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6. Abstract This document represents the outcome of a conference sponsored by the office of Motor Carriers to review the current medical standard covering commercial drivers with diabetes mellitus. The standard (49 C.F.R. section 391.41(b)(3)) permits qualification of individuals to drive a commercial motor vehicle if that person has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control. Four task force papers which carefully review the administrative rule with reference to advances in the care of diabetes since 1970 are contained in this report. The papers have been reviewed by the task forces and discussed at a plenary session. Following further in-depth discussion by members of the Steering Committee, these recommendations are made: 1. Certified commercial driven who develop diabetes mellitus after driving for five (5) Years and who require insulin therapy may continue to be certified On an annual basis if they meet certain criteria. 2. Persons with diabetes mellitus who use insulin and who have no demonstrated history of safety on the highway as commercial driven are not eligible for certification. 3. All persons with diabetes mellitus who do not require insulin therapy are eligible for certification as commercial driven unless disqualified by an organ complication of diabetes as defined under current Federal standards.					
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CONFERENCE
DIABETIC DISORDERS AND COMMERCIAL DRIVERS

EXECUTIVE SUMMARY

The Office Of Motor Carriers (OMC), Federal Highway Administration (FHWA) U.S. Department of Transportation (DOT), sponsored a conference on September 9 and 10, 1987 to review the current medical standards for truck driven with diabetes mellitus. Conference participants numbered twenty-four and included physicians and scientists experienced in the care of people with diabetes, and representatives from the motor carrier industry. The current standard (FHWA regulations, 49 C.F.R. section 391.41(b)(3), as published in the Federal Register on April 22, 1970) permits qualification of individuals to drive a commercial motor vehicle if that person has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control. There is no provision for a waiver of the minimum physical requirement with respect to the individual with insulin-taking diabetes in the Federal Motor Carrier Safety Regulations.

The administrative rule applied to the commercial driver with diabetes mellitus was reviewed as are the many advances in the care of diabetes accrued since 1970. After careful review by four task forces, discussion at a plenary session, and following further in-depth discussion by members of the Steering Committee, the following recommendations are made:

- 0 Certified commercial drivers who develop diabetes mellitus after driving for five (5) years and who require insulin therapy may continue to be certified if they meet the particular criteria:
 - Absence of recurrent hypoglycemia that results in ~~IOU~~ loss of consciousness or seizure;
 - Absence of seizure or coma without antecedent prodromal symptoms of hypoglycemia;
 - Absence of recurrent diabetic ketoacidosis or hyperosmolar non-ketotic coma; and
 - Documentation of regular medical followup.
- 0 Persons with diabetes mellitus who use insulin and who have no demonstrated history of safety on the highway as commercial drivers are not eligible for Certification.
- 0 All persons with diabetes mellitus who do not require insulin therapy are eligible for certification as commercial drivers unless disqualified by an organ complication of diabetes as defined under current Federal standards.

- o For those drivers who use insulin, a careful history and physical examination will be recorded on a standardized form by a physician with subsequent review and evaluation of this status by a diabetes specialist.

Following this evaluation, the completed form is forwarded to a Medical Advisory Board (MAB) of the FHWA which makes a recommendation to the Director within the Office of Motor Carriers with regard to certification. The MAB will include physicians experienced in the care of people with diabetes. An appeal mechanism is suggested. Following the initial certification, annual waiver renewal will be required. Mechanisms for monitoring the compliance of the commercial driver who uses insulin and subsequent recertification are recommended. These means include review of violation and accident rates when possible, glycemetic logs and driving logs, and evidence of attendance at an acceptable formal diabetes education Program. These data will be reviewed by an MAB annually at the time of waiver renewal.

The conference members are pleased to recommend to the DOT that certified commercial drivers requiring insulin for diabetes management be considered eligible for continued certification while emphasizing the initial eligibility for drivers who develop diabetes requiring insulin therapy and who have proven safety skills as commercial drivers, the conferees encourage the DOT to accrue prospective data on these drivers after certification. These data will facilitate reevaluation of these recommendations after a suitable period of time to study the feasibility of including the person with insulin-taking diabetes who wishes to become a commercial driver.

Additionally, it is recommended that

- * All drivers with diabetes should have annual examinations for visual impairment, neurological function, and cardiovascular disease (including hypertension).
- o If poor control of the diabetic state based on the suggested guidelines of the American Diabetes Association exists, certification will be deferred until control is improved:
- o Drivers taking oral agents should be informed about possible interactions of these drugs with other medications they may be taking and about possible hypoglycemic risk associated with missed meals.

TASK FORCE I REPORT: DIABETES MELLITUS WITHOUT INSULIN

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DIABETES MELLITUS WITHOUT INSULIN

Background

In the United States, most of the individuals with diabetes mellitus who do not take insulin fall into the category of Type II or noninsulin-dependent diabetes mellitus (NIDDM) as defined by the National Diabetes Data Group. The majority of these individuals are obese, have a family history of diabetes, and frequently are asymptomatic. Many remain asymptomatic for years and the disease process progresses to a more severe form slowly. If at all, individuals with NIDDM are usually over forty years of age, although a form of this disorder may appear in adolescents or young adults (maturity-onset diabetes of youth or MODY). Individuals with diabetes mellitus who do not require insulin are not prone to ketosis and are unlikely to develop ketoacidosis. Circulating insulin levels in this group of patients may be normal, relatively or absolutely low, or even high when compared to the corresponding blood glucose. When patients with NIDDM are stressed by infection, myocardial infarction, trauma, heat, humidity, general fatigue, or job-related stresses, insulin therapy may be required to control the metabolic abnormalities. Often such insulin therapy can be discontinued when the stressful situation subsides.

The etiology of NIDDM involves the interplay of environmental factors superimposed upon a genetic susceptibility. Overeating and obesity are the major environmental factors. Some degree of insulin resistance characterizes all noninsulin-dependent patients. Medical treatment of the noninsulin-taking patient involves dietary regulation, exercise, with or without the administration of oral hypoglycemic agents.

The chronic complications of diabetes mellitus, namely, large blood vessel disease (macroangiopathy) and small blood vessel disease (microangiopathy), as well as involvement of the peripheral and autonomic nervous system and precocious appearance of cataracts, occur in people with noninsulin-taking diabetes as well as in those requiring insulin. In a report from the Carter Center at Emory University, the prevalence of noninsulin-dependent diabetes in the United States was stated as 5,069,000. However, surveys suggest that almost double that number of individuals have undiagnosed diabetes or impaired glucose tolerance. Of individuals in the United States with diabetes, between 85-90 percent fall into the category of noninsulin-dependent diabetes of whom approximately one-third (1.5 million) require insulin therapy.

Currently, the regulatory criteria specify the examination guidelines that apply to commercial motor vehicle drivers with diabetes. The actual medical standards are found in Federal Motor Carrier Safety Regulations (49 C.F.R. section 391.41). These criteria state:

- o Anyone with an established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control is prohibited from driving a commercial bus or truck in interstate traffic or foreign commerce.
- o If the diabetes can be controlled by the use of oral medication and diet, then an individual may be qualified under the present rule.
- o Persons with an arm, foot, or leg which interferes with the ability to perform normal tasks associated with operating a motor vehicle are unqualified to drive a commercial motor vehicle unless they apply for and are granted a waiver.

- o Persons with established neuromuscular or vascular disease which interferes with their ability to control or operate a motor vehicle safely may not be certified to operate a commercial motor vehicle in interstate commerce.
- o Persons with visual acuity with correction that is less than 20/40 in each eye separately may not be certified to operate a commercial motor vehicle in interstate commerce.

Hypoglycemia

The major reason for the exclusion of people with insulin-treated diabetes mellitus (IDDM) from receiving permission to drive commercial vehicles in interstate traffic has been the concern for hypoglycemia and its consequences--particularly if hypoglycemia occurs without warning. Hypoglycemia is rare among diabetic patients not taking insulin. The most frequent cause of hypoglycemia in such patients relates to the use of oral hypoglycemic agents. In the United States, the only oral hypoglycemic agents available are members of the sulfonylurea family. One group of these agents has been available in the United States since 1955 and comprises "the first generation compounds"; the second group, available in the United States since 1983, are known as "second generation compounds." In all instances, the basic chemical structure of the compounds is similar.

Although relatively rare, hypoglycemia can be a complication of oral agent therapy. The longer-acting agents, chlorpropamide and glyburide, have a greater hypoglycemic potential but any oral agent may produce hypoglycemia. Elderly people with diabetes are particularly susceptible to hypoglycemia from these agents. Renal or hepatic disease or congestive heart failure also potentiate these agents. In addition to these various abnormal clinical states, the effects of the sulfonylurea drugs may be potentiated by other drugs including sulfonamides, salicylates, and pyrazolone derivatives such as phenylbutazone. The duration of sulfonylurea action is prolonged by the anticoagulant, dicumarol and the antibiotic chloramphenicol. Salicylates, beta-adrenergic blocking agents, as well as alcohol may enhance the hypoglycemic effects of the sulfonylureas. Irregular meals or excessive physical activity also can be associated with hypoglycemia.

Currently regulations that affect interstate commercial drivers do not mention oral hypoglycemic agents or, in fact, those pharmacological agents that might potentiate their action. To this end:

- o Physicians examining applicants with diabetes should take a detailed medical history and record whether the individuals are taking oral hypoglycemic agents and/or other compounds that may augment the effects of such agents.
- o Federal guidelines should require that informational material be given drivers taking oral hypoglycemic agents to inform them of the consequences of missed meals and the effects of other pharmacological agents on the duration of action of the sulfonylureas.

Hyperglycemia

Poor diabetic control can lead to fatigue, lethargy, and sluggishness. Any and all of these symptoms may be detrimental to a driver of an interstate vehicle. Current guidelines require the examining physician to assess the level of diabetic control, but no definitive

guidelines are provided. Guidelines suggested by the American Diabetes Association for varying degrees of control are:

I TABLE I-I: Biochemical Indices of Metabolic Control: Top Limits

<u>Biochemical Index</u>	<u>Normal</u>	Acceptable	Poor
Fasting plasma glucose	115	140	~200 mg/dl
Postprandial (2-hr) plasma glucose	140	200	>235 mg/dl
Glycosylated hemoglobin	6	8	>10%

*Adjust for normal values of laboratory.

The status of a patient's 'control' needs to be reported. Certification of drivers demonstrating poor control by these guidelines should be deferred until diabetic control has improved. When improved control is achieved, full certification may be appropriate. For continued certification, driven with diabetes who do not use insulin are required to be reassessed (not recertified) by their own physician at a minimum of every six months.

Self-Monitoring of Blood Glucose

Self-monitoring of blood glucose levels is an important adjunct in the management of noninsulin-requiring diabetes. Regular monitoring as advised by their personal physician is strongly encouraged as an indicator of metabolic control.

Complications

Retinopathy and Eye Disease

Fifty percent of all patients with diagnosed diabetes mellitus for ten years or more have some element of diabetic retinopathy. Since the duration of diabetes mellitus in the patient with NIDDM is often unknown, patients with this form of diabetes mellitus should receive regular funduscopic examinations. Background retinopathy with microaneurysms and intraretinal hemorrhages is common after 5-7 years of diabetes mellitus. In many cases, the retinopathy does not progress beyond this stage. However, visual impairment in patients with background retinopathy may be due to a macular edema and/or hard exudates in the proximity of the macula. Hard exudates are usually detected by direct ophthalmoscopy while macular edema may require slit lamp examination.

For certification

- o All applicants with diabetes should be evaluated by an ophthalmologist (or should receive a careful eye exam by their physician).
- o Any major decrease in visual acuity in the patient with diabetes mellitus also warrants ophthalmological evaluation.

- o Followup, depending on the degree of eye pathology, should be at the discretion of the ophthalmologist.

Neuropathy

Many physical and mental demands are placed upon drivers of trucks and buses. These drivers use perceptual and manipulative skills to apply brakes, shift gears, and perform the other driving tasks that are associated with large vehicles. The presence of peripheral neuropathy may hinder the ability of a driver to perform such routine tasks. Severe deficits involving the extremities, characteristics of diabetic neuropathy may impair response time in the application of brakes or the adjustment of foot movements on the accelerator. A careful neurological examination to assess the driver's qualifications under regulation 49 C.F.R. section 391.41(b)(2) and (9) should be performed with each certification examination.

Macrovascular Disease

Accelerated atherosclerosis is a major complication of diabetes involving the coronary, cerebral, and peripheral vessels. People with diabetes mellitus have an increased incidence of cardiovascular disease compared with nondiabetic individuals and are twice as likely to die of coronary disease. People with diabetes also have a higher incidence of 'silent' or painless myocardial infarctions than nondiabetic people. As with those individuals with insulin-taking diabetes, every person with noninsulin-taking diabetes mellitus should be required to have an electrocardiogram biennially. If cardiovascular disease is detected the regulatory criteria for cardiovascular disease (49 C.F.R. section 391.41(b)(4)) should be followed. Since hypertension is a major risk factor in diabetes and its complications, blood pressure values exceeding 160 mmHg systolic and 90 mmHg diastolic requires evaluation and therapeutic intervention. Followup should be in accordance with regulation 49 C.F.R. section 391.41(b)(6) and its criteria.

TASK FORCE II REPORT: DIABETES MELLITUS WITH INSULIN

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DIABETES MELLITUS WITH INSULIN

Our charge is to determine if overriding concerns for safety on the highways of America will be endangered by allowing individuals with insulin-treated diabetes mellitus (ITDM) to engage in careers as commercial drivers in interstate commerce. Regulatory decisions depriving large classes of citizens of their right to pursue gainful employment should be based upon data demonstrating danger or risk in excess of that already accepted. To be fair to all parties, we must avoid making recommendations based upon anecdotes not reflective of the community at large.

This task force report will approach the issue of certification of persons with ITDM as interstate commercial drivers. We will first review the historical experience of drivers with diabetes, followed by a risk analysis of the effects of certification relative to accident rates. Possible means of reducing these risks will be reviewed, and comparison to current accident rates will be made.

At the present time, the Federal Motor Carrier Safety Regulations section 391.41(b)(3) specifically excludes from certification to drive a commercial motor vehicle in interstate commerce any individual with 'an established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control'... (April 22, 1970). Because of this ruling, there are no U.S. data concerning accident rates among ITDM interstate commercial drivers. Although not strictly comparable, it may be useful to examine studies of outcomes of licensure of ITDM general driven. It must be remembered, however, that commercial drivers are exposed to variable road and weather conditions and irregular hours. Their driving exposure is five times the exposure of a non-commercial driver. These studies of the general driving public with ITDM additionally, are flawed by selection bias, ascertainment bias, or the absence of control data and report widely discrepant results in rates of traffic violations, accidents, and hypoglycemia. Furthermore, the contrast in size and weight between a commercial motor vehicle and a private automobile is sufficiently large to question the wisdom of applying data from studies of the general driving public to commercial vehicle driving.

Table II-1 summarizes several of these studies performed worldwide.

TABLE II-1: Literature Review of Diabetic Drivers

STUDY	VIOLATION RATE		ACCIDENT RATE	
	CONTROL	DM	CONTROL	DM
Ysander n-256 ITDM	15.3%	11.7%	7.7%	5%
Waller n-2612 ITDM	3.3/10 ⁶ mi	4.6/10 ⁶ mi	87/10 ⁶ mi	155/10 ⁶ mi
Davis	26.4%	37%	7.1/100 8.7/100 4.8/100	7.4/100 both 9.2/100 males 4.7/100 females
Crancer & Murray	81/100 116/100	73/100 99/100	27.6/100 36/100)	31.4/100 both 41/100 males

As can be seen, ITDM drivers have been reported to have a 23.5% reduction (Ysander et al.) or a 40% increase (Davis et al.) in traffic violation rates as compared to controls. Likewise, accident rates are reported as 35% reduced (Ysander et al.) or 78% increased (Waller et al.) in ITDM drivers. Although as many as 76% of ITDM drivers report hypoglycemic reactions (Michigan DRTC), the frequency of these reactions resulting in a traffic accident is approximately 12% (Frier). Hypoglycemia, however, may play a role in less than one out of every 10,000 traffic accidents (Arnold, Herner, and Gratton). These data illustrate the difficulty in drawing conclusions concerning the effects of certifying people with ITDM for driving commercial vehicles.

Even in those countries that currently permit limited certification of commercial drivers with ITDM (i.e., United Kingdom, Denmark, Norway, Finland, Sweden, and Canada), we are aware of no data concerning their safety record. As a result, we cannot depend upon precedent to make our recommendations. Therefore, the remainder of this report will assume limited certification of people with ITDM for commercial driving and estimate its potential impact on accident rates as determined by risk analysis.

The exact number of people with ITDM who would seek medical certification is unknown. In order to conduct this analysis, two assumptions have been made: 1) that the prevalence of individuals with ITDM seeking certification will be the same as the general population; and 2) a substantial number of ITDM applicants will be excluded as a result of concurrent medical limitations such as ophthalmological, renal, cardiac, or cerebrovascular disease.

The age group eligible for certification includes individuals from age 20 to over 65. Our subsequent calculations omit six percent of drivers who are 65 and older. The National Health Interview Survey has identified 854,000 people with diabetes in the age group 20-44 and 2.5 million people with diabetes in the age group 45-64. Of these, 46 percent and 22 percent, respectively, are insulin treated (Diabetes in America, 1985). The eligible population of people with ITDM would therefore be 948,000. Assuming that the same percentage of the eligible ITDM population as the general population would seek certification, one would anticipate 31,950 ITDM applications. The actual number of potential applicants that would be excluded because of associated medical conditions is unknown, but if we accept the assumptions made in the FAA Report, approximately 32 percent would be disqualified, leaving 21,726 individuals with ITDM who would be expected to be eligible and to seek certification for commercial driving. This would result in an increase in the pool of commercial drivers of 0.4 percent.

The effect of these additional drivers is the decisive factor in determining the advisability of granting medical certification. To what extent will ITDM drivers affect public safety by increasing accident rates? One may assume that ITDM drivers will share all of the accident risks of drivers who do not have diabetes, but we must also consider the additional risk engendered by insulin-induced hypoglycemia, the danger of which cannot be overemphasized. Even moderate degrees of hypoglycemia may impair color vision, prolong reaction times, slow cortical activity, and result in neuropsychological deterioration (Harrad; Herold; Pramming). At worst, hypoglycemia may result in loss of consciousness and even death.

There is no question that collapse due to severe hypoglycemia occurring at the wheel of a motor vehicle could result in a vehicular accident. Less severe reactions may have an unpredictable effect on a driver's ability to maintain control of a motor vehicle. For purpose of this analysis, we will assume that severe reactions will result in an accident

100% of the time, while a less severe reaction will increase the risk of an accident 10 fold (FAA Report).

Data concerning the incidence of hypoglycemic reactions are limited by under-reporting as well as by the selectivity and therapeutic intervention of the study group. In prospective studies of insulin therapy, such as the Diabetes Control and Complications Trial (DCCT), the accurate determination of the occurrence of hypoglycemic episodes is good, but the frequency may not reflect that of the general diabetic population. This study is limited to individuals with Type I diabetes and provides no data on the larger population of individuals with Type II insulin-taking diabetes. Retrospective community-based studies, such as those by Casparie and the Michigan Diabetes Research and Training Center (DRTC), may be more reflective of the general diabetic population, but may suffer similarly from ascertainment errors. Furthermore, definitions of degrees of hypoglycemia are not uniform. This is the probable reason for the wide disparity in frequency and prevalence of severe hypoglycemia between these two studies. Nevertheless, they provide an opportunity to calculate projected accident rates resulting from severe hypoglycemia on a best-are, wont-case basis.

A commercial driver spends approximately 1760 hours per year on the road (DOT), or 20.13% (1760 hours divided by 8760 hours yearly) of his or her time. The frequency of hypoglycemic reactions occurring while driving is therefore: (reaction/person/year) x 0.2013 = (reactions/person/year while driving). Since we assume an accident will result from a severe hypoglycemic reaction 100% of the time, then this calculation also yields accidents/person/year. There is no way of predicting the severity of an accident resulting from hypoglycemia and so all degrees of severity are combined. The projected accident rate per ITDM driver occurring as a result of a severe hypoglycemic reaction is shown in Table II-2.

TABLE II-2: Projected Hypoglycemic Reactions and Subsequent Accident Rates

STUDY	TYPE I PROJECTED		TYPE II PROJECTED	
	REACTIONS (per person/year)	ACCIDENTS (per person/year)	REACTIONS (per person/year)	ACCIDENTS (per person/year)
Mulhauser	0.19	0.038	-----	-----
DCCT intensive	0.54	0.109	-----	-----
conventional	0.17	0.034	-----	-----
Casparie	0.115	0.023	0.045	0.009
Hiss (Michigan DRTC)	1.7	0.342	1.3	0.26

We will assume that 10% of our eligible population are Type I and 90% are insulin-taking Type II individuals. Thus, severe hypoglycemic reactions would result in an increase in the number of accidents per year as determined by:

- 1) (accidents/Type I diabetic driver/year) x (number of Type I diabetic driven), and

2) (accidents/Type II ITDM driver/year) x (number of Type II ITDM driven)

Using data from Casparie and the Michigan DRTC projected ranges of accidents are as follows:

TABLE II-3: Projected Cumulative Accidents Per Year in Diabetic Drivers

<u>STUDY</u>	<u>TYPE I</u>	<u>TYPE II</u>	<u>TOTAL</u>
Casparie	50	176	226
Mich. DRTC	743	5084	5827

The effect of mild reactions on the accident rate is more difficult to calculate because the frequency of these reactions is more difficult to determine. The Michigan DRTC reports that 100 percent of people with Type I diabetes and 68 percent of people with insulin-treated Type II diabetes experience mild hypoglycemic reactions. If we assume that drivers with Type I diabetes experience 50 mild reactions per year, while 68 percent driven with insulin-taking Type II diabetes who have any reaction will experience 10 reactions per year, then;

- 1) 2173 Type I diabetic driven will have 108.650 mild hypoglycemic reactions yearly, and
- 2) 19.553 insulin-taking Type II diabetic driven will have 132.960 mild hypoglycemic reactions yearly.

The frequency of mild hypoglycemia occurring while driving is then:

(number of mild reactions/year x (1760 hours driving/8760 hours/year))

Thus, Type I driven could experience 21.730 mild reactions while driving and insulin-taking Type II drivers could experience 26,592 mild reactions while driving.

The Federal Highway Administration reports a general accident rate for 1985 of 39,273 accidents/5,000,000 drivers or 0.00785 accidents/driver/year. If mild hypoglycemia increases this risk 10-fold (FAA Report), then the frequency of an accident becomes 0.0785/driver/year.

The cumulative effects of both mild and severe hypoglycemia on vehicular accidents can then be summarized on Table II-4

TABLE II-4 Projected Cumulative Accidents Per Year Due to Hypoglycemia

<u>STUDY</u>	<u>Severe Reactions</u>		<u>Mild Reactions</u>		<u>Total</u>
	<u>Type I</u>	<u>Type II</u>	<u>Type I</u>	<u>Type II</u>	
Casparie	50	176	1	1	228
Mich. DRTC	743	5084	1	1	5829

The projected effect of certifying applicants with Type I diabetes would be the addition of 51-744 accidents per year due to both mild and severe hypoglycemia or an increase of 0.13-1.9%. Certification of all eligible applicants with insulin-treated Type II diabetes would result in 177-5085 additional projected accidents due to hypoglycemia or an increase of 0.4- 12.9%. The cumulative effect of certifying people with ITDM (see Table II-S) would be 228-5829 additional projected accidents due to hypoglycemia or an increase of 0.6-14.8%.

TABLE II-5: Projected Outcome of Certification of Diabetic Commercial Drivers

	General	Caspaie			DRTC		
	<u>Population</u>	<u>Type I</u>	Type II	Total	Type I	Type II	Total
Accidents/ year	39,273	(+031%)	(+04%)	(+06%)	744 (+1.9%)	5085 (+12.9%)	5829 (+14.8%)
Accidents/ driver/year	0.007	0.02 (+186%)	0.009 (+28.5%)	0.011 (+57%)	0.34 (+4757%)	0.26 (+3614%)	0.27 (+3757%)

This projected increase in accidents due to hypoglycemic events presumes no selection of ITDM drivers on the basis of glycemic control, history of unconscious hypoglycemic reactions, or participation in an education program. Recommendations for reducing the risks of hypoglycemia include self-monitoring of blood glucose together with insulin adjustment and education concerning the premonitory symptoms of hypoglycemia together with appropriate ingestion of rapid-acting carbohydrate for treatment. In addition, clustering of severe hypoglycemic reactions within a small percentage of a study population has been noted (DCCT), which may allow exclusion of those few individuals with ITDM who are responsible for the largest percentage of hypoglycemic reactions. Historical criteria, education, and specific forms of medical intervention may result in substantial lowering in the frequency of hypoglycemia and accidents consequent to it.

Complications related to acute hyperglycemia also may affect a driver's capability of operating a motor vehicle. Ketoacidosis and hyperosmolar states significantly impair cognitive function, but their onset is gradual and frequency is sufficiently low as to preclude any significant effect on accident rates. We will assume a negligible effect of acute hyperglycemia on diabetes-related accidents.

Recommendations

All entry-level applicants with ITDM seeking certification as interstate commercial drivers should be excluded. Currently certified interstate commercial drivers who develop ITDM or intrastate driven with established ITDM may be waived from exclusion, if they meet the following criteria during the insulin-takiig period prior to certification:

- o Absence of recurrent hypoglycemia resulting in loss of consciousness or seizure;
- o Absence of development of seizure or coma without antecedent prodromal symptoms; and

- o Absence of recurrent ketoacidosis.

in addition. individuals seeking a waiver must present documentation of regular medical followup and a regular monitoring system,

If these recommendations are adopted, we strongly recommend that appropriate procedures be introduced to determine accurately their impact (e.g., prospective data collection on certified driven with ITDM

Discussion

This analysis is limited by a number of uncertainties. These include:

- 1) Absence of consistent data on the frequency of hypoglycemia as reported in different studies;
- 2) Impact of hypoglycemia on accident rates;
- 3) Impact of various forms of diabetic management on incidence of hypoglycemia;
- 4) Effects of variable work hours and physical activity on hypoglycemia;
- 5) Ability to differentiate Type I from Type II diabetes in all individuals with insulin-taking diabetes;
- 6) Impact of acute hyperglycemia on accident rates; and
- 7) Unknown percentage of people with ITDM who would seek certification.

There are no historical precedents upon which to base a decision on certification of ITDM commercial drivers. Extrapolation from data on general drivers fails to show any consistent trend in accident rates between diabetic and nondiabetic drivers. The potential impact of hypoglycemia remains the critical factor in the ability of an individual with ITDM to operate a commercial motor vehicle.

There appears to be a consistency in the frequency of hypoglycemia as reported by Mulhauser, Casparie, and the DCCT (standard treatment group) (see Table II-2). Based upon a review of these data, it appears that certification of medically screened drivers with ITDM will not likely have a marked impact on accident rates. Although the Michigan DRTC data would project a much larger impact, their data appear to be inconsistent with published data from several other sources.

Furthermore, the projections of the number of applicants with ITDM seeking certification is based on the distribution of the general population. We believe this projection may fail to accurately estimate the actual number who would seek certification. The number of ITDM certified should gradually increase related to previously certified drivers who develop ITDM and their required recertification as an ITDM driver or for those intrastate ITDM drivers who seek certification for interstate driving.

In order to preserve public safety and the livelihood, health, and well-being of currently certified drivers who develop a need for insulin therapy, we have proposed a system that would allow drivers with insulin-treated diabetes to apply for a waiver.

Current regulations preclude all ITDMs from certification as interstate commercial drivers. The proposed waiver system would allow those currently certified drivers who develop ITDM to be waived from exclusion if they meet specific criteria and comply with the required monitoring program as outlined in our recommendations. These drivers will have proven themselves as competent operators and will understand the life style demands

when driving a commercial vehicle. Their experience and maturity as commercial drivers should permit the addition of insulin therapy without substantial alteration of risk.

The uncertain impact of ITDM on the driving record of the commercial motor vehicle operator together with the unproven ability of an entry-level driver persuade us to recommend the current exclusion of these latter individuals at this time. Demographics suggest that this restriction would have a limited impact. If subsequent data reveal the substantial safety of driven with ITDM, we envision the inclusion of entry-level ITDM drivers at a future time. Based on previously recorded statistics, some 6000 ITDM entry-level drivers might be affected by this exclusion. We believe this stepwise approach to the introduction of ITDM driven into the commercial driving pool to be prudent in respect to public safety.

Performance criteria including job assessments by supervisors, glycemic logs, and violation and accident rates on all certified ITDM drivers should be maintained in a prospective fashion on a yearly basis. These data should be available under the monitoring and recertification systems proposed by task forces 3 and 4 and should be used to assess the impact of these revised regulations. At an appropriate time in the future, these data will serve as the basis for further rulemaking in regard to commercial motor vehicle drivers with ITDM.

Bibliography

- Arnold D.R. 'Driving License Problems in Diabetics; Rules, Frequency Of Accidents and Legislation,' *Diabetes Care* June 1985, 147(24): 1951-1955.
- Campbell E. Ellis, KG. "Chronic Medical Conditions and Traffic Violations and Accident Experience of Diabetic Drivers," *Diabetes Care* November 1969 Vol. 24 No. II, 29-31.
- Casparie A.F., Elving L.D. "Severe hypoglycemic in Diabetic Patients: Frequency, Causes, Prevention," *Diabetes Care* March-April 1985 8(2): 141-145.
- Clarke B., Ward J.D., Enoch B.A. "Hypoglycemia in Insulin-Dependent Diabetic Drivers," *Medical Clinics of North America* August 1980. 281(6240):586.
- Craner A., McMumay L. 'Accidents and Violation Rates of Washington's Medically Restricted Drivers,' *Journal of the American Medical Association* 1968. 205: 272-276.
- Davis T.G., Wahling E.H., Carpenter R.L. 'A Study Of Selected Medical Conditions of Oklahoma's Medically Restricted Drivers;' *Journal of Oklahoma State Medical Association*, 1973. 66:322-327.
- Frier B.M., Steel J.M., Matthews D.M., Dorman L.J.P. 'Driving and Insulin-Dependent Diabetes.' *Lancet*, June 7, 1980, 1232-1234..
- Gratton E., Jeffcoate G.O. 'Medical Factors and Road Accidents,' *Diabetes Care* Journal, 1968, 1: 75-79.
- Harrad R-A., Cockram C.S., Plumb A.P., Stone S., Feowick P, Sonksen P H 'The Effect of Hypoglycemia on Visula Function a Clinical and Electrophysiological Study,' *Science*, 1985, 69: 673-679.
- Herner B., Smedley, Ysander L. "Sudden Illness as a Cause of Motor Vehicle Accidents," *British Journal of Industrial Medicine*, 1966,23:37-41.
- Herold KC., Polonsky K.S., Cohen R.M., Levy J., Douglass F "Variable Deterioration in Cortical Function During Insulin-induced Hypoglycemia," *Diabetes*, 1985 34: 677-685
- Hiss R.G., Lengyel M.C. 'Diabetes in Communities,' Michigan Diabetes Research and Training Center and Department of Postgraduate Medicine and Health Professions Education, University of Michigan Medical School, Ann Arbor. Michigan, 1986.
- Mulhauser I., Berger M., Sonnenberg G., Koch J., Jorgens V., Schernthaner G Scholz v Padagogio O. 'Incidence and Management Of Severe Hypoglycemia in 434 'Adults with Insulin-Dependent Diabetes Mellitus,' *Diabetes Care* 1985 May-June, 8(3): 268-273.
- National Diabetes Data Group -Diabetes in America Diabetes Data compiled 1984 * US Department Of Health and Human Services, DHS, NIH, NIDDK,NIH Publication No 85-1468, August 1985.

- Pramming S., Thorsteinsson B., Theilgaard A., Pinner E.M., Binder. C. "Cognitive Function During Hypoglycemia in Type I Diabetes Mellitus British Medical Journal, 1986, 292: 647-650.
- The DCCT Research Group. "Diabetes Control and Complications Trial (DCCT)," Diabetes Care, January-February 1987, 10(1): 1-19.
- U.S. Department of Transportation. Federal Aviation Administration. "Guide for Aviation Medical Examiners." October 1981.
- Waller J.A. 'Chronic Medical Conditions and Traffic Safety. Review of the California Experience,' New England Journal of Medicine - 1965 273(26): 1413-1420.
- Ysander L. Sick and Handicapped Driven.' ACTA Otolaryngologica Scandinavica 1970 Supplement, i-82.

TASK FORCE III REPORT: MEDICAL CERTIFICATION SYSTEM

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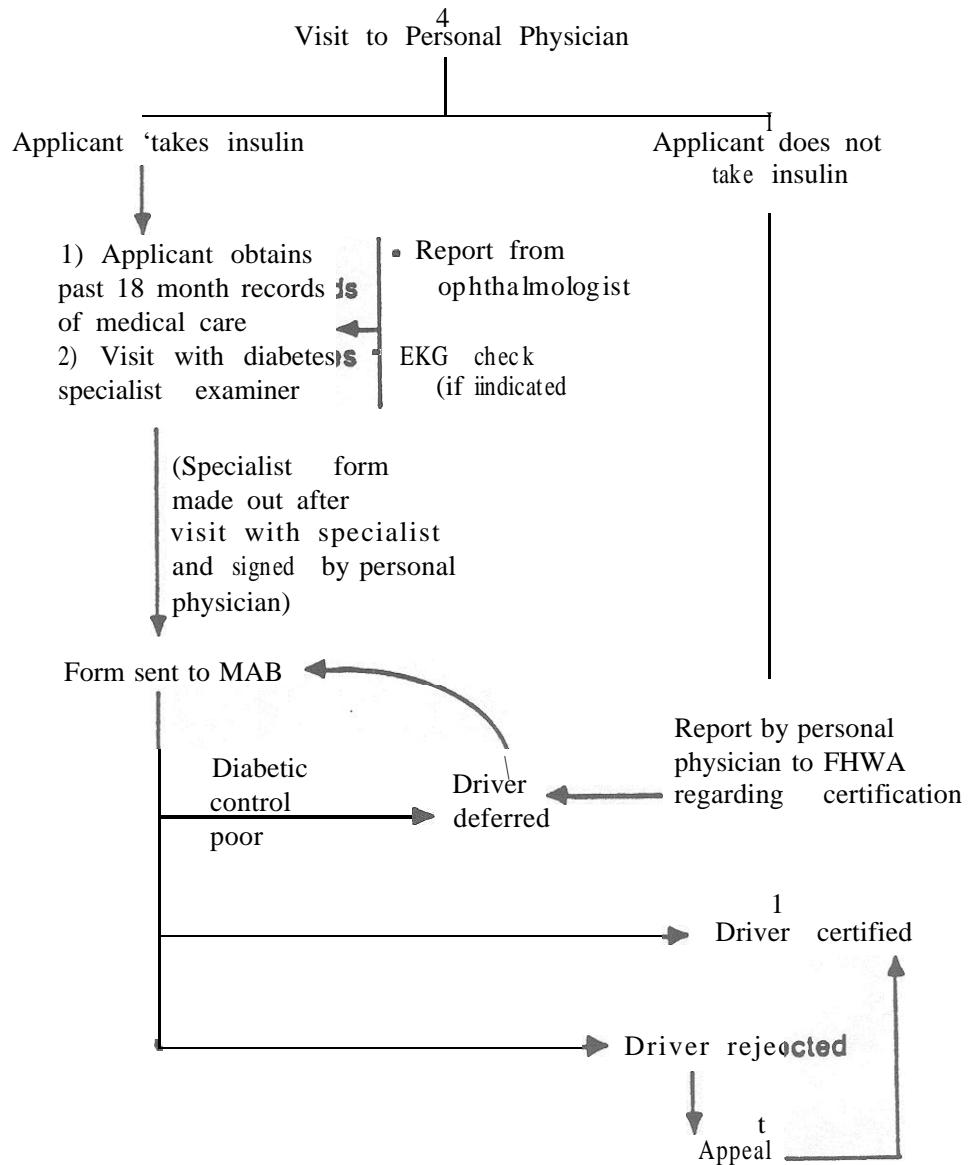
Dr. Karl Sussman

MEDICAL CERTIFICATION SYSTEM

If people treated with insulin are to be certified for commercial interstate driving, it is of utmost importance to ensure that certification is done under conditions that will minimize the likelihood that the presence of diabetes would interfere with the safe performance of their job. No distinction should be made between insulin-dependent diabetes and insulin-treated diabetic individuals. The best assurance that individuals requiring insulin therapy will perform their job in a safe fashion would be the institution of an appropriate medical evaluation system (see Table III-I).

TABLE III-I: Medical Evaluation System

Driver with Diabetes Desires Certification



The system should involve an initial examination and evaluation of the applicant by any licensed physician of the applicant's choice as is currently the procedure. This physician will complete the appropriate standardized form that is used by all applicants. In addition, if the applicant is being treated with insulin, he will be evaluated by a diabetes specialist, who will fill out the more detailed form (Table III-2) as well as review the job performance characteristics form submitted by the applicant (Table III-3). The applicant signs this form verifying the accuracy of the historical information. Even if the initial examination is provided by a diabetes specialist, this does not eliminate the second examination by another diabetes specialist. An eye examination should be performed by an ophthalmologist within three months of submission of the application. A copy of the eye examination as well as the completed form is then returned to the initial examining physician, who countersigns it. All of these medical forms are then submitted to a Medical Advisory Board of the DOT, which should include physicians who are experienced in diabetes and its complications, but should not necessarily be limited to such individuals. The Advisory Board's recommendation to the Director could be for medical certification or disapproval. In addition, the Advisory Board could request further information before making a recommendation.

The evaluation by the diabetes specialist should address those areas and risk factors that might make the individual with insulin-treated diabetes more susceptible to being involved in traffic accidents. While the major concern is the development of hypoglycemia, the control of the diabetes and the presence of diabetic retinopathy and neuropathy also must be considered. The evaluation should also include an assessment of the individual's knowledge of diabetes and the adequacy of self-management of the disease. This information includes the individual's knowledge of the symptoms of hypoglycemia, the ability to recognize, avoid, and treat insulin reactions, and the frequency, severity, and conditions under which he has experienced hypoglycemic reactions. The frequency of self-blood glucose monitoring and the results obtained should be ascertained. Information should be obtained as to whether the applicant has a source of carbohydrate on his person at all times. Information should be obtained relative to diet, frequency of meals and snacks, and, if available, a meal plan. The diabetes specialist should assess the applicant's diabetic control based on blood glucose and hemoglobin A_{1c} determinations done during the previous year. The hemoglobin A_{1c} values must have been analyzed by a certified laboratory. The individual must provide evidence that he has satisfactorily completed an acceptable diabetes education course within the past three years. He should also visit his physician at least four times a year and have his blood glucose and hemoglobin A_{1c} measured at that time. While persistent hyperglycemia would avoid the potential problems of hypoglycemia, this is not an appropriate approach to the problem since an individual with the poorly controlled diabetes may be more susceptible to the long-term complications of diabetes and may have other symptoms that impair his ability to drive safely in interstate commerce. Persistent hyperglycemia may be the basis for denial of certification.

The actual physical examination would include very specific items and would focus on those areas most likely to impair the individual's ability to drive safely. The eye examination would assess visual acuity, presence of lenticular opacities, and a careful examination of the retina for evidence of any indication of diabetic retinopathy or macular edema. The presence of microaneurysms, exudates, or other findings of background retinopathy, by themselves, would not be sufficient grounds for disqualification unless visual acuity is lowered and prevents the candidate from meeting current visual standards. However, individuals with active proliferative retinopathy or vitreous hemorrhages should not be certified. If proliferative retinopathy has been successfully treated with photocoagulation and the condition is stable with adequate visual acuity as evaluated by the ophthalmologist,

the individual could be certified to drive in interstate commerce. Adequate visual acuity is defined in 49 C.F.R. section 391.41(b)(9)(10).

The neurologic examination should evaluate the sensory modalities of pain, light touch, Position, and vibratory sensation in the toes, feet, fingers, and hands. Motor strength should be tested as well as assessment of the presence of autonomic neuropathy. The blood pressure and pulse rate should be obtained lying and standing and the variation of the heart rate with respiration should be determined.

In view of the Progressive nature of the complications of diabetes, the individual should be recertified once a year.

This system should also include provisions for an appeal of the decision of the Director. The appeal would be made to the Associate Administrator for Motor Carriers in accord with the administrative procedures of 49 C.F.R. section 386.

TABLE III-2: Medical Evaluation Form

This form is to be completed by a Diabetes Specialist.

Form for Medical Evaluation
of Insulin-Taking Diabetic Individual for Certification
to Drive Commercial Motor Vehicles in Interstate Commerce

Applicant's Name _____ Date _____

Address _____ Date of Birth _____

Job Description of Applicant

Type of commercial motor vehicle generally driven _____

How many hours of consecutive driving daily _____

How many hours On duty not driving daily _____

Loads or unloads the vehicle YES _____ NO _____

Average annual mileage driven in a commercial motor vehicle _____

Other Information: _____

Diabetes History

Date of diagnosis and presenting symptoms _____

Number of hospitalizations for diabetes and reasons during the past two years _____

Does the individual know the symptoms of hypoglycemia?

YES _____ NO _____

If the individual has hypoglycemic reactions, does he/she recognize them?

YES _____ NO _____

Does the individual have an explanation for hypoglycemia?

YES _____ NO _____

Patient Name _____

If yes, what is it? _____

How does the individual treat his/her hypoglycemia? _____

Number of hospitalizations for hypoglycemia in past YEAR: (Hospitalization implies overnight admission to the hospital; an emergency ward visit that did not result in hospitalization does not apply.) _____

If any, give specific reasons: _____

Number of emergency ward visits for hypoglycemia in past YEAR _____

If any, give specific reasons: _____

How many times during the past YEAR did the patient experience hypoglycemia of such severity that the patient

a) lost consciousness without seizure? _____

b) lost consciousness with seizure? _____

How many times during the past YEAR did the patient experience hypoglycemia of such severity that the patient required professional medical assistance, including placement of an IV or an intravenous injection of glucose? _____

How many times during the past YEAR did the patient experience hypoglycemia of such severity as to require the assistance of another person, such as the administration of parenteral glucagon, but not require any of the assistance described above? _____

How many times during the past YEAR did the patient experience hypoglycemia of such severity as to require the assistance of another person but did not require any of the help described above? _____

How many times during the past MONTH did the patient experience hypoglycemia which was mild enough for the patient to treat himself/herself? _____

What is the total number of times EVER that the patient has lost consciousness due to hypoglycemia? estimate _____

Has the patient experienced more than two hypoglycemic seizures and/or coma during the past two years? YES _____ NO _____

Does the patient have a history of recurrent hypoglycemic episodes resulting in cerebral impairment (e.g., coma, severe confusion, seizure) before the development of warning symptoms of hypoglycemia (e.g., excessive sweating, tremors etc.)?

YES _____ NO _____

Patient Name _____

Routine Diabetic Care

Insulin Treatment

Types, amounts, and times of injections _____

Diet (total number of calories, distribution of carbohydrate, protein and fat, time and number of meals and snacks/day. If available, a copy of meal plan. _____

Glucose Monitoring YES _____ NO _____

- a) On the average, how many times per week does the patient monitor his/hers * urine for glucose? (IF ZERO, WRITE 00) _____
- b) On the average, how many times per week does the patient monitor his/her blood for glucose? (IF ZERO, WRITE 00) _____
- c) Does the patient adjust his/her insulin dose based on the results of self-blood glucose monitoring YES _____ NO _____

Results and times of blood glucose tests during last six months including self-monitored glucose determinations) _____

Number and results of hemoglobin A_{1c}, determinations during the previous year (give normal values for the laboratory) _____

During the past 18 months how many routine, scheduled physician visits did the individual have for diabetes care? _____

Date of attendance, address, and telephone number of the diabetes education programs _____

Other medications _____

Patient Name _____

Comment on review of 18 month's data from personal physician _____

Physical Examination

Height _____ Weight _____

Supine blood pressure Systolic _____ Diastolic _____ Pulse _____

Standing blood pressure _____ Pulse _____

EYE EXAM (see attached ophthalmologic report)

Distant Visual Acuity:

	Uncorrected-	
Right	_____	_____
Left	_____	_____
Binocular	_____	_____

	<u>RIGHT</u>		<u>LEFT</u>	
	<u>Normal</u>	<u>Abnormal</u>	<u>Normal</u>	<u>Abnormal</u>
Extraocular muscles	_____	_____	_____	_____
Pupils	_____	_____	_____	_____
Cataract	_____	_____	_____	_____
Fundi	_____	_____	_____	_____

If abnormal, specify: _____

Cardiovascular system

	Regular	Irregular
Rhythm	_____	

	Absent	Present
Cardiomegaly	-	-
Murmurs	-	-

Patient Name _____

Peripheral Pulses:

- a) Indicate the grade of the peripheral pulses using the following scale for the right and left pulse.

	<u>RIGHT SIDE</u>			<u>LEFT SIDE</u>		
	<u>Normal</u>	<u>Diminished</u>	<u>Absent</u>	<u>Normal</u>	<u>Diminished</u>	<u>Absent</u>
Carotid	_____	_____	_____	_____	_____	_____
Radial	_____	_____	_____	_____	_____	_____
Femoral	_____	_____	_____	_____	_____	_____
Popliteal	_____	_____	_____	_____	_____	_____
Posterior Tibial	_____	_____	_____	_____	_____	_____
Dorsalis Pedis	_____	_____	_____	_____	_____	_____

- b) Indicate the presence or absence of bruits.

	<u>RIGHT</u>		<u>LEFT</u>	
	<u>Absent</u>	<u>Present</u>	<u>Absent</u>	<u>Present</u>
Femoral	_____	_____	_____	_____
Carotid	_____	_____	_____	_____
Other:	_____	_____	_____	_____

If present, specify. _____

Patient Name _____

Extremities

	<u>RIGHT</u>		<u>LEFT</u>	
	<u>Absent</u>	<u>Present</u>	<u>Absent</u>	<u>Present</u>
Ulceration	_____	_____	_____	_____
Skin discoloration		_____	_____	_____
Gangrene		_____	_____	_____
Charcot joint		_____	_____	_____
Deformity		_____	_____	_____

If present, specify: _____

Neurologic Examination

	<u>RIGHT</u>		<u>LEFT</u>	
	<u>Normal</u>	<u>Abnormal</u>	<u>Normal</u>	<u>Abnormal</u>
Pin-prick sensation	_____	_____	_____	_____
Light touch	_____	_____	_____	_____
Position sensation	_____	_____	_____	_____
Vibration sensation	_____	_____	_____	_____
Muscle strength	_____	_____	_____	_____
Ankle jerks	_____	_____	_____	_____
Knee jerks	_____	_____	_____	_____

Laboratory

CBC _____

	<u>Glucose</u>		<u>Protein</u>		<u>Sediment</u>	
	<u>Normal</u>	<u>Abnormal</u>	<u>Normal</u>	<u>Abnormal</u>	<u>Normal</u>	<u>Abnormal</u>
Urinalysis	_____	_____	_____	_____	_____	_____

Glucose _____ Sodium _____ Potassium _____ Creatinine _____

Bicarbonate _____ HgbA1c _____ Other _____

Date Performed _____

Patient Name _____

Please give your assessment of the individual's ability to operate safely a commercial motor vehicle _____

Physician's Signature _____

Physician's Name _____

Phone Number _____

Address _____

Certified Internal Medicine YES _____
Certified Endocrinology and Metabolism YES _____

I certify that information I have provided to the physician concerning my diabetes is accurate. Falsification of examination information may affect the final determination on medical certification.

Applicant's Signature _____ Date _____

Initial Examining Physician's Signature _____

Physician's Name _____

Phone Number _____ License Number _____

Address _____

TABLE III-3 Job Performance Characteristics Form

Few people outside the motor carrier industry fully appreciate the mental and physical demands placed on commercial drivers. Medical examiners should not apply automobile driving experience to evaluate the fitness of commercial driver applicants.

The physical demands of commercial driving and related tasks vary considerably with the type of vehicle and duties involved. To effectively match job demands with an applicant's ability to meet these demands, the examining physician must know the type of vehicle driven, job demands, and the environment involved.

This form is to be completed by a motor carrier official (preferably the applicant's immediate supervisor) and co-signed by the subject driver. The driver or motor carrier will then provide the original copy as part of the driver's waiver application.

The following is a universal job task description. Direct your attention to those boxes checked as pertinent to the particular driver.

A. Vehicle Type

- a. Straight Trucks - are used mainly for local pickup and delivery and may have up to five axles, utilizing van, flatbed, tank or dump bodies. Drivers may spend hours climbing in and out of the truck and loading and unloading cargo.
- i. Gross vehicle weight rating (GVWR) less than 10,000 pounds _____
- ii. GVWR between 10,000 and 26,000 pounds _____
- iii. GVWR greater than 26,000 pounds _____
- b. Tractor-Trailers - are used for both local and long haul operations and are comprised of a power unit (tractor) and one or more trailers. Assume a GVWR of greater than 26,000 pounds.
- i. Short-relay drives 4-5 hours to a turnaround point, exchanges trucks and drives back to the starting point.
- ii. Long-relay drives 8-10 hours, sleep for 8 hours and returns to the starting point.
- iii. Straight-through to destination, including coast to coast operations; typically is away from home for _____ nights at a time.
- iv. Sleeper-team drives constantly for 4 hours followed by 4 hours in the bunk while co-driver drives; typically is away from home for _____ nights at a time.

B. Environmental Factors

The particular driver may be subject to:

- a. Abrupt duty hour changes
- b. Sleep deprivation
- c. Irregular work/rest cycles
- d. Temperature and weather extremes
- e. Long trips without regular meals
- f. Short notice of assignment of run
- g. Tight delivery schedule
- h. Delay en route
- i. Other: _____

C. Physical Demand

Moderate physical activity levels are associated with commercial vehicle driving. Perceptual skills are needed to monitor the driving situation for relevant information. Manipulation skills are needed to turn the steering wheel, apply brakes and shift gears, etc. The demands imposed on the particular driver's sensory organs and musculoskeletal systems are briefly described below.

- Gear Shifting: the movement of the gear shift lever(s) requires moderate strength, timely coordination, and complex manipulation skills of the upper right and lower left extremity. This individual's vehicle will have a _____ speed manual transmission.
- Vehicle is equipped with a fully automatic transmission.
- Control of steering wheel requires strength, mobility and power grip of upper extremities while maintaining stability of trunk.
- Operation of break and accelerator pedal requires moderate strength, mobility and coordinated movement in lower extremities.
- Various tasks during driving, such as operating light switches, windshield wipers, directional signals, emergency lights and horn. etc.; requires moderate strength, mobility and manipulative skills of upper extremities.
- Backing and parking: requires good depth perception, strength and coordinated manipulative skills.

- Vehicle inspection: driver must evaluate the mechanical condition of the various vehicular system such as tires, brakes, suspensions, engines and cargo. Climbing, bending, kneeling, crawling, reaching, stretching, turning and twisting are essential for proper vehicle inspection.
- Cargo handling and inspection: drivers may be required to handle cargo, climb up and down perpendicular ladders, and enter/leave the cab or cargo body many times a day.
- Coupling and uncoupling: tractor-trailer drivers may hook up one or more trailers; this requires strength and full range of motion to climb, balance, turn, grip -and pu ll
- Mounting snow chains on tires requires pulling and lifting motions in the range of 35-90 pounds.
- Changing tires requires a combination of pulling, pushing and lifting motions in the range of 100-175 pounds.
- Vehicle modification(s) made for the particular driver are _____

Motor Carrier signature _____ Date _____
Company Official

Telephone Number

Driver signature _____ Date _____

Reviewed by:

Personal Physician _____ Date _____

DiabetesSpecialist _____ Date _____

TASK FORCE IV REPORT MONITORING, COMPLIANCE, AND RECERTIFICATION

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Dr. Donald Dawson
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MONITORING, COMPLIANCE, AND RECERTIFICATION

Recommendations for Annual Monitoring of Diabetic Status and Recertification Process

We recognize that individuals with diabetes treated with insulin are subject to acute and chronic complications that may interfere with their ability to drive commercial motor vehicles. These complications are hypoglycemia, retinopathy, cardiovascular disease, and neurological disorders. These conditions require careful and frequent monitoring by qualified health care personnel. Additionally, we recognize that diabetes care must also include a continuing program of education to promote maintenance of self-care, compliance to self-testing, and recognition of acute and chronic complications.

The introduction of waivers and the resulting need for medical surveillance mandates greater operational participation by the Federal Highway Administration in the certification and recertification of drivers.

Hypoglycemia

Whereas the detection and management of both hyperglycemia and hypoglycemia are important aspects of the overall medical management of a person with diabetes, the detection and management of hypoglycemia is more relevant to safety considerations in the certification of commercial motor vehicle drivers. A severe hypoglycemic reaction is defined as one in which the individual is so incapacitated that he/she is unable to take corrective action and, if driving, would be unable to maintain control of the vehicle. Estimates have been made of the frequency of serious hypoglycemic events in insulin-treated diabetes and extrapolated to the setting of commercial drivers. These estimates are inherently unreliable, however, since the assumptions involved are unverifyable. It is not known, for example, how many people with insulin-treated diabetes will choose driving as a profession or choose to remain driving. Nor is it known whether excluding people with known susceptibility to serious hypoglycemia will eliminate the risk of new serious hypoglycemic events. Therefore, while it is assumed that the risk of accidents due to serious hypoglycemia is present in ITDM, this risk cannot be quantified by currently available data but can be minimized by the recommended certification and recertification requirements.

Significant advances in the monitoring of blood glucose levels now make it possible to obtain accurate and reliable data pertaining to the level of metabolic control throughout the day. It is to be emphasized that a substantial percentage of hypoglycemic reactions occur without evidence of prodromal clinical signs. For all individuals with insulin-taking diabetes it is essential to monitor blood glucose levels at six hour intervals during work periods to reduce the chance of hypoglycemia.

Recent evidence has shown that many individuals with diabetes could obtain more accurate and reliable blood glucose data by using reflectance meters designed not only to measure blood glucose instantaneously but also to record these data for later recall. Such memory-based reflectance meters can store up to 330 glucose values with the time and date of each value. These data can be recalled by the patient or physician and used to determine how well-controlled he/she is throughout a single day, week, or month. Data from memory-based reflectance meters can be transmitted by home telephone modem to diabetes centers reducing the need for frequent office visits while permitting expert evaluation of glucose patterns. These reflectance meters can be purchased in 1987 for \$175 + \$225 with additional cost for the chemical strips which reflect the blood glucose level.

Processed by a microcomputer, data from the memory-based reflectance meter can also determine the periods of time when there is a pattern of hypoglycemia or hyperglycemia.

New methods of evaluating metabolic control using this technology have also been developed, which will help both patient and physician identify consistent patterns of hypoglycemia and hyperglycemia and suggest ways of improving treatment. These approaches may identify repeated hypoglycemic events and can quickly gauge whether a different treatment modality will be effective.

The combination of memory-based reflectance meters computer analysis and new means of interpretation will have the effect of reducing the likelihood of hypoglycemic and hyperglycemic events, by reinforcing appropriate patient performance and providing reliable and verified glucose data.

We recognize three methods for evaluating hypoglycemia:

- 0 Self-reported events during medical history determined by the following questions.

During the past year.

--Have You had emergency treatment for hypoglycemia (insulinreaction, low blood sugar loss of consciousness, confusion or other event), which may have been due to low blood sugar?

--Have you been treated by another person for a change in your ability to think clearly, for confusion, slurred speech, coma, or other evidence of hypoglycemia (insulin reaction, low blood sugar)?

--Have you had any episode of serious hypoglycemia such as confusion slurred speech, coma, or other change in mental status?

If the answer to any of the above is "yes," please provide details.

- o Verified blood glucose data from memory-based reflectance meters.

The availability of this technology to record permanently and verify glycemic patterns is available, although it would involve additional expense. If an ITDM driver is certified, it is recommended that he/she be required to maintain a verifiable glycemic log for all of the hours he/she is driving. This log should record blood glucose prior to driving and prior to each meal or every 6 hours using a memory-based reflectance meter technology so that an electronic record of date, hour, and glucose value (recorded every 6 hours) can be produced upon request. It is recommended that each insulin-taking diabetic driver who is certified be required to submit a driving log and glycemic log developed while driving for the entire year. Judgment concerning the significance of the glycemic log as it relates to serious hypoglycemia will be made by the DOT Medical Review Board.

- o DOT reportable accidents or other work-related accidents in which the ITDM driver is involved will be reviewed for possible relevance to hypoglycemic cause

The Federal Highway Administration should establish a review mechanism, through either in-house capacity of contact, to review medical history, glycemic logs, and accident history to determine if serious hypoglycemia has occurred. If such review raises the question that serious hypoglycemia occurred, the certification of the driver involved should be terminated, it is envisioned that this review mechanism will require a small office involving one or two staff Persons trained in the process.

Ophthalmological Review

The recommendations of the National Eye Institute (applicable to all patients with diabetes) shall be observed for ITDM drivers. Each ITDM driver shall have an annual evaluation by an ophthalmologist and a written report from this physician submitted as part of the annual recertification process. To be recertified, an ITDM driver must have visual acuity of at least 20/40 corrected, no active proliferative or preproliferative retinopathy, and meet the other Federal vision requirements.

Cardiovascular Review

The recommendations of Task Force 1 pertaining to original certification will continue to be observed at each annual recertification.

Neurologic Status

The examining physician shall annually determine that the driver's neurologic status will permit safe and proper driving mechanics.

With the exception of an ophthalmologic review, most of the components of assessing a driver's cardiovascular and neurologic status should be considered to be part of a normal physical examination conducted by a qualified primary care physician.

Prior to certification, each ITDM driver shall have completed a formal diabetes education program that shall include, at a minimum, instruction on: symptoms of hypoglycemia and hyperglycemia and their management, insulin administration, self-monitoring of blood glucose, food care, diet to synchronize with insulin use, ophthalmologic aspects of diabetes, and management of Intercurrent illness. Each ITDM driver shall attend a diabetes education update Program at least every five years. Documentation of participation should be part of the driver's record.

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U.S. Department of Transportation
Washington, D.C.

Michael F. Trntacostt
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Eliane VINTR
Medical Assistant
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Appendix C

CONFERENCE SPEAKERS

Dennis P. McEachen, Highway Safety Specialist, Office of Motor Carrier Standards, Federal Highway Administration, U.S. Department of Transportation, Washington, D.C.

Robert Ratner, M.D., Assistant Professor of Medicine, Division of Endocrinology & Metabolism, George Washington University Medical Center, Washington, D.C.

Michael F. Trentacoste, Director, Office of Motor Carrier Standards, Federal Highway Administration, U.S. Department of Transportation, Washington, D.C.

Fred Whitehouse, M.D., Head, Division of Metabolic Diseases, Henry Ford Hospital, Detroit, Michigan.

Appendix D

CONFERENCE AGENDA

September 9

1230 p.m. REGISTRATION

1:00 p.m. CALL TO ORDER and INTRODUCTIONS
--Fred Whitehouse, M.D., Steering Committee
Chairman

REGULATORY MEDICINE AND COMMERCIAL DRIVERS
--Michael F. Trentacoste, Office of Motor Carrier
Standards

MEDICAL CERTIFICATION SYSTEM FOR COMMERCIAL
DRIVERS
--Dennis P. McEachen, Office of Motor Carrier Standards

2:00 p.m. DIABETES MELLITUS WITH INSULIN
--Robert Ramer, M.D., George Washington University

4:30 p.m. BREAK

4:15 p.m. TASK FORCE MEETINGS

September 10

7:30 a.m. CONTINENTAL BREAKFAST

8:00 a.m. TASK FORCE MEETINGS

10:00 a.m. BREAK

10:30 a.m. TASK FORCE REPORTS

EXECUTIVE SUMMARY and CLOSING REMARKS
--Fred Whitehouse, M.D.

12:00 p.m. STEERING COMMITTEE MEETING