context of an appeal.

## Appeal Documents

The issues addressed by the Appeal Panel are limited to those relevant to the appeal made by the ROP. The Appeal Panel, the ROP and the PAS representative will be provided with the results reviewed by the PAS in making its recommendation and the letter notifying the ROP of the accreditation decision. Changes made by the ROP after the determination decision was made will not be considered by the Appeal Panel.

## Panel Decisions

The function of an Appeal Panel is to review the accreditation decision based on the record that was before the PAS when the accreditation decision was made. If the accreditation decision is overturned, the case will be sent back to the PAS for a decision which is not inconsistent with the findings of the Appeal Panel.

The Appeal Panel shall give deference to the PAS' discretion in interpreting and applying the standards and these procedures. A discretionary decision made by the PAS may only be grounds for a successful appeal if the decision was arbitrary or lacking in any reasonable basis. Further, the Appeal Panel shall give deference to the PAS factual determinations, and a factual determination will be presumed reasonable unless it is lacking in any reasonable basis. The Appeal Panel in its sole discretion may consider additional factual information not available to the PAS at the time when making its recommendation.



## Reporting of the Decision of the Panel

The report of the Appeal Panel, including the decision and the reasons for it, shall be completed within 30 days of the date the Appeal Panel made its decision; the report shall be sent to the medical director of the ROP. The CEO of ASTRO, the chair of the ASTRO Board of Directors, and the co-chairs of the PAS will be sent a notification of the decision.

# Complaints

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## Facilities

ASTRO will review each complaint received about accredited ROPs and, in its sole discretion, will determine whether the allegation(s), if true, would indicate that the ROP may not be compliant with one or more of the APEx Standards at the time of the complaint. If a complaint meets this requirement, it will be sent to the ROP for response. Once the response is received, the PAS may resolve the matter and inform the ROP of its resolution. The PAS may also vote to pursue the matter further, either by further correspondence with the ROP or by means of a facility visit to provide additional information on which to reach a decision on the accreditation status of the ROP. The ROP may respond to and/or comment on any additional information provided to the PAS based on the facility visit.

## Surveyors

The ROP may file a complaint regarding the actions of surveyors. An executive-level representative must send a notification to [APExSupport@astro.org](mailto:APExSupport@astro.org) of the ROP's intent to file a complaint within seven (7) days after completion of the facility visit. Complaints must be filed within 30 days of the notification of intent to submit the complaint. Anonymous complaints shall not be considered. The complaint should be addressed to ASTRO and must:

1. identify the ROP submitting the complaint and the surveyor(s) who is/are the subjects of the complaint;
2. provide a clear description of the incident or other facts that form the basis of the complaint in question, including supporting documentation if available; and
3. grant permission to send the complaint, in its entirety and without redaction, to the surveyor team.

ASTRO will review each complaint and, in its sole discretion, will determine whether the allegation(s), if true, would indicate that the surveyor may not be in compliance with APEx Surveyor policies and procedures in place at the time referred to in the complaint. Receipt of a complaint meeting these requirements shall be acknowledged in writing by ASTRO and may be referred to the PAS for appropriate investigation and action.

ASTRO will afford the surveyor(s) in question an opportunity to respond to the complaint and will engage in other efforts to gather information regarding the allegation. ASTRO will make a determination regarding the allegation and assess whether it influenced the content of the facility visit report and the outcome of the accreditation process. Where ASTRO determines the issue regarding the surveyor affected the accreditation review and/or outcome, ASTRO will take the action it deems appropriate to address the matter.



## Processing an Accreditation Complaint that is in Litigation

If, in the course of processing a complaint, ASTRO finds that the party against which the complaint is filed is involved in litigation or other form of governmental action involving substantially the same issue, ASTRO, upon advice from legal counsel, may exercise its discretion in determining the most appropriate action to take. ASTRO shall consider a number of factors, including whether the complainant is willing to cooperate with ASTRO and/or the PAS, how protracted the litigation is likely to be, whether the failure to initiate action against the ROP immediately might damage the public interest, and the impact on the confidentiality of the PAS deliberations if its files are subpoenaed during the course of litigation. In all instances, ASTRO and the PAS should consider the potential effect of its action upon the interests of the public and the profession.

## Confidentiality

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ASTRO will use its best efforts to maintain the confidentiality of information obtained through the accreditation process. Such information shall be shared only as specified in these APEX Policies and Procedures, ASTRO's Terms of Use and Privacy Policy, and any applicable Facility Agreement and Business Associate Agreement, and otherwise shall be kept confidential except:

1. Listings of accredited ROPs published on the ASTRO website.
2. Disclosures that ASTRO or the PAS are required to make by law or believe in good faith are necessary to respond to publication of false or incomplete information related to ASTRO, APEX and an ROP's application or accreditation.
3. Information that is generally known to the public or becomes known to the public other than through ASTRO.
4. Information on a specific facility may be made available upon request of the ROP to other accrediting agencies by which the institution has been accredited or whose accreditation it is seeking.
5. In the event of an appeal, the PAS record and decision are made available to the Board of Directors of ASTRO, the appeal panel and other parties as necessary to process the appeal.

The records and files related to an ROP's application, accreditations, or appeals are the property of ASTRO and the ROP shall not have the right to view such materials except as set forth in the APEX Policies and Procedures.

All APEX materials and other confidential information are the exclusive property of ASTRO, and no facility is permitted to reproduce, copy, distribute, transmit or otherwise share outside of the facility's practice.

Contact [APEXSupport@ASTRO.org](mailto:APEXSupport@ASTRO.org) with questions.