invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves contact information along with the education and experience of a person seeking to be appointed as an FAA Designated Engineering Representative (DER). The information to be collected will be used to determine the eligibility and qualifications of the DER applicant.

DATES: Written comments should be submitted by January 6, 2020.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By mail: Scott Geddie, 6500 S MacArthur Blvd., ARB 308, Oklahoma City, OK 73169.

By fax: 405–954–2209.

FOR FURTHER INFORMATION CONTACT: Scott Geddie by email at: *Scott.Geddie@faa.gov,* phone: 405–954–6897.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0033.

Title: Representatives of the Administrator, 14 CFR part 183.

Form Numbers: FAA Form 8110–14.

Type of Review: Renewal of an information collection.

Background: Information in this collection is voluntarily submitted by persons applying to become an FAA Designated Engineering Representative (DER). DERs represent the FAA on aircraft certification projects. They examine engineering design data and determining whether aircraft built according to that data comply with published FAA airworthiness standards. Collecting this information allows the FAA to evaluate the eligibility and qualifications of the DER applicant.

This application form, 8110–14, Statement of Qualifications, provides the FAA with contact information for the applicant, along with the applicant's requested authorities. It outlines the applicant's education and pertinent experience that, in conjunction with additional narratives and other detailed information, allows the FAA to make an informed decision whether to appoint the applicant as an FAA representative.

Respondents: Persons applying to become an FAA Designated Engineering Representative.

Frequency: One time submittal.

Estimated Average Burden per Response: 1.5 hours.

Estimated Total Annual Burden: One time submittal. No annual burden.

Issued in Washington, DC.

Joy Wolf,

Directives & Forms Management Officer (DMO/FMO), Aircraft Certification Service.

[FR Doc. 2019–24316 Filed 11–6–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2019–0899]

Special-Issuance Medical Certification: Diabetes Protocol for Applicants Seeking To Exercise Airline Transport, Commercial, or Private Pilot Privileges

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice; request for comment.

SUMMARY: With this notice, the Federal Aviation Administration (FAA) informs applicants for airman medical certification with insulin-treated diabetes mellitus (ITDM) of a new protocol available to evaluate pilots seeking to exercise pilot privileges as airline transport, commercial, or private pilots. The FAA may only certificate pilots with ITDM through the special-issuance process with case-by-case assessment of overall risk and available risk mitigation. Previously available medical science, treatment, and monitoring have allowed the FAA to safely provide special issue third-class medical certificates for private pilot privileges since 1996, but was not sufficient to meet the higher levels of safety demanded for applicants considered for airline transport or commercial pilot duties. The new FAA risk assessment protocol, based on established advances in medical science since 1996, makes it possible to mitigate flight safety risk so that applicants seeking first- or second-class special-issuance medical certification may be considered for the exercise of either airline transport or commercial pilot privileges. Applicants for third-class special issuance may apply under the existing third-class-only protocol or the new protocol.

DATES: The protocol is effective November 7, 2019.

Send comments on or before January 6, 2020.

ADDRESSES: You may send comments identified by docket number FAA–2019–0899 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 on the ground floor of the West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Judi Citrenbaum, Office of Aerospace Medicine, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–9689, email. *Judi.M.Citrenbaum@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

FAA Experience Applying Special-Issuance Procedures for Diabetes

Under Title 14 of the Code of Federal Regulations (14 CFR), §§ 67.113(a), 67.213(a), and 67.313(a), insulin-treated diabetes mellitus (ITDM) is considered medically disqualifying for pilots. The Federal Air Surgeon has discretion under 14 CFR 67.401 to authorize special issuance of airman medical certificates to applicants who are otherwise disqualified. Historically, the FAA has used this discretion to special issue only third-class medical certificates to applicants with ITDM

seeking to exercise private pilot privileges.

In determining whether an authorization for special issuance may be granted to an applicant, the Federal Air Surgeon considers whether the privileges permitted by the class of medical certificate requested can be performed without endangering public safety for the duration of the medical certificate. The FAA must always consider risk when implementing its licensing and credentialing programs, and the medical certification process is no exception. As specified in 14 CFR 67.401, the Federal Air Surgeon ''considers the freedom of an airman, exercising the privileges of a private pilot certificate, to accept reasonable risks to his or her person and property that are not acceptable in the exercise of commercial or airline transport pilot privileges, and, at the same time, considers the need to protect the safety of persons and property in other aircraft and on the ground.'' Much less risk is acceptable in the exercise of commercial or airline transport pilot privileges in order to protect public safety.

Long-term medical risks associated with diabetes include cardiovascular, neurological, ophthalmological, and renal complications. These factors pose additional hazards to aviation and require special scrutiny. Of particular concern with insulin-treated diabetes, more so than for oral hypoglycemic treated diabetes, is the short-term or immediate risks posed by hypoglycemia or low blood glucose. Hypoglycemia can produce impaired cognitive function, seizures, unconsciousness, and even death. The functional incapacitation associated with hypoglycemia may occur subtly and be undetected by the individual or others. Inadequately controlled diabetes (with resulting high blood sugar [hyperglycemia]) also can lead to impaired function and, effectively, incapacitation. Thus, the symptoms that result from both diabetes and its treatment can affect flight safety.

The FAA has incrementally updated the special-issuance medical certification protocol for applicants with diabetes. The FAA initially did so, in the early 1980's, for individuals who control their diabetes with diet and non-insulin hypoglycemic drugs. In 1996, the FAA began allowing insulin use for third-class medical certification, which limits the applicant to exercising private pilot privileges. This incremental approach has been very successful, and the FAA has now authorized approximately 500 ITDM pilots for third-class medical certification. The third-class special issuance protocol, in part, requires a process of finger-stick glucose testing before and during flight. The agency has a separate, internal program under FAA Order 3930.3B (Air Traffic Control Specialist Health Program) to permit FAA Air Traffic Control Specialists (ATCSs) with ITDM to continue their safety-related duties.

Applicants with diabetes considered for third-class, special-issuance medical certification are carefully evaluated and must submit to monitoring under a specific medical protocol, just as they would for any other specifically disqualifying medical condition under Part 67. Special-issuance conditions include careful evaluation of the individual's medical history, risk stratification, and the efficacy of the individual in controlling the disease. To develop diabetes protocols, the FAA considered the input of expert endocrinologists and diabetes specialists. The FAA continually reviews its protocols (for diabetes and other diseases) to ensure they remain viable and appropriate given ever-evolving medical advances. In this regard, the agency validates its experience and ensures that safety of flight is maintained.

Discussion

Recommendations To Expand the Protocol

Authorization for ITDM pilots to exercise pilot privileges beyond private pilot has been a topic of much discussion for several years within the aviation sector. While the FAA has discretion under § 67.401 to consider allowing ITDM special issuance for higher-rated pilots, it has chosen to proceed cautiously. The American Diabetes Association and several affected pilots have urged the FAA to update its special-issuance process for ITDM beyond third-class medical certification by developing an ITDM special-issuance protocol to allow the exercise of commercial and airline transport pilot privileges.

In 2013, the FAA suggested the American Diabetes Association consider convening a panel of experts to recommend how to risk stratify ITDM pilots for consideration beyond the private pilot certification level, to include recommending a protocol for identifying a subset of individuals at very low risk for hypoglycemia. The American Diabetes Association panel concluded that updating the protocol to airline transport and commercial pilots was justified. In their findings submitted to the FAA, the ADA panel indicated the following:

The treatment of insulin treated diabetes has improved dramatically over the past thirty-five years with the advent of accurate determinations of blood glucose levels using meters with sophisticated memory chips and built in analytical programs. These developments also include continuous glucose monitors, continuous subcutaneous insulin infusion pumps, and improvements in short and long acting insulin analogues. These improvements permit real-time measurement of blood glucose levels, and have made it far easier for people with insulin treated diabetes to maintain near-normal blood glucose levels. This, in turn, dramatically reduces the risk of both short and long term complications of diabetes with significant reduction in the rate of both hyper- and hypoglycemic glucose levels. Careful monitoring and management of insulin treated diabetes is now routine and the processes involved have become streamlined such that school children often self-manage their glucose levels with minimal or no adult intervention.

In addition, the ADA panel concluded the following:

After considering all the evidence and clinical experience, the expert panel concluded that there are pilots with insulin treated diabetes whose risk of incapacitation in flight is equivalent to, or lower than pilots who do not have insulin treated diabetes. Their risk, like the risk presented by pilots who do not have insulin treated diabetes, is nonzero, but extremely improbable. It is the recommendation of the Expert Panel that FAA policy should be updated to reflect current diabetes medicine and permit such pilots medical certification at the first, second, and third class level.

The FAA reviewed the ADA 2013 recommendations and determined they provided impetus for a way forward. At the time, however, FAA medical experts and consultants were not satisfied that the level of medical treatment and technology was sufficiently advanced to consider moving forward with higher-level ITDM certification. As such, the FAA continued to pursue identifying a protocol that could be used for identifying a subset of individuals at very low risk for hypoglycemia. Unable to identify such a subset, the FAA turned to its own data on third-class ITDM pilots.

FAA Study of Third-Class ITDM Protocol

In 2015, the FAA Civil Aerospace Medical Institute (CAMI) evaluated the experience of U.S. private pilots flying with ITDM in a study entitled: ''Risk Assessment in the U.S. Pilot Population from 1983 to 2005: Diabetes Prevalence and Flight Safety.'' [1] CAMI conducted this study to evaluate trends for obesity and diabetes as reflected in the U.S. pilot population and explore the effects on flight safety and longevity of pilots

[1] See DOT/FAA/AM–15/5; March 2015.

with these conditions. The study noted that the prevalence of diabetes and obesity has increased worldwide, almost doubling between 1980 and 2014. This study found that the number of pilots with diabetes in the U.S. active pilot population rose from 2,768 in 1983 to 10,806 in 2005, an almost four-fold increase, reflecting both the increased prevalence in the population and the 1996 change in FAA policy. Limited prior evidence had suggested that aviators with reported diabetes controlled by hypoglycemic medication and diabetes controlled by diet alone were at greater accident risk than aviators without these conditions. The study reviewed NTSB accident reports from 1997–2005, reporting only 18 general aviation events involving insulin-dependent pilots.[2] Two accidents resulted in fatalities; one resulted in non-fatal injuries, and only one was conducted under instrument flight rules. All but one incident (mechanical, not pilot-related) were human factors-related and attributed to pilot error. The study concluded that, overall, the NTSB data did not indicate that diabetes directly contributed to the accidents.

Monitoring Innovations

Subsequent to the 2015 CAMI study, the FAA continued to follow the advances in diabetes medical science, including innovative progress with diabetes treatment (*e.g.,* medications), but most particularly with an individual's ability to efficiently self-monitor using continuous glucose monitoring (CGM) devices. CGM is wearable technology that provides a reliable and accepted means for accurately monitoring blood sugar levels, and predicting when a change is occurring. CGM monitoring, along with standard clinical follow up, reduces the risk of hypoglycemia, both inflight and outside the flight environment. CGM technology allows affected pilots to address their particular situation with good reassurance regarding short- and long-term stability. CGM usage allows the FAA to identify a low-risk subset and consider applicants whose glycemic stability is sufficiently controlled for safety of flight, even for commercial operations. Whereas the existing third-class protocol of finger-stick glucose testing before and during flight has proven sufficient at the private pilot level, the FAA has determined that CGM monitoring sufficiently increases the level of safety necessary to effectively validate higher-level piloting. With CGM, the FAA has been able to develop evidence-based protocols that ensure that each applicant vetted and granted a special issuance to their medical certificate is capable of maintaining diabetic control appropriate for safety of flight.

Experience of Other Countries Allowing ITDM Pilots To Exercise Pilot Privileges Commercially

The FAA is aware of two civil aviation authorities (CAAs) with experience in allowing individuals with ITDM to exercise their equivalent of commercial and airline transport pilot privileges. The Canadian CAA has approximately two decades of experience implementing a more flexible ITDM policy for commercial operations. Pilots (both commercial and airline transport pilots) with ITDM also are considered for medical certification in the United Kingdom. These CAAs link operational limitations and protocols to the medical certificate that must be strictly followed. These protocols may include limiting flights to multi-crew operations; informing the other pilot of the diabetes diagnosis; and training the other pilot on the recognition and treatment of hypoglycemia. Commercial pilots with ITDM from other CAAs have been flying internationally, including in U.S. airspace, for many years with no reported adverse impact on safety.

While the ITDM protocols from other CAAs have resulted in safe operations, the FAA has decided to take a different approach that it believes will enhance safety. Rather than imposing operational limitations and protocols via the medical certificate,[3] the FAA has developed an approach that is focused on the applicant's health. The FAA's ITDM protocol employs updated and proven medical technologies and best practices that allow for continuous monitoring and oversight of the ITDM individual, thereby reducing the potential for incapacitation. Under the FAA's ITDM protocol, the FAA will issue a first- or second-class special issuance medical certificate to an ITDM applicant only if the FAA has determined that safety of flight can be maintained with the use of CGM technology.[4]

Exercising Pilot Privileges Internationally With an FAA Special-Issuance Medical Certificate

Under International Civil Aviation Organization (ICAO) standards, diabetes controlled by insulin is considered specifically disqualifying just as it is in the United States. However, ICAO Annex 1 standard 1.2.4.9 (like U.S. regulation 14 CFR 67.401) applies a flexibility clause allowing signatory states (like the United States) to use discretion in issuing medical certificates. U.S. regulation refers to this discretion as special issuance, whereas ICAO standard refers to it as ''accredited medical conclusion'' as follows:

1.2.4.9 If the medical Standards prescribed in [ICAO Annex 1] Chapter 6 for a particular license are not met, the appropriate Medical Assessment shall not be issued or renewed unless the following conditions are fulfilled:

(a) accredited medical conclusion indicates that in special circumstances the applicant's failure to meet any requirement, whether numerical or otherwise, is such that exercise of the privileges of the license applied for is not likely to jeopardize flight safety;

(b) relevant ability, skill and experience of the applicant and operational conditions have been given due consideration; and

(c) the license is endorsed with any special limitation or limitations when the safe performance of the license holder's duties is dependent on compliance with such limitation or limitations.

The ICAO Manual of Civil Aviation Medicine (Doc 8984) states:

The methods used to treat diabetic patients have improved over recent decades and individuals that require insulin to maintain satisfactory blood glucose levels may apply, or re-apply, for a license to fly or to undertake air traffic control work. Although Annex 1, 6.3.2.16 (and 6.4.2.16, 6.5.2.16 for Class 2 and 3, respectively) normally precludes certification of insulin-treated diabetic applicants for any class of Medical Assessment, several Contracting States permit such applicants to exercise license privileges, utilizing the flexibility Standard 1.2.4.9, and others may wish to consider doing so.

U.S. pilots flying under special issuance on U.S.-registered aircraft have always been recognized as ICAO-compliant. They have been accepted flying in airspace outside of the United States, just as the United States accepts foreign air carrier pilots with special issuance (including for ITDM) exercising pilot privileges within U.S. airspace.

[2] *Id.* at 11.

[3] The FAA notes that it may not condition the continued effect of any first-class medical certificate based on compliance with functional limitations. *See* 14 CFR 67.401(d)(4); *see also Delta Air Lines, Inc.,* 490 F. Supp. at 918–919 (finding the FAA cannot regulate, restrict, or place functional limitations on the cockpit duties an airline transport pilot may perform because it usurps the authority of the airline).

[4] As with all cases the FAA reviews, an authorization for special issuance will be based on a favorable determination that safety of flight can be maintained. *See* 14 CFR 67.401(a).

New FAA Protocol

Rationale for Considering ITDM Applicants Seeking To Exercise Higher-Rated Pilot Privileges

After extensive deliberation and careful consideration, the FAA has developed a new FAA ITDM protocol to allow special issuance, based on CGM technology, for any class of medical certificate for ITDM individuals who meet specific criteria. As discussed, several factors contributed to the FAA's decision to develop a new ITDM protocol: Input from the expert medical community; years of experience with private pilots being special-issued for ITDM; the 2015 CAMI study validating safety; the experience of other CAAs with no adverse impact on flight safety; medical advances in the treatment of diabetes; and maturation of CGM technology.

Individuals with ITDM seeking to exercise airline transport or commercial pilot privileges may submit an application via MedXpress for medical review and consideration. CGM use will be implemented for first- or second-class special issuance medical certification for ITDM applicants. As with all cases the FAA reviews, an authorization for special issuance will be based on a favorable determination that safety of flight can be maintained. Also, applicants for third-class special issuance may apply under the existing protocol or the new CGM-based protocol.

Interested applicants should work with their Aviation Medical Examiner, appropriate medical specialists (endocrinologist, cardiologist, ophthalmologist, etc.), and the FAA to coordinate submission of the appropriate documentation needed for consideration. For consideration, potential applicants will need to demonstrate stability and adequate control of ITDM using CGM technology for a minimum of at least 6 months. In keeping with 14 CFR 67.413 requirements to provide the FAA with medical history to ensure appropriate fitness for flight, applicants applying for the new protocol must be able to provide the following:

(1) Initial comprehensive report from the treating, board-certified endocrinologist
(2) Initial comprehensive laboratory panel
(3) Finger-Stick Blood Sugar (FSBS) glucose monitoring data
(4) Continuous Glucose Monitoring (CGM) data for at least the preceding 6-month period (using a device legally marketed in the United States in accordance with Food and Drug Administration requirements and containing protocol-specific features needed for appropriate in-flight monitoring.).
(5) Excel spreadsheet or similar that identifies CGM data for all flights for the past 6 months and any actions taken to address low or high glucose levels.
(6) Eye evaluation (from a board certified ophthalmologist)
(7) Cardiac risk evaluation (from a board certified cardiologist)

For more information, applicants interested in applying for an ITDM special issuance should consult the specific ITDM protocols, including CGM features needed for proper in-flight monitoring, by searching ''ITDM'' in the Guide for Aviation Medical Examiners at: *www.faa.gov/go/ITDM.*

Individuals who may have submitted an application to the FAA in advance of this announcement will be contacted if further information is needed to process their submission.

This notice is not legally binding in its own right and will not be relied on by FAA as a separate basis for affirmative enforcement action or other administrative penalty. Unless otherwise required by statute or regulation, conformity with the new protocol described here is voluntary only. Nonconformity will not affect rights or obligations under existing statutes and regulations.

Inviting Comments

The FAA is requesting comments on the new ITDM protocol described herein. The agency will consider comments received on or before January 6, 2020. The new ITDM protocol may be revised based on comments received.

Issued in Washington, DC, on October 30, 2019.

Michael A. Berry,

Federal Air Surgeon.

[FR Doc. 2019–24150 Filed 11–6–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2019–75]

Petition for Exemption; Summary of Petition Received; Elbe Flugzegwerke GmbH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before November 27, 2019.

ADDRESSES: Send comments identified by docket number FAA–2019–0565 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Michael H. Harrison, AIR–673, Federal Aviation Administration, 2200 South 216th Street, Des Moines, WA 98198, phone and fax 206–231–3368, email *Michael.Harrison@FAA.gov.*

This notice is published pursuant to 14 CFR 11.85.