



### **Standard Operating Procedures**

#### *Purpose*

Supported by an active directive (*VA DIRECTIVE 1158*), the Clinical Assessment, Reporting and Tracking (CART) Program is tasked with monitoring and enhancing the quality and safety of invasive cardiac procedures throughout the VA Healthcare System. To fulfill this mission, a number of safety programs have been developed and maintained to facilitate peer review of cardiovascular services and procedures:

- Site Review: A review of the non-procedural and procedural cardiovascular services provided at a site
- Lab Review: A review of the procedural cardiovascular services provided at a site
- Ad Hoc Review: A review of a single procedural case at a site via peer review
- Major Adverse Event: A review of a single procedural case at a site that resulted in a major adverse event

The CART Program will provide a timely and expert opinion after completing each of these reviews, both to the site being reviewed as well as the requesting organization. The review will provide feedback on the cardiovascular care provided as well as a summary recommendation based on the following definitions consistent with an active directive (*VA DIRECTIVE 1190*):

- Level 1: The level at which most experienced and competent clinicians would have managed the case in a similar manner
- Level 2: The level at which most experienced and competent clinicians would have managed the case differently but it remains within the standard of care
- Level 3: The level at which most experienced and competent clinicians would have managed the case differently

*Procedures: Site and Lab Reviews*

The general procedures for site and lab reviews review are summarized in the **Table** below.

	<i>Site Review</i>	<i>Lab Review</i>
<i>Requesting Organization</i>	<ul style="list-style-type: none"><li>• Site</li><li>• VISN</li><li>• VACO</li></ul>	<ul style="list-style-type: none"><li>• Site</li><li>• VISN</li><li>• VACO</li></ul>
<i>Review Case Volume</i>		1-30
<i>Review Committee</i>		2-4 Subject Matter Experts

Site or lab reviews can be requested by multiple parties for cause or in the context of clinical restructuring, when a facility begins providing a novel procedure. The review process for site or lab reviews involves the following members:

- Subject Matter Experts: There are 2-4 subject matter experts (interventional cardiologists / electrophysiologists) that will be identified to provide a site or lab review. Generally, these subject matter experts are recruited from areas outside the VISN of the facility being reviewed with the following qualifications:
  - Subject Matter Expert
    - Interventional Cardiology
    - Electrophysiology
    - Structural Heart Intervention
  - Recognized as a director of their respective procedural area
- CART Program Safety Manager: The safety manager is responsible for all administrative duties related to the safety programs, including serving as a point of contact during the review process. This individual is alerted when a review is requested and ensures that clinical documentation and imaging data are available to complete a peer review.

After a site or laboratory review is requested, each individual case will be reviewed in parallel by at least two independent subject matter experts. Review of these cases will include perusal of clinical documentation as well as any relevant imaging studies that are made available by the facility being reviewed on an internally developed and maintained web platform

(<https://vaww.artmae.va.gov>) only available on the intranet. The subject matter experts will then provide independent comments as well as a level rating in each of the following domains:

- Documentation
- Medical Care - Appropriateness
- Medical Care – Technical Quality
- Medical Care – Timeliness
- Overall Assessment

After all of the reviews are completed, a summary report will be distributed to the requesting organization and the site under review that includes the proportion of levels in each category as well as narrative comments for potential improvement from the reviewers. This documented is intended to be incorporated in the local peer review and quality improvement process as the facility deems appropriate. Of note, a site visit may be performed in conjunction with these reviews though is coordinated by the National Program Office for Cardiology and independent of the CART Program.

*Procedures: Ad Hoc and Adverse Events Reviews*

The general procedures for ad hoc and major adverse event reviews are summarized in the **Table** below.

	<i>Ad Hoc Review</i>	<i>Adverse Event Review</i>
<i>Requesting Organization</i>	<ul style="list-style-type: none"><li>• Site</li><li>• VISN</li><li>• VACO</li></ul>	Automatic
<i>Review Case Volume</i>		1
<i>Review Committee</i>	5 - 12 Subject Matter Experts via Committee	

The requesting process for an ad hoc and adverse event review are distinct. As outlined above, an ad hoc review can be requested by a variety of organizations throughout the healthcare system. In contrast, an adverse event review is *automatically* triggered when one of the following events are noted by operators performing a given procedure:

- Coronary Procedures
  - Periprocedural Death
  - Periprocedural Stroke
  - Periprocedural Emergent Cardiac Surgery
- Electrophysiologic Procedures
  - Periprocedural Death
  - Periprocedural Tamponade
- Structural Heart Procedures
  - Periprocedural Death
  - Periprocedural Emergent Cardiac Surgery

The review process for these cases involves the following groups, with separate committees for coronary procedures, electrophysiologic procedures and structural heart procedures:

- Committee Chairperson: The chairperson of the safety committee is selected by the CART Program and is responsible for conducting any committee meetings as well as providing a summary report once a decision has been reached.
- Committee Members: In addition to the chairperson, there are 8 – 12 subject matter experts (interventional cardiologists / electrophysiologists) that are appointed to these committees for a three-year term. Each fiscal year, half of the committee will rotate off and new members will be added. Suggestions for new members from the current committee members may be made at the transition though all committee members must fulfill the following qualifications:
  - Subject Matter Expert
    - Interventional Cardiology
    - Electrophysiology
    - Structural Heart Intervention
  - Recognized as a director of their respective procedural area
- CART Program Safety Manager: The safety manager is responsible for all administrative duties related to the safety programs, including serving as a point of contact during the review process. This individual is alerted when a review is requested and ensures that clinical documentation and imaging data are available to complete a peer review. This individual is also responsible for providing the summary report after completed.

After an ad hoc or adverse event review has been initiated and the relevant review data obtained, two reviewers outside the VISN of the procedure in question are randomly assigned with different tasks:

- Reviewer 1 will review the electronic medical record, procedural documentation and imaging data as well as to speak with the primary operator that performed the case. A summary or their comments and level designation will then be provided via an internally developed and maintained web platform (<https://vaww.artmae.va.gov>) only accessible via the intranet.
- Reviewer 2 will review the electronic medical record, procedural documentation and imaging data and provide their comments and level designation via an internally developed and maintained web platform (<https://vaww.artmae.va.gov>) only accessible via the intranet.

If both reviewers designate the case a **Level 1**, a summary letter will be automatically generated and submitted to the site and requesting organization (if any). If one or both reviewers designate the case a **Level 2** or **Level 3**, the case will be discussed among the entire committee at the next scheduled meetings. Full committee meetings are held on the second Friday of each month from 0800 – 1000 Mountain Time. Should a case go for full committee review, the CART Program Safety Manager will approach all committee members to provide access to the case on an internal developed and maintained web platform. Each committee member is expected to review the case and provide comments and a final level designation prior to the full committee meeting. During the meeting, the committee chair leads the discussion of the case and solicits the input from Reviewer 1 and Reviewer 2. Time is then given to allow each additional committee member to opine, after which a final tally of votes is taken to arrive at level designation. A summary report is then sent to the site and requesting organization. Should the committee offer a **Level 2** or **Level 3** rating, the summary report is sent only to the attending physician on the case after which s/he has one week to appeal. An appeal allows the physician to participate in the next meeting to defend

the case after which the committee will be given the opportunity to reconsider the final level provided.

### *Responsibilities*

These processes are not a replacement for local peer review, though can supplement the local process with national expert opinion. The local facility is thus responsible for incorporating the findings of the CART Program review into their own recommendations and subsequent action plans as they deem appropriate.

### *Documentation*

All documents containing reviewer comments and levels are retained in an internally developed and maintained web platform for quality assurance purposes. Any documentation generated during this process is deemed protected according to 38 U.S.C. 5705 as part of organizational quality assessment.