CARDIOLOGY

Certification Updates with Clinical Aspects

Presented to: Civil Aviation Medical Association
Annual Scientific Meeting 2017
By: John S. Raniolo, D.O.
Date: September 14, 2017
Cardiac Conditions and Certification Changes
Cardiac Conditions and Certification Changes

2012 Roundtable discussion (OKC, AAM 100 & 200)

• reviewed the current FAA cardiology policies that were in use
• identified policies that were outdated
• identified policies that were inconsistent or in conflict
• made recommendations to bring the current FAA cardiology policies in line with current clinical practices as outlined in the ACC guidelines
Cardiac Conditions and Certification Changes

- **Coronary artery disease that require:**
  - Coronary stents (bare metal or drug-eluting)
  - Percutaneous transluminal coronary angioplasty (PTCA)
  - Percutaneous transluminal coronary rotational athrectomy (PTCRA)
- **Coronary artery disease requiring Coronary artery bypass surgery**
- **Myocardial infarctions** (with or without PCI)
Cardiac Conditions and Certification Changes

- **Valve replacements** (aortic, mitral)
- **Pacemakers**
  - single chamber
  - dual chamber
  - bi-ventricular (with and without ICD)
- **Hypertrophic cardiomyopathy**
  - (HCM)
- **Atrial fibrillation**
- **Under Construction**
Cardiac Conditions and Certification Changes

Coronary Artery Disease
Initial certification
Post PCI
Cardiac Conditions and Certification Changes
Initial certification

Applicants for 1\textsuperscript{st} and 2\textsuperscript{nd} class medical certification

- The recovery time was reduced from 6 months to 3 months
- No change in the documentation is required, i.e.,

Hospital records to include

- Admission H&P
- Discharge summary
- Consultation reports (All)
- Procedure reports
- CD of the diagnostic & interventional procedure
Cardiac Conditions and Certification Changes

Initial certification

Current cardiovascular status report (CVE) to include diagnosis, prognosis and treatment plan.

“should make mention that the airman demonstrates attempting to meet goal regarding the modifiable risk factors as recommended by the ACC or AHA guidelines”

(i.e., lipid control, weight reduction, smoking cessation, etc.)
Cardiac Conditions and Certification Changes
Initial certification

- Current laboratory data to include a fasting serum glucose, HgbA1C (DM) and 12 hour fasting lipid panel
- will require a nuclear treadmill stress test
- A post-event cardiac catheterization
- FASCC Panel review
Cardiac Conditions and Certification Changes
Initial certification (PCI)

Applicants for 3rd class medical certification

- No change in the documentation required, i.e.,
- Hospital records to include
  - Admission H&P
  - Discharge summary
  - Consultation reports (All)
  - Procedure reports
  - CD of the diagnostic & interventional procedure
Cardiac Conditions and Certification Changes
Initial certification

- Current laboratory data to include a fasting serum glucose, HgbA1C (DM) and 12 hour fasting lipid panel
- routine exercise treadmill stress test
- *no cardiac catheterization required*
- *no FASCC Panel review*

**WILL NO LONGER REQUIRE A 90 DAY RECOVERY PERIOD**
Cardiac Conditions and Certification Changes
Initial Certification

Left main stents
Cardiac Conditions and Certification Changes
Initial Certification

Left main stents

Applicants for 1\textsuperscript{st} and 2\textsuperscript{nd} class medical certification

- previously required a 6 month recovery period and will remain unchanged
- A current cardiac status report
- nuclear treadmill stress test
- laboratory data (to include a fasting serum glucose, 12 hour fasting lipid panel and HgbA1C if diabetic)
- FASCC Panel review
Cardiac Conditions and Certification Changes

Initial Certification

Left main stents

Applicants for 3\textsuperscript{rd} class medical certification

- A current cardiac status report
- Laboratory data (to include a fasting serum glucose, 12 hour fasting lipid panel and HgbA1C if diabetic)
- Routine exercise stress test
- \textbf{WILL NO LONGER REQUIRE A 90 DAY RECOVERY PERIOD}

All classes will require a post-event cardiac catheterization
Cardiac Conditions and Certification Changes

Recertification
Cardiac Conditions and Certification Changes Recertification

Applicants for **ALL CLASSES** medical certification

- A current cardiovascular status report (CVE)
- Laboratory data to include a fasting serum glucose and 12 hour fasting lipid panel
- Routine exercise treadmill stress test using the **Bruce protocol**
Cardiac Conditions and Certification Changes

• **Bruce protocol:** increasing speed & elevation
  • 1.7mph @ 10% grade
  • 2.5mph @ 12% grade
  • 3.4mph @ 14% grade

• **Heart rate achieved:**
  • must be no less than 85% of the calculated maximum predicted heart rate

• **Airman must walk for:**
  • a minimum of 9 minutes under the age of 70
  • a minimum of 6 minutes 70 and older
Cardiac Conditions and Certification Changes

Prior to these changes, airmen possessing a 1\textsuperscript{st} or 2\textsuperscript{nd} class medical certificate were routinely placed on a 12/24 schedule.

Now, all airmen requesting recertification will only require a \textbf{routine} exercise treadmill stress test, \textbf{unless a} “caveat” exists.
Cardiac Conditions and Certification Changes

Caveats include:

• Complete left bundle branch block (CLBBB)
• Uninterpretable electrocardiogram
• False-positive study
Cardiac Conditions and Certification Changes

Caveats for treadmill stress testing

Complete Left bundle branch block (CLBBB)
  • Idiopathic
  • Pacemaker induced

the airman will be required to provide a pharmacologic stress test for initial certification.

Recertification will require a pharmacologic stress test alternating with a routine exercise treadmill stress test on a 12 month basis.
Cardiac Conditions and Certification Changes

Caveats for treadmill stress testing

- uninterpretable electrocardiogram
- false-positive study

Airmen will be asked to provide some combination of nuclear treadmill stress testing, routine exercise treadmill stress testing and stress echocardiogram, alternating on a 12 month basis
Cardiac Conditions and Certification Changes

EXERCISE TREADMILL STRESS TEST

It will no longer be required to include:

• METS
• Double product

in the treadmill stress test reports.

It is considered of minimal clinical value
Cardiac Conditions and Certification Changes

Airman will **not** be asked to routinely discontinue Beta-blockers or calcium channel blockers prior to treadmill stress testing.

However, it does not change the requirement to achieve both the required heart rate and time duration.
Cardiac Conditions and Certification Changes

Medication

Current ACC guidelines for stents recommend dual anti-platelet therapy with Aspirin and one of the approved anti-platelet medications (Plavix (Clopidogrel), Brilinta (Ticagrelor) or Effient (Prasugrel))

- a minimum of one year for Drug-eluting stents
- a minimum of thirty days for bare metal stents
Cardiac Conditions and Certification Changes

*Remember:

Any established history or clinical diagnosis of coronary artery disease, that is clinically significant or has required treatment, is one of the 16 “specifically disqualifying conditions”
Cardiac Conditions and Certification Changes

Coronary artery bypass surgery
Cardiac Conditions and Certification Changes
Initial Certification

Coronary artery bypass surgery

Applicants for 1st and 2nd class medical certification

• The recovery time remains 6 months
• The same documentation is required, i.e.,
• Hospital records to include
  o Admission H&P
  o Discharge summary
  o Consultation reports (All)
  o Operative reports
Cardiac Conditions and Certification Changes

Initial certification

- A current status report (CVE)
- Current laboratory data to include a fasting serum glucose, 12 hour fasting lipid panel and HgbA1C (DM)
- provide a nuclear treadmill stress test
- A post-event cardiac catheterization is required.
- FASCC Panel review is required
Cardiac Conditions and Certification Changes
Initial certification

Applicants for 3rd class medical certification

• The same documentation is required, i.e.,
• Hospital records to include
  o Admission H&P
  o Discharge summary
  o Consultation reports (All)
  o Operative reports
Cardiac Conditions and Certification Changes

Initial certification

Applicants for 3rd class medical certification

• Current status report (CVE)
• Current laboratory data to include a fasting serum glucose, 12 hour fasting lipid panel and HgbA1C (DM)
• A routine exercise treadmill stress test is required
Cardiac Conditions and Certification Changes
Initial certification

- There is no FASCC Panel review
- There is no post-event cardiac catheterization required.
- WILL NO LONGER REQUIRE A 6 MONTH RECOVERY PERIOD

However, should the airman have an abnormal routine exercise stress test, he or she will be required to provide a nuclear study.

Should the nuclear study be abnormal (ischemia), a cardiac catheterization will be required before a Special Issuance can be considered.
Cardiac Conditions and Certification Changes
Initial certification

*An applicant presents to you with a history of coronary artery disease, with or without a history of myocardial infarction, followed by bypass surgery.

The AME’s responsibility is to:

• explain the Special Issuance process
• outline and assist the applicant with the necessary workup
• defer the case to Aerospace Medical Certification Division (AMCD)
Cardiac Conditions and Certification Changes

MYOCARDIAL INFARCTION
Cardiac Conditions and Certification Changes

Initial certification

Applicants for 1\textsuperscript{st} and 2\textsuperscript{nd} class medical certification

- The previously 6 month recovery period has been decreased to 3 months
- Hospital records to include
  - Admission H&P
  - Discharge summary
  - Consultation reports (All)
  - Procedure reports (if performed)
  - CD of interventional procedure (if the procedure is performed)
Cardiac Conditions and Certification Changes

- A current status report (CVE)
- Current laboratory data to include a fasting serum glucose, 12 hour fasting lipid panel and HgbA1C (DM)
- Nuclear treadmill stress test
- A post-event cardiac catheterization
- FASCC Panel review
Cardiac Conditions and Certification Changes

Applicants for 3rd class medical certification

- A current status report (CVE)
- provide a routine exercise treadmill stress test
- Current laboratory data to include a fasting serum glucose, 12 hour fasting lipid panel and HgbA1C (DM)
- FASCC Panel review is not required
- No post-event cardiac catheterization is required.

NO SPECIFIED RECOVERY TIME IS REQUIRED
Cardiac Conditions and Certification Changes

However, should the airman have an abnormal exercise treadmill stress test, he or she will be required to provide a nuclear study.

Should the nuclear study be abnormal (ischemia), a cardiac catheterization will be required before a Special Issuance can be considered.
Cardiac Conditions and Certification Changes

MYOCARDIAL INFARCTION

Not due to coronary artery disease
Cardiac Conditions and Certification Changes

MYOCARDIAL INFARCTION
Not due to coronary artery disease

Examples:

- epinephrine injections
- cardiac trauma
- Hyper-coagulopathies, e.g., Factor V Leiden deficiency
- Complication of cardiac catheterization
Cardiac Conditions and Certification Changes

Applicants for 1\textsuperscript{st} and 2\textsuperscript{nd} class medical certification

- A current status report (CVE)
- Current laboratory data to include a fasting serum glucose, 12 hour fasting lipid panel and HgbA1C (DM)
- Airmen will be required to provide a nuclear treadmill stress test
- FASCC Panel review is required

This information will be forwarded to the FASCC Panel for review. A post-event cardiac catheterization will be required, only if recommended by the FASCC Panel review.
Cardiac Conditions and Certification Changes

Applicants for 3rd class medical certification

• Current status report (CVE)
• Current laboratory data to include a fasting serum glucose, 12 hour fasting lipid panel and HgbA1C (DM)
• *a routine exercise treadmill stress test*
• *There is no FASCC Panel review*

WILL NO LONGER REQUIRE A 90 DAY RECOVERY PERIOD
Cardiac Conditions and Certification Changes

Applicants for 3rd class medical certification

- Should the airman have an abnormal exercise treadmill stress test, he or she will be required to provide a nuclear study.
- Should the study be abnormal (ischemia), a cardiac catheterization will be required before a Special Issuance can be considered.
Cardiac Conditions and Certification Changes

MYOCARDIAL INFARCTION
Recertification for all classes

Airmen will be required to provide information consistent with the FAA Coronary artery disease policy (Requirements are listed in the Authorization for Special Issuance)
Cardiac Conditions and Certification Changes

*Remember, when the disqualifying condition is coronary artery disease, there is an AASI for 3\textsuperscript{rd} class only.

For recertification, only if an AASI has been granted and the airman has had no change in his or her condition, and all data supplied meet FAA standards, only then, can the AME issue the time-limited medical certificate

\((NVFAC \textit{after} \textquoteleft 12 \textit{months}\textquoteright)\)
Cardiac Conditions and Certification Changes
VALVE REPLACEMENTS
Cardiac Conditions and Certification Changes

Previous policy had provisions for medical certification for:

- A single tissue valve replacement
- A single mechanical valve replacement

New change:
Double valve replacement can now be considered for medical certification on an individual basis.
Cardiac Conditions and Certification Changes

Double valve replacement
Applicants for 1\textsuperscript{st} and 2\textsuperscript{nd} class medical certification (INITIAL)

• 6 month recovery period
• Hospital records to include
  • Admission H&P
  • Discharge summary
  • Consultation reports
  • Operative reports
Cardiac Conditions and Certification Changes

Double valve replacement

- Current cardiovascular status report (CVE)
- 2D/M-mode echocardiogram, cardiac doppler with color flow (No peri-valvular leaks)
- 24 hour Holter monitor
Cardiac Conditions and Certification Changes

Double valve replacement

• Routine exercise treadmill stress test may be required
• Mechanical valves that require Coumadin. Airmen must provide INR’s (80% within 2.5 to 3.5 unless St. Jude bi-leaflet valve or ON-X then allow 1.5 to 2.5)
• Manufacturer’s recommendations.

• Remember: The new oral anticoagulant agents cannot be used for prosthetic valves.
Cardiac Conditions and Certification Changes

Double valve replacement

- Path report, if available (Cystic medial necrosis remains disqualifying)
- FASCC Panel review
- The FASCC Panel’s recommendation will be sent to AAM-200 for final decision on a case by case basis
Cardiac Conditions and Certification Changes

**Double valve replacement**
Applicants for 3rd class medical certification

The only change will be

**NO SPECIFIED RECOVERY TIME REQUIRED**
Cardiac Conditions and Certification Changes

Double valve replacement

Recertification for all classes
Cardiac Conditions and Certification Changes

Double valve replacement

• Current status report (CVE)
• 2D/M-mode echocardiogram, cardiac doppler with color flow
• 12 lead electrocardiogram
• Routine exercise treadmill stress test, unless otherwise specified, e.g., if coronary artery disease exists.
Cardiac Conditions and Certification Changes

Double valve replacement

INR requirements are the same for mechanical valves (80% of the values must be between 2.5-3.5 for most valves. On-x valves should have 80% of the values between 1.5 – 2.5)
Cardiac Conditions and Certification Changes

Initial certification

*The 1st step in discovering valvular heart disease is the physical examination.

Heart murmurs:

- Timing (systolic v. diastolic)
- Character (harsh, soft, blowing)
- Intensity, grade 1 thru 6
- Location
- Radiation
- Any change with respiration
Cardiac Conditions and Certification Changes

Initial certification

- Functional v. pathologic
- 2D/M-mode echocardiogram, cardiac doppler with color flow

*If you conclude that the murmur is functional, enter these remarks in Block 60 and issue the medical certificate.
Cardiac Conditions and Certification Changes

PACEMAKERS
Cardiac Conditions and Certification Changes
Cardiac Conditions and Certification Changes
Cardiac Conditions and Certification Changes

PACEMAKERS
Initial certification for all classes

• Single chamber pacemaker
• Dual chamber pacemaker
• Bi-ventricular pacemaker
• Biventricular pacemaker with ICD

*ICDs are disqualifying for all classes
Cardiac Conditions and Certification Changes

PACEMAKERS

• Initial pacemaker implantation recovery time is 2 months

• Lead replacement and generator replacement recovery time is 2 months
  • Acute thresholds, post-implant
  • Chronic thresholds, 8-12 weeks post implant

• Generator replacement can be certified as soon as the airman has fully recovered (as little as 10 days)
Cardiac Conditions and Certification Changes
Initial Certification

For all classes
All hospital records to include:
• Operative report
• Consultation report
• Discharge Summary
A current status report by the treating cardiologist
24 hour Holter monitor
Cardiac Conditions and Certification Changes
Initial Certification

For all classes

- 2D/M-mode echocardiogram, cardiac doppler with color flow
- Lipid profile and fasting serum glucose
- Exercise treadmill stress test
- FAA Pacemaker protocol worksheet
# PACEMAKER PROTOCOL WORKSHEET

Please take the following form to your cardiologist and have them enter the requested information in the space provided.

1. Date Pacer Data below was obtained

2. Pacer Manufacturer and Model

3. Date Pacer (or generator) implanted

4. Does the Pacer have a Defib circuit that is ENABLED? [Circle one] Yes  No

5. Estimated battery longevity (years:months)

6. Pacer Mode (DDDR, VVIR, etc)

7. Current atrial output (pace impulse - volts)

8. Current ventricular output (pace impulse - volts)

9. Current atrial impedance (in Ohms)

10. Previous atrial impedance (in Ohms)

11. Current ventricular impedance (in Ohms)

12. Previous ventricular impedance (in Ohms)

13. Is the airman pacer dependent (Class 1 and 2)? [Circle one] Yes  No

   **Annual:** Obtain 3 min strip, sitting, pacer reset to 30:

   **Dependent:** If remains paced, becomes symptomatic or blood pressure drops

14. In the past 12 months has the pacemaker functioned normally with no significant abnormality in cardiac response? [Circle one] Yes  No

   IF LEADS OR GENERATOR REPLACED - CIRCLE NO

15. To your knowledge, have there been any lead or generator recalls? [Circle one] Yes  No

   [Cardiologist Signature] Date

---

Civil Aviation Medical Association
Annual Scientific Meeting
September 14, 2017
Cardiac Conditions and Certification Changes

PACEMAKER DEPENDENCY

13. Is the airman pacer dependent (Class 1 and 2)?  Yes  No

**ANNUAL:** Obtain a 3 minute rhythm strip, sitting, pacer reset to 30.

**Dependent:** If remains paced, symptomatic or blood pressure drops
Cardiac Conditions and Certification Changes

PACEMAKER DEPENDENCY

The pacemaker is to be set at its lowest rate (30) PPM for 3 minutes.

A rhythm strip is to be obtained to document the underlying rhythm.

If the underlying rhythm remains paced rhythm, or if the airman develops symptoms or if the blood pressure falls, the airman will be considered “pacemaker dependent”.

3rd class only can be issued a medical certificate if “pacemaker dependent”.
Cardiac Conditions and Certification Changes

All the information should be forwarded to OKC or to the RFS for review.
Cardiac Conditions and Certification Changes

Recertification
Cardiac Conditions and Certification Changes

**Recertification**

Pacemaker analysis will be required every 6 months with completion of pacemaker worksheet.

6 and 12 month worksheets will be submitted with a current status report from the airman’s treating cardiologist (as long as the Estimated Battery Longevity is more than 18 months).
Cardiac Conditions and Certification Changes

Recertification

If the estimated battery life is less than 18 months:

• A current status report will be required at each six (6) month interval.

• The pacemaker analysis and pacemaker worksheets will be required every six (6) months.

• The information will be forwarded to OKC or your RFS every six (6) months.
Cardiac Conditions and Certification Changes

Recertification

When the EBL reaches 6 months, the airman will be **DENIED**.

Once the generator has been replaced, the airman can apply for recertification.

The airman can potentially be in Limbo for up to six months.
Cardiac Conditions and Certification Changes

HYPERTROPHIC CARDIOMYOPATHY (HCM)
Cardiac Conditions and Certification Changes Initial Certification
(for all classes)

MAJOR risk factors used to determine whether or not the airman is considered high risk:

• Family history of sudden death
• Unexplained syncope
• Documented ventricular tachycardia
• Symptoms of angina
Cardiac Conditions and Certification Changes
Initial Certification
(for all classes)

Risk factors used to determine whether or not the airman is considered high risk:

• Congestive heart failure
• Lack of blood pressure augmentation during exercise treadmill stress testing
• Left ventricular wall thickness ≥ 30mm
Cardiac Conditions and Certification Changes
Initial Certification
(for all classes)

If the applicant has **any** of these risk factors, the applicant will be considered high risk and **denied** consideration for medical certification.
Cardiac Conditions and Certification Changes
Initial Certification
(for all classes)

If the airman has none of the high risk factors, the airman’s medical information will be reviewed by the FASCC Panel, and their recommendations will be forwarded to AAM-200 for further reconsideration.
APICAL HYPERTROPHIC CARDIOMYOPATHY
Cardiac Conditions and Certification Changes
Cardiac Conditions and Certification Changes
Initial Certification
(for all classes)

Hypertrophic cardiomyopathies that have undergone **alcohol septal ablation** or **surgical myomectomy** will be evaluated in the same manner following an appropriate recovery time from the procedure.
Cardiac Conditions and Certification Changes
HYPERTROPHIC CARDIOMYOPATHY

4. Cardiomyopathies
   a. Hypertrophic Cardiomyopathy (HCM): formerly called hypertrophic obstructive cardiomyopathy (HOCM); idiopathic hypertrophic sub-aortic stenosis (IHSS)

   Definition: unexplained LV hypertrophy (>15 mm) associated with non-dilated ventricular chambers in the absence of another cardiac or systemic disease that itself would be capable of producing the magnitude of hypertrophy evident in a given patient.

   Aeromedical Concerns: the most common progressive genetically-related structural cardiovascular with potential to manifest at any age, with younger patients (<65 years) tending to have a worse prognosis. Most individuals will have a normal life-span, but HCM puts individuals at unpredictable risk for:
   - sudden incapacitation due to sudden cardiac death (SCD), sustained ventricular tachycardia (VT), angina/ischemia, or atrial fibrillation with altered ejection fraction, rapid ventricular response, or embolic stroke;
   - sudden incapacitation due to left ventricular outflow tract obstruction (LVOTO); heart failure with preserved ejection fraction (HFpEF) = diastolic dysfunction; heart failure with reduced ejection fraction (HFrEF) = systolic dysfunction; or related mitral valve abnormalities

   Initial Airman Certification/ATCS Clearance – Requirements:

   Minimum of 6 months recovery following any procedure (e.g., septal myectomy, alcohol septal ablation, papillary muscle/chordal realignment, ablation for atrial fibrillation)

   Documentation:
   1. Complete records of prior cardiac-related evaluations or treatment, to include records for any procedures performed (e.g., myectomy, alcohol ablation, papillary muscle/chordal realignment, etc.)
   2. A complete cardiovascular evaluation (CVE) to include:
      a. History that specifically addresses:
         - family history of unexplained SCD
         - personal history of nsVT or unexplained syncope
         - Resting EKG
         - 2D/Doppler resting echocardiogram (with report and digital images)
         - Holter monitor report with data summary and representative EKG readings (minimum 24 hours)
         - Maximal exercise stress test, with worksheet and representative EKG tracings [to exclude CAD]
         - Other testing or studies - not required for submission but may be considered:
            - If determined to be clinically indicated by treating physician as part of the evaluation;
            - If conducted as part of prior cardiovascular evaluations, or
            - If specifically requested by FAA Cardiology Consultant
HYPERTROPHIC CARDIOMYOPATHY

- Examples:
  1. Cardiac MR to include report and digital actual images (if done as part of work-up, especially if echocardiogram testing deemed technically difficult or equivocal);
  2. Genetic testing results;
  3. Myocardial nuclear perfusion imaging, to include report and actual digital images;
  4. Cardiac catheterization, to include report and actual digital images;
  5. EP studies;
  6. 30-d event monitor/loop recording monitor.
- HCM Risk stratification statement by the treating physician, to include prognosis for SCD or other sequelae of HCM, activity restrictions, medical management, recommendations for ICD (yes/no), or treatment for LVOTO (surgical myectomy, septal ablation, or papillary muscle/chordae repositioning, etc.).
- Recommendations/treatment as indicated for:
  - atrial fibrillation, to include CHA2DS2-VASc score
  - treatment for LV outflow tract obstruction
  - other cardiac issues, e.g., mitral valve repair/replacement
- Estimated 5-year risk of SCD stratification (Low/Intermediate/High) using the HCM Risk-SCD model calculator at [http://docsite.com/hcm/webHCM.html](http://docsite.com/hcm/webHCM.html) to document the following:

<table>
<thead>
<tr>
<th>Data element</th>
<th>Data</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Years</td>
<td>age at evaluation</td>
</tr>
<tr>
<td>Maximum LV wall thickness</td>
<td>__ mm</td>
<td>Transthoracic Echocardiographic measurement</td>
</tr>
<tr>
<td>Left atrial size</td>
<td>__ mm</td>
<td>Left atrial diameter determined by M-Mode or 2D echocardiography in the parasternal long axis plane</td>
</tr>
<tr>
<td>Max LVOT gradient</td>
<td>___ mmHg</td>
<td>The maximum LV outflow gradient determined at rest or with Valvulov provocative (whichever is greater)</td>
</tr>
<tr>
<td>Family History of SCD</td>
<td>No / Yes</td>
<td>History of sudden cardiac death in 1 or more first degree relatives under 40 years of age or SCD in a first degree relative with confirmed HCM at any age (past or ante-mortem diagnosis).</td>
</tr>
<tr>
<td>Non-sustained VT</td>
<td>No / Yes</td>
<td>3 consecutive ventricular beats at a rate of 120 beats per minute and &gt;4 hrs in duration on Holter monitoring (minimum duration 24 hours) at evaluation or documented any time previously.</td>
</tr>
<tr>
<td>Unexplained syncope</td>
<td>No / Yes</td>
<td>History of unexplained syncope or at prior to evaluation.</td>
</tr>
</tbody>
</table>
HYPERTROPHIC CARDIOMYOPATHY

AMCD Evaluation: review by FAS Cardiology Consultant Panel into the following risk categories:

<table>
<thead>
<tr>
<th>Items for consideration</th>
<th>Risk Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCM 5-yr Risk for SCD (model calculation)</td>
<td>Low  Intermediate High</td>
</tr>
<tr>
<td>ICD in place</td>
<td>No&lt;6 %</td>
</tr>
<tr>
<td>Prior unexplained SCD, sVT, VF</td>
<td>No Yes</td>
</tr>
<tr>
<td>LVOTO:</td>
<td></td>
</tr>
<tr>
<td>• Asymptomatic, and procedure is:</td>
<td>No&lt;6%</td>
</tr>
<tr>
<td>• Symptomatic</td>
<td></td>
</tr>
<tr>
<td>• s/p myomectomy/ablation</td>
<td></td>
</tr>
<tr>
<td>Heart failure: HFpEF or HFrEF</td>
<td></td>
</tr>
<tr>
<td>Additional potential risk modifying factors:</td>
<td></td>
</tr>
<tr>
<td>• Atrial fibrillation</td>
<td></td>
</tr>
<tr>
<td>• Other cardiac issue (e.g., CAD)</td>
<td></td>
</tr>
<tr>
<td>• Other co-morbid conditions</td>
<td></td>
</tr>
</tbody>
</table>

Medical Determination – FASCC recommendations regarding Special Issuance:

- Low Risk: May consider for any class
- Intermediate Risk: May consider for third class only
- High Risk: Not considered for any class

Note 1: If the a/m also has other medical conditions, especially cardiac (e.g., AF, CAD, etc.), those issues must be addressed individually, and then the composite risk must be addressed.

Note 2: Risk for future development of atrial fibrillation (AF) due to left atrial enlargement (LAE) is not considered disqualifying. As a risk factor, it is considered a marker for sudden cardiac death in the 5-Year HCM Risk equation, even though AF by itself may be incapacitating but rarely results in mortality. LAE will be followed on echo, and factored into the follow-on risk calculations.

Note 3: Treatment for LV outflow tract obstruction (e.g., alcohol ablation, surgical septal myomectomy): following appropriate time for recovery and observation, the FASCC may consider on a case basis.

Caution: HCM may be over- or under-diagnosed by the treating cardiologist or echocardiographer. Typical basal septal hypertrophy must be at least 15 mm in the absence of other LV thickening that would suggest concentric LV hypertrophy. Other findings that may be labelled “HCM” include sigmoid septum (common with aging, resulting in a false measurement of the basal septum due to an oblique measurement angle), isolated papillary muscle hypertrophy, or abnormalities of the papillary muscle/mitral valve apparatus causing systolic anterior motion (SAM) +/- LVOTO.
HYPERTROPHIC CARDIOMYOPATHY

Consideration requires annual submission of:

1. Complete records of any interval cardiac-related evaluations or treatment
   a. detailed history update (any changes)
   b. Resting EKG
   c. 2D/Doppler resting echocardiogram (with report and digital images)
   d. Holter monitor report with worksheet and representative EKG tracings (minimum 24 hours)
   e. Maximal treadmill exercise stress test, with worksheet and representative EKG tracings
   f. Other testing performed
   g. Updated estimate of 5-year risk of SCD stratification (Low/Intermediate/High) using the HCM Risk-SCD model calculator at http://doc2do.com/hcm/wobbHCM.html

   • AMCD Determination:
     o If no new adverse medical events/findings and no change in calculated 5-year risk, SU/SC may be renewed by AAM-390 special issuance review
     o Otherwise, refer back to either a FAS cardiology consultant, Cardiology Panel, or AAM-240.

Background and Aetiological Discussion: The 2011 ACCF/AHA Hypertrophic Cardiomyopathy Guidelines identified several risk markers:
   • Prior personal history of sudden cardiac death or ventricular fibrillation;
   • Family history of unexplained sudden cardiac death;
   • Unexplained syncope;
   • Non-sustained ventricular tachycardia (nSVT);
   • Maximal apical LV wall thickness; and
   • Abnormal augmentation of systolic blood pressure response during exercise.

These risk markers did not consider age (known to be inversely correlated with risk), factors associated with atrial fibrillation or LVOTO, or potential additive/multiplicative interactions. Abnormal augmentation of systolic blood pressure has only been weakly associated with outcomes.

Current AAM risk stratification is now based on the more recent 2014 European Society for Cardiology (ESC) guidelines and a risk model based on a mathematical risk formula to calculate a 2-year risk for sudden cardiac death (SCD). The algorithm was developed in a well-designed retrospective multi-center study of 3675 HCM patients, and validated by an independent retrospective study of 764 HCM patients and a small observational study of 48 HCM patients with implanted ICDs. The formula validates several accepted risk factors, incorporates additional risk factors (e.g., age, left atrial dilatation), and mathematically integrates continuous and discontinuous variables.

   • Validated risk variables:
     o Continuous variables: age, maximum LV wall thickness, left atrial size, and maximal LVOT gradient (resting or Vasalva);
     o Categorical variables: family history of unexplained SCD, personal history of nSVT or unexplained syncope
   • Abnormal systolic response during exercise was not validated.
   • Other “risk factors” that either do not substasitively add to the above risk stratification or need further validation:
HYPERTROPHIC CARDIOMYOPATHY

- Genetic testing: positive genetic testing for known familial variants is useful in identifying individuals at potential risk, but only 60% of HCM individuals demonstrate known familial variants, and it is not currently useful for individual prognosis.
- CMR/lite gadolinium enhancement (LGE): though proposed to be a continuous variable risk factor, to date studies have not definitively shown CMR/LGE to improve risk stratification. In the current ESC guidelines model, maximal LV wall thickness is the closest surrogate to the amount of myocardial replacement fibrosis.
- Brockenbrough-Braunwald-Norris sign ("Brockenbrough phenomenon") sign can be used to differentiate HCM from aortic stenosis. In individuals with aortic stenosis, after a premature ventricular contraction (PVC), the following ventricular contraction will be more forceful, and the pressure generated in the left ventricle will be higher. Because of the fixed obstruction that the stenotic aortic valve represents, the post-PVC ascending aortic pressure will increase as well. In individuals with HCM, however, the degree of obstruction will increase more than the force of contraction will increase in the post-PVC beat. The result of this is that the left ventricular pressure increases and the ascending aortic pressure decreases, with an increase in the LVOT gradient. However, while useful for specifying the cause of LVOTO, there is no literature-based evidence to indicate that this finding is useful in risk stratification or prognosis.
- Abnormal response on nuclear myocardial perfusion imaging: not a validated finding for risk stratification. Abnormal MPI should prompt studies to rule-out coronary artery disease. On a case basis, evidence of reversible ischemia in the anatomic area of fibrosis hypertrophy may be considered. However, abnormalities unassociated with the area of hypertrophy in the absence of CAD are of unknown significance.

* Treatment for LV outflow tract obstruction: following appropriate time for recovery and observation, the FSACD may consider on a case basis.

References:

HYPERTROPHIC CARDIOMYOPATHY

b. Other cardiomyopathies

- Ischemic cardiomyopathy (ICM), due to CAD or microvascular disease (e.g., diabetes): includes HFpEF and/or HFrEF: to be considered under CAD.
- Non-ischemic cardiomyopathy (NICM): pending
- Hypertensive heart disease: pending
- Athlete’s heart: pending
- Infiltrative cardiomyopathies (e.g., Noonan’s syndrome): pending
- Arrhythmogenic right ventricular dysfuncion/cardomyopathy (ARVD/C): pending
Cardiac Conditions and Certification Changes

Recertification
Cardiac Conditions and Certification Changes
Recertification

For all classes

All information as required by the Authorization for Special Issuance will be sent to OKC for review and disposition.
Cardiac Conditions and Certification Changes

ATRIAL Fibrillation
Cardiac Conditions and Certification Changes
Cardiac Conditions and Certification Changes

ANTICOAGULATION
Cardiac Conditions and Certification Changes

CHADS$_2$ score

- Congestive heart failure (1)
- Hypertension (1)
- Age (75) (1)
- Diabetes mellitus (1)
- Stroke (2)
Cardiac Conditions and Certification Changes

• A score of 0 requires no anticoagulation
• A score of 1, requires Aspirin (can opt to use Coumadin)
• A score of 2 or higher, requires anticoagulation with Coumadin or one of the new oral anticoagulants (Xarelto, Eliquis or Pradaxa)
Cardiac Conditions and Certification Changes

CHA$_2$DS$_2$VASc
This was based on two groups of risk factors

**DEFINITIVE** risk factors
- Prior history of stroke or TIA
- Age 75 or older

**COMBINATION** risk factors
- Hypertension
- Heart failure
- Diabetes mellitus
- Age 65-74
- Female gender
- Vascular disease
Cardiac Conditions and Certification Changes

CHA$_2$DS$_2$VASc

- **C**: Congestive heart failure or LV dysfunction 1
- **H**: Hypertension 1
- **A$_2$**: Age (75 or older) 2
- **D**: Diabetes mellitus 1
- **S$_2$**: Stroke/TIA/TE (thromboembolism) 2
- **V**: Vascular disease (CAD, MI, PAD or Aortic plaque) 1
- **A**: Age 65-74 1
- **Sc**: Sex category 1

**High risk equals a score of two or greater**
Cardiac Conditions and Certification Changes

CHA$_2$DS$_2$VASc v. CHADS$_2$

CONCLUSION

The CHA$_2$DS$_2$VASc scoring tool has now replaced the CHADS$_2$ scoring tool in most atrial fibrillation guidelines worldwide.

The FAA now uses the CHA$_2$DS$_2$VASc scoring system
Cardiac Conditions and Certification Changes

24 HOUR HOLTER MONITOR

• The maximum average heart rate was changed from 100 to 110 beats per minute.
• 3 second or greater pauses remain disqualifying if the airman is symptomatic or if occurring during waking hours with activity.
• Increased vagal tone during sleep is not disqualifying.
Cardiac Conditions and Certification Changes

AMBULATORY ECG MONITORING

Holter monitors

These recorders are typically used for 24 or 48 hours to record events which might reasonably be expected to occur within that time-frame, i.e., frequent, or at least once a day symptoms.
Cardiac Conditions and Certification Changes

AMBULATORY ECG MONITORING

Intermittent recorders: These are generally for recording infrequent symptoms, and are one of two types:

• **Event recorders**, which store only a brief recording of ECG activity when activated by the patient in response to symptoms.

• **Loop recorders**, which record the ECG in a continuous fashion, but store only a brief record when activated by the patient or triggered by the preprogrammed parameters.

Both types of intermittent recorder may be worn by patients for periods of many weeks in order to capture infrequently occurring events.
Cardiac Conditions and Certification Changes

AMBULATORY ECG MONITORING

Implantable loop recorders (ILR)

It is used to record the heart rate and rhythm and help diagnose whether symptoms like fainting, dizziness, palpitations and unexplained seizure-like episodes have a cardiovascular cause.
Cardiac Conditions and Certification Changes

**Indications** for ambulatory monitoring

- Patients with syncope, near syncope or dizziness
- Patients with palpitations
- Continuous ECG monitoring for AF is useful to detect silent paroxysmal AF in patients without previously documented arrhythmic episodes, such as those with **cryptogenic stroke**.

Early diagnosis enables earlier treatment for both primary and secondary stroke prevention
Cardiac Conditions and Certification Changes

AMBULATORY ECG MONITORING

• may be used to assess a patient's response to anti-arrhythmic treatment, e.g., the rate of atrial fibrillation, or pro-arrhythmic responses to drugs.

• may be used to assess the function of a pacemaker device or ICD.
Cardiac Conditions and Certification Changes

CACI
Cardiac Conditions and Certification Changes

**CADI – Mitral Valve Repair Worksheet (Updated 2/4/2015)**

The Examiner must review a current status report by the treating physician and any supporting documents to determine the applicant’s eligibility for certification. If the applicant meets all the acceptable certification criteria listed below, the Examiner can issue. Applicants for first- or second-class must provide this information annually; applicants for third-class must provide the information with each required exam.

<table>
<thead>
<tr>
<th>AME MUST REVIEW</th>
<th>ACCEPTABLE CERTIFICATION CRITERIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>The airman had Mitral Valve Repair surgery 5 or more years ago for primary mitral valve disease (not secondary MR or functional MR due to coronary heart disease, MI, ischemic disease, or cardiomyopathy).</td>
<td>[ ] Yes</td>
</tr>
<tr>
<td>A current status report from the treating cardiologist verifies the airman:</td>
<td>[ ] Yes</td>
</tr>
<tr>
<td>- Is asymptomatic and stable;</td>
<td></td>
</tr>
<tr>
<td>- Has no other current cardiac conditions*;</td>
<td></td>
</tr>
<tr>
<td>- Has not developed any new conditions, arrhythmias, or complications that would affect cardiac function;</td>
<td></td>
</tr>
<tr>
<td>- Requires no more than a routine annual follow-up; and</td>
<td></td>
</tr>
<tr>
<td>- No additional surgery is anticipated or recommended.</td>
<td></td>
</tr>
<tr>
<td>The airman has NO history of:</td>
<td>[ ] Yes</td>
</tr>
<tr>
<td>- Connective tissue disorder (Marfan's or Ehlers-Danlos, etc.);</td>
<td></td>
</tr>
<tr>
<td>- Lung disease: COPD (moderate or higher), or pulmonary HTN; or</td>
<td></td>
</tr>
<tr>
<td>- Other cardiac disease (e.g., Congestive Heart Failure, ischemia, other valve disease, etc.)</td>
<td></td>
</tr>
<tr>
<td>The most recent echo was performed within the last 24 months shows:</td>
<td>[ ] Yes</td>
</tr>
<tr>
<td>- Mitral valve regurgitation (if present) is classified as mild;</td>
<td></td>
</tr>
<tr>
<td>- No other abnormalities on echo such as:</td>
<td></td>
</tr>
<tr>
<td>- Dilated aorta greater than 4 cm;</td>
<td></td>
</tr>
<tr>
<td>- Hypertrophic cardiomyopathy or other cardiomyopathy;</td>
<td></td>
</tr>
<tr>
<td>- Left Atrial Enlargement;</td>
<td></td>
</tr>
<tr>
<td>- Regurgitation of any valve moderate or higher; or</td>
<td></td>
</tr>
<tr>
<td>- Structural abnormalities (dilated ventricle, etc.);</td>
<td></td>
</tr>
</tbody>
</table>

*Notes:*
- If any valve other than mitral was involved, the information must be submitted to the FAA for review.
- An annual echo is not required for each FAA exam for the CADI.
- Anticoagulation is not routinely required for mitral valve repair. If Coumadin or other anticoagulation (other than ASA) is required for a cardiac condition, the AME should defer.
- *Mitral stenosis treated with ablation and received is allowable.

**AME MUST NOTE in Block 60 one of the following:**

- [ ] CADI qualified Mitral Valve Repair.
- [ ] Not CADI qualified Mitral Valve Repair. Issued per valid SI/ASI. (Submit supporting document.)
- [ ] NOT CADI qualified Mitral Valve Repair. I have deferred. (Submit supporting documents.)
Aortic root dilatation and ascending aortic aneurysm

- Top normal dimension is 37mm (3.7cm)
- >37mm and <40mm (4.0cm) do not get a Special Issuance but fall under General review
- 40mm (4.0cm) to <50mm (5.0cm) will be placed on a Special Issuance
- Currently 50mm (5.0cm) is disqualifying
Aortic root dilatation and abdominal aortic aneurysm

- 50mm-55mm (5.0-5.5 cm): LIMBO
- 55mm or greater consider surgical repair

Pertinent values on echocardiogram will need to be reviewed by the AME in order to issue a medical certificate. **This disqualifying condition will likely remain as an Special Issuance and not become a CACI.**

New policy to address airmen in LIMBO is in progress
The New oral anticoagulants (NOAC) (Pradaxa, Eliquis, Xarelto)

Current policy requires a status report from the treating physician every six (6) months. It is being considered to extend to every twelve (12) months.
UNDER CONSTRUCTION

12 Lead Electrocardiogram

Normal, Normal variants and Abnormal

The criteria have been placed in the AME guide, along with the required testing for the abnormal ECGs
Pacemaker worksheet

- Currently, the only way to get a worksheet is when it is included in the authorization (AASI or SI) to the airman
- It will be going into the AME guide
UNDER CONSTRUCTION

Hypertrophic Cardiomyopathy

It is not currently in the AME Guide but plans are being made for it to be placed under the protocol section.
Cardiac Conditions and Certification Changes
Cardiac Conditions and Certification Changes

Other Cardiac Conditions The following conditions must be deferred:
1. Cardiac Transplant – see Disease Protocols.
2. Cardiac decompensation.
3. Congenital heart disease accompanied by cardiac enlargement, ECG abnormality, or evidence of inadequate oxygenation.
4. Hypertrophy or dilatation of the heart as evidenced by clinical examination and supported by diagnostic studies.
5. Pericarditis, endocarditis, or myocarditis.
6. When cardiac enlargement or other evidence of cardiovascular abnormality is found, the decision is deferred to AMCD or RFS. If the applicant wishes further consideration, a consultation will be required, preferably from the applicant’s treating physician. It must include a narrative report of evaluation and be accompanied by an ECG with report and appropriate laboratory test results which may include, as appropriate, 24-hour Holter monitoring, thyroid function studies, ECHO, and an assessment of coronary artery status. The report and accompanying materials should be forwarded to the AMCD or RFS.
7. Anti-tachycardia devices or implantable defibrillators.
8. With the possible exceptions of aspirin and dipyridamole taken for their effect on blood platelets, the use of anticoagulants or other drugs for treatment or prophylaxis of fibrillation may preclude medical certification.
9. A history of cardioversion or drug treatment, per se, does not rule out certification. A current, complete cardiovascular evaluation (CVE) will be required. A 3-month observation period must elapse after the procedure before consideration for certification.
10. Any other cardiac disorder not otherwise covered in this section.
11. For all classes, certification decisions will be based on the applicant’s medical history and current clinical findings. Certification is unlikely unless the information is highly favorable to the applicant. Evidence of extensive multi-vessel disease, impaired cardiac functioning, precarious coronary circulation, etc., will preclude certification. Before an applicant undergoes coronary angiography, it is recommended that all records and the report of a current cardiovascular evaluation (CVE), including a maximal electrocardiographic exercise stress test, be submitted to the FAA for preliminary review. Based upon this information, it may be
possible to advise an applicant of the likelihood of favorable consideration.
12. A history of low blood pressure requires elaboration. If the Examiner is in doubt, it is usually better to defer issuance rather than to deny certification for such a history.
THE END
Cardiac Conditions and Certification Changes

QUESTIONS
Cardiac Conditions and Certification Changes

QUESTIONS
Cardiac Conditions and Certification Changes

$\text{CHA}_2\text{DS}_2\text{VASc}$ v. $\text{CHADS}_2$

- $\text{CHADS}_2$ left too many gray areas and sometimes used as an excuse not to prescribe Warfarin
- $\text{CHADS}_2$ failed to consider women’s greater stroke risk with atrial fibrillation where $\text{CHA}_2\text{DS}_2\text{VASc}$ does.
- When women do take Coumadin and have comparable INR control, the risk of stroke is reduced and “they are not more likely to suffer a major bleed”.
Cardiac Conditions and Certification Changes

\[ \text{CHA}_2\text{DS}_2\text{VASc} \]

An additional way of identifying who should be on anticoagulants

Question 1. Age 75 or older?.............if yes, oral anticoagulant. If no, then:

Question 2. History of Stroke, TIA or thromboembolic event? If yes, then oral anticoagulation. If no, then:


If female, go to risk factors. If female + one risk factor, then oral anticoagulation.