

1. Report No. FAA-AM-71-25	2. Government Accession No.	3. Recipient's Catalog No.	
4. Title and Subtitle THE PHILOSOPHY AND LIMITATIONS OF FAA AEROMEDICAL STANDARDS, POLICIES AND PROCEDURES		5. Report Date June 1971	6. Performing Organization Code
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9. Performing Organization Name and Address Office of Aviation Medicine Federal Aviation Administration 800 Independence Avenue, S. W. Washington, D. C. 20590		10. Work Unit No.	11. Contract or Grant No.
12. Sponsoring Agency Name and Address Office of Aviation Medicine Federal Aviation Administration 800 Independence Avenue, S. W. Washington, D. C. 20590		13. Type of Report and Period Covered  OAM Report	
14. Sponsoring Agency Code		15. Supplementary Notes	
16. Abstract  Designated Aviation Medical Examiners need available basic information concerning the FAA medical certification system, the philosophy which underlies standards, policy and procedures, and certain limitations of the system. It is through such information that errors adverse to safety can be forestalled and differences in opinions between equally dedicated and knowledgeable physicians can be best averted. Regulatory medicine must have orientation different from that in the private practice of medicine. Insofar as these necessary differences and limitations are recognized, the FAA mission of safety and promotion of aviation should be enhanced by a more effective and equitable system of medical certification.			
17. Key Words Standards (Aeromedical) Examination (Aeromedical) Training (Aviation medical examiners)		18. Distribution Statement Availability is unlimited. Document may be released to the National Technical Information Service, Springfield, Virginia 22151, for sale to the public.	
19. Security Classif. (of this report) Unclassified	20. Security Classif. (of this page) Unclassified	21. No. of Pages 7	22. Price \$3.00



# THE PHILOSOPHY AND LIMITATIONS OF FAA AEROMEDICAL STANDARDS, POLICIES AND PROCEDURES

While basic aviation medicine is much the same all over the world, there are at times some rather large differences between Air Force, Army, Navy and civil aviation medicine as to outlook, attitudes or philosophy. It is germane that civilian Aviation Medical Examiners (AMEs) be apprised of some of the philosophy and system idiosyncrasies if they are to provide fair and equitable decisions as to the medical qualifications of American civilian airmen under those rules, policies, guidelines and procedures promulgated by the Federal Air Surgeon of the Federal Aviation Administration.

In order to gain a perspective of the present-day regulatory and certification system, three aspects will be considered:

- I. The certification system and its overall effects.
- II. Philosophy of medical certification and standards.
- III. Limitations of the system.

## **I. The Medical Certification System and Its Overall Effects.**

A. *Basics.* For those who have had relatively little experience with the FAA, the following will give a few of the basics as related to medical certification of civilian airmen. Airmen are pilots, certain other flight crewmembers and air traffic controllers (ATCs). Pilot licenses are issued based upon demonstrated skill, knowledge and experience. These licenses are periodically validated by obtaining a medical certificate:

1. Airline pilots (First Class) are medically examined for the FAA every 6 months.
2. Other commercial airmen (Second Class) are examined every 12 months.
3. Private and student pilots (Third Class) are examined every 2 years.

In 1927, 4,200 medical certificates were issued as compared with 490,000 in 1970—an average

of about 1,400 each day. Over 50,000 new airmen come into the system each year.

B. *Aviation Medical Examiners (AMEs).* All medical examinations are presently performed by an AME. The airman pays the physician. The FAA does not regulate fees other than by asking that fees be commensurate with the going rate in the community. There are over 7,000 AMEs (including 700 military and 300 international). Forty percent are pilots and some 15% were formerly military flight surgeons. The AME's role is a unique one in that he is the only representative of the FAA with whom every pilot has a regular and required contact. He is ideally situated to participate in grass roots aviation and to contribute to ongoing airman education. In practicing preventive medicine, he can be instrumental in the early detection of conditions which, when vigorously treated, will preserve the careers, health and well being of America's airmen. We realize that the AME is required to make line decisions:

1. He can be boxed in by pilots who are friends.
2. He often works under heavy workloads.
3. He may have limited information upon which to base a decision.
4. He may have to deal with a pilot who is evasive.

The designated AME system has worked well. It provides a nucleus of aviation-oriented physicians to perform careful examinations and to recognize positive findings of significance to aviation and public safety. The designation system has made the FAA seminar program feasible. This system was expanded in 1960 to cover examinations for third-class certificates. There are many reasons to designate, even if some family physicians are excluded. Not all family physicians want to do it. Many have no special interest in medicine as related to flying. No rule is any better than those charged with its

administration, and AME failure would mean system failure. In the real world a system required by law also requires control, yet some states define physicians as anyone in the healing arts—to include homeopaths and faith healers. The designation system overcomes these problems.

Unfortunately, it is also true that while many physicians have no special interests or knowledge in the medical aspects of flying, all physicians have at least one pilot as a patient, a friend who is a pilot, or patients who are passengers in the air transport system. It is indeed unfortunate when such a physician unknowingly prescribes a certain course of therapy, perhaps surgery, that is one of several alternatives and, in making the choice, takes away the career of his pilot patient.

The designated AME has been authorized or empowered to issue medical certificates for the FAA. These certificates are, in effect, a legal document. Having a valid medical certificate can be of some legal consequence for any airman involved in an accident or incident, for example, the legality of his performing certain duties and even the validity of his insurance. The certificates are also in the public domain and are a matter of public record. The medical records themselves are, of course, privileged.

*C. Processing of Medical Applications.* The FAA reviews each AME report when submitted to the Aeromedical Certification Branch in Oklahoma City. It is reviewed for completeness and for conformation with agency policy and procedures. Instead of an FAA physician reviewing each AME report, the information from the report is submitted to a computer for screening. If the data fail the edits of the computer, the report is flagged for manual review. Problems that go beyond simple clerical errors are referred to an FAA physician. This physician may write for additional information such as hospital records, specialty examination, or medical flight testing. After all the information is in, eligibility for medical certification is decided and the computer record is updated, creating a data bank for special studies. Since AME failure would mean system failure, the computer is also used to periodically survey the work of all AMEs to assure that each continues to strive to maintain a high level of responsibility toward

safety by performing careful examinations and issuing medical certificates in keeping with agency standards, policies and procedures.

*D. Appeals for Reconsideration.* When FAA physicians review the medical evidence of problem cases, some will be completely cleared. There are nine conditions that always require denial: myocardial infarction, angina or other evidence of coronary heart disease, psychosis, character and behavior disorder manifested by overt acts, epilepsy, disturbance of consciousness without satisfactory medical explanation, drug addiction, chronic alcoholism, and diabetes requiring drugs. A pilot with a history or clinical diagnosis of one of these conditions can only be further considered through the special appeal called a petition for exemption, provided for in Part 11 of the Federal Aviation Regulations (FARs).

Except for the nine specific conditions, the medical standards contain a provision for special issue of medical certificates by FAA full-time medical personnel, provided for in FAR 67.19. For this latter type of reconsideration, special tests are often required. Some will be issued a medical certificate with special restrictions or limitations not authorized for use by AMEs. The applicant may have to submit special follow-up reports. He may be limited operationally as by "Valid for Daylight Operations Only". Use of limitations allows certification of airmen not otherwise possible and at the same time allows control over the level of risk to safety. Less than 1% will be denied, many being the new airmen. New airmen comprise 28% of all applications, yet receive 50% of the denials.

Any airman who receives a final denial from the FAA is advised that he may appeal to the National Transportation Safety Board (NTSB) for a "rules of evidence" type of hearing to determine if the regulations were properly applied. Parties are usually represented by legal counsel. Testimony is presented to a hearing examiner who subsequently issues his "Initial Decision". Either party may appeal this initial decision to the Full Board. Here legal briefs are prepared, but no further testimony is allowed. For the airman who has suffered one of the nine conditions previously named, an appeal to the NTSB would serve no useful purpose unless the airman is prepared to contest the propriety of

his being labeled with such a history or clinical diagnosis.

In any one year, about 400 will appeal to the Federal Air Surgeon. About 350 will petition for an exemption and about 80 will petition the NTSB. Of these 800, about 125 will eventually be certified, most with operational limitations and/or careful surveillance through special follow-up medical examinations. The valid question might be whether we are endangering safety in denying so few. The answer has been given. Limitations help control the level of risk taken. We must tailor our decisions to the individual. Individual rights and promotion of aviation must be given practical consideration. Livelihoods and investments in aircraft and training are at stake. These factors would lead us to take a look at the philosophy underlying medical certification and standards.

## II. The Philosophy of Medical Certification and Standards.

A. *FAA Mission.* The FAA mission is "to promote aviation while assuring safety in the air and for those below".

B. *The Individual.* Airmen share the medical burden—FAR 61.45 states in part:

"No person may act as pilot—when he has a known physical deficiency or increase of a known physical deficiency that would make him unable to meet the physical requirements of his current medical certificate."

C. *Medical Criterion.* The primary criterion is sudden, unpredictable incapacitation. We are most interested in those organ systems most likely to be associated with incapacitation—the special senses, the cardiovascular system, the nervous system and the respiratory system. It is sometimes forgotten that poor judgment can be incapacitating.

Many everyday diseases will react quite differently with altitude. There can be subtle and cumulative effects from altitude, alcohol, tobacco, and mild emphysema. Special emphasis is obviously placed upon arteriosclerotic heart disease, hypertension, diabetes, epilepsy, mental disorders and indiscriminate use of drugs and alcohol. Medication is of importance not solely because of incapacitating side effects. Its use may indicate significant underlying pathology. At the same

time that the drug treats, it may make it more difficult to ascertain the stage of the disease process by suppression of clinical signs and symptoms. One aim is to try to correlate pathology and its treatment to performance. This refers not only to motor skills, but also to judgment. Early incipient disorders as of the personality provide a hearty challenge to all examiners.

D. *Levels of Concern.* As with drivers' licenses, we consider flying a privilege and not a right. There is ingrained in our society the concept of individual rights, and a voluntary exposure to risk is highly valued as one of those rights. In accepting the right of the individual to incur personal risk, this right must be balanced against society's interest in the safety of the individual, and even more against the overriding considerations that limit the individual's right to incur risk when the exercise of that right creates a risk for others. It is the latter consideration of risk to others that disposes organized society to consider activities as flying or driving to be a privilege and not an incontestable right of the individual. On the other hand, if performance is demonstrated to be adequate, we feel that the individual's personal risk is by and large the individual's own decision. The paraplegic who flies modified aircraft and who has demonstrated his capabilities is not likely to be suddenly incapacitated due to his paraplegia. However, he may run a high personal risk if he is subjected to fire following an unavoidable non-fatal accident.

There are other levels of concern. In carrying out the statutory safety responsibilities, the FAA recognizes that society's interests in safety are diverse, the range and intensity of interest depending upon the individual's relationship to air transportation:

1. People who pilot aircraft and people who do not;
2. People who are pilots and those who are passengers;
3. Those who fly and those on the ground whose person or property may be affected by aircraft operations.

There are also the incongruities some have labeled as the "gore factor". Even the low incidence and crash rate in common carriers elicits a much greater expression of public concern than

the much larger number of persons who die as the result of accidents in the very active private sector. Our society accepts the concept that those holding out their services to the public will be held to a higher standard of care. This concept is especially meaningful in aviation where the passenger has neither choice nor bargaining power in selecting the particular aircraft, the crew, or the flight path for his trip. The Federal Aviation Act of 1958 directs us to give full consideration, in issuing certificates and prescribing standards, to the duty resting upon air carriers to perform their services with the highest possible degree of safety. Expecting a higher degree of safety, the public assumes that there is less risk than in the private sector and is less forgiving of lapses.

### III. Limitations of the System.

With this background of philosophy, how does the agency go about promulgating safety rules, regulations or standards?

A. *The Legislative Basis for Medical Standards.* The Federal Aviation Act makes it clear that our mission is to promote safety of flight by prescribing minimum standards governing the design, materials, workmanship, construction and performance of aircraft and to issue airman certificates to those individuals who demonstrate their qualifications to exercise the privileges of the certificate sought or held. The Act does not address itself to specifics of minimum standards but does direct and serves as the administrative authority to establish standards.

The Administrative Procedures Act outlines rather specific procedures that must be followed by all regulatory agencies. It is the rules for rule makers. It assures that the public, in general, and those being regulated, in particular, get a fair and legal "shake" and have their say in court. This Act also accords any interested person the right to petition for issuance, amendment or repeal of any rule.

Further, the Administrator of the FAA prescribes, in the form of an agency order, those policies and procedures to be followed in rule making. This order assures that those subject to Federal Aviation Regulations are consulted and that the public has opportunity to participate in rulemaking. This is not to say that the responsibility for rulemaking is passed to others

or that regulations are adopted by popular vote. Rules are developed by people who have a statutory responsibility for representing the public interest.

Finally, all rules must stand the tests of review by the courts. They must be within the statutory power of the agency. They must not infringe upon constitutional rights, must not be arbitrary or capricious and must not abuse the discretionary authority. They must be supportable by substantial evidence.

The role of the Office of Aviation Medicine in air safety is predominately a regulatory one. In prescribing reasonable minimal medical standards, we practice regulatory medicine. While this has traditionally been accepted as our role, it has been accepted by some with reluctance and continued questioning since decisions in medicine are often based on highly-skilled intuition. Being judgmental they cannot be reduced to an equation or practiced by the numbers.

Yet, the need for medical standards is obvious. The uncontrolled diabetic or epileptic has no role in the safe operation of aircraft. On the other hand, when criteria are set, when lines are drawn, they are seldom irrevocable and hopefully never completely arbitrary. While our rules are not made to be broken, when individual consideration is given to applicants, some will be waived. The only stipulation is that the Federal Air Surgeon feels that the final decisions concerning certain conditions should be made by those who are in the full-time practice of aviation medicine and who have the ultimate responsibility for ensuring safety.

Before leaving the subject of rule development or genesis, a few short words should be said about cost-benefits and safety. It may seem crass to some to speak of costs in considering safety. Yet, in the real world such considerations must be made. On one hand the acceptance of calculated risks is a part of our general attitude toward life. On the other hand, a goal of absolute safety would impose economically intolerable expenditures. We must seek and maintain a level of safety obtainable with reasonable resources which is in balance with cost and efficiency. Achieving this objective requires the development of criteria and methods aimed at improving air safety. This is most difficult in

writing minimal medical regulations where we attempt to regulate as little as possible, consistent with the mission of safety. Considerable professional judgment is necessarily involved.

*B. The Origin of our Standards Lies Largely in Empiricism.* On leaving the development of new standards and looking to their earliest origins, we note that our first aeromedical standards of 1926, under the Bureau of Air Commerce, were an outgrowth of military standards. Back in World War I many of those rejected from the infantry became pilots. It was soon obvious that the accident rate of those airmen with physical defects was much higher than the rate of those without defects. This realization led to the first medical standards for pilots and the development of aviation medicine as a specialty.

No one had prior experience and the first standards by and large were arbitrary or geared to the equipment and type of flying—goggles and open-cockpit aircraft. In the beginning goggles could not be ground to prescription, and vision had to be normal without correction. The standards were fairly rigid, and, when one was grounded, there were no established avenues of appeal. The standards remained much the same for years. However, with the advent of the FAA, a new philosophy concerning civil aeromedical standards became apparent. As experience accumulated, it was determined that for some deficiencies pilots could perform safely—as through use of glasses or special training. Certain standards were relaxed, waivers were issued and an appeals system was established.

The military continues to use the same airspace, same Air Traffic Control system, and sometimes, the same airports. However, military aviation is mission-oriented. It does not foster many of the individual freedoms which characterize civil aviation and which are reflected in our standards. While our earlier rules were founded largely in empiricism, we are now entering a different phase. The modern tools of data analysis are being applied to the certification system to better determine precisely what conditions appear to be most closely associated with accidents.

*C. The Standards are not Detailed.* At a given general physical examination, there are almost no limits to historical detail or to the number of tests that might be employed. The procedures

chosen will depend upon exercise of clinical judgment. On the other hand a good physical examination will be much the same regardless of purpose. Our minimal medical regulations, like a good screening physical examination, must be directed toward those relatively few areas where discovery of disease or risk to safety would be more likely. Such regulations give more room to individualize. This is essential to good medical practice. It would be improper to treat each disease or condition the same way every time. It would be impractical to address the regulations to each disease and its variable manifestations. The regulations required will depend upon how effectively each Aviation Medical Examiner exercises his options—how well the certification system operates. The greater the reliability, the fewer the standards that are needed.

*D. The Standards Must be Applied to Documented Medical Evidence.* We realize that in the daily practice of medicine, practical limitations and compromises in data accumulation and interpretation will lead to some professional differences of opinion. Further, there is a fundamental difference between private practice of medicine, where physician-patient relationships are paramount, and the practice of regulatory medicine, where what is in the public interest must be the foremost consideration. It is often because this fundamental difference is not appreciated by airmen or physicians that misunderstandings arise between equally dedicated and competent physicians. Basic to both practices is the fact that we have to depend upon what the individual reveals by history and what is found on examination.

Many pilots share a basic mistrust of flight surgeons and AMEs. They are required to undergo a physical examination at regular intervals, to pay for something they often do not want or think unnecessary. AMEs serve as a threat to their careers as pilots or the pleasure or the investments they have in flying. But the AME also serves as an influence in the formation or suppression of these attitudes. Knowing they exist, we can be more alert to the evasiveness of some applicants. A carefully documented history and examination is fundamental to the reliability of the certification system and in assuring, as best we can, safety. Without reliable medical information obtained from a

conscientious airman by a thorough physician, the medical standards on the printed page are indeed impotent. The certification decision made must be consistent with this evidence in the written record of the individual. This places the burden of proof upon the individual and upon his consultant physician. Unfortunately, for every pilot who knows and conceals a severe condition, somewhere there is a physician who knows and keeps back the information by omission or, rarely, by commission.

Flight instructors commonly write on behalf of applicants, confusing skill and knowledge with health factors. However, these comments are useful, especially in consideration of any functional limitations. Physicians occasionally express strong opinions about the eligibility of an airman with pathology, pathology that the physicians would normally consider outside the range of their expertise. They argue:

1. As examining physicians, we are in the best position to know.
2. You of FAA make arm-chair decisions.

We agree, but contend that there are other factors:

1. We often obtain specialty reports unknown to the physician.
2. The specialist in aviation medicine may know of factors that the busy practitioner may not have considered.
3. Extensive medical records may be on file with the FAA that were not available to the examining physician.
4. Every effort is made to take into account the limitations imposed by a strictly paper operation.
5. When in doubt, the agency will often offer its own facilities for additional evaluation.

It is wise to keep the channels of communication open and to confer with the Regional Flight Surgeon or with the Aeromedical Certification Branch in Oklahoma City. When in doubt as to what to do, the AME should not issue. And one final word as relates to differences of opinion. While the FAA usually has no objection to the AME testifying in behalf of his pilot patient, caution should be exercised in examining an airman in order to qualify to give testimony in litigation against the FAA. This may raise questions as to conflict of interest.

*E. The Need for Education.* In looking at the pitfalls and limitations of rules, it is understandable that education is preferred to regulation. The FAA has neither the inclination nor the manpower to keep America's civilian pilots under perennial surveillance. Much will depend upon the knowledge and honesty of the individual pilot. He should be indoctrinated to the physiological consequences of illness, fatigue, drugs and alcohol. Questions related to such knowledge are now included in most of the written FAA pilot examinations. Also, formal physiological lectures and chamber rides are available to pilots for a minimal fee.

There is a continuing need for AME education also. Several seminars are held each year in locations scattered throughout the contiguous states. Longer, more advanced seminars are held at the Civil Aeromedical Institute (CAMI) in Oklahoma City and offer AMEs opportunity for physiological training and chamber rides.

While there have been military schools of aviation medicine for many years the first residency program for comparable civilian training was established at Ohio State University in 1958. A similar program was started by the University of Oklahoma in cooperation with the FAA at CAMI in 1967. AMEs are also provided with further assistance through the Guide for Aviation Medical Examiners. The Guide and seminars are designed to assist in using a set of regulations that allow latitude in interpretation.

#### **IV. Summary.**

The medical certification system has been sketched to explain the role of the AME and processing of applications by the FAA. The overall effects of the system have been portrayed to reflect the rather liberal modes of appeal available to the present-day airman. To better understand these effects, the philosophy of certification and standards was reviewed. While incapacitation is of primary concern to safety, promotion of aviation leads to other considerations to include individual rights, levels of concern, and differing responsibilities.

In considering system limitations, the manner in which new regulations are developed, the empirical origins of our regulations, their brevity, the need for documentation and education were each touched upon. Much has not been covered



that pertains to the FAA medical certification system. Much could be stated about the man-machine aspects of our total aviation system, with the present imbalance of emphasis heavily weighted toward the machines. Much could be stated about the human maintenance concept as applied to civilian airmen.

Of fundamental concern is that each AME strive to practice good sound medicine consistent with the state of the art and as related to the special environment of flying. The basic premise would also include the intent to consider the

individual and his total circumstance—medical, social, and economic. Certification decisions must be practical and hopefully without arbitrary preconceptions.

We all have responsibilities to the pilot and his reliability; to the Air Traffic Controller who at times must be the eyes and ears of the pilot; to the passengers who would like to fly *and*, if it should come to that, to survive any accident; and even to the public who wants the service but not the noise and pollution problems of the modern day airport.

