



Expert Panel Recommendations

Chronic Kidney Failure and Commercial Motor Vehicle Driver Safety

Medical Expert Panel Members

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Presented to

The Federal Motor Carrier Safety
Administration

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Table of Contents

Introduction.....	1
Scope of Recommendations Document.....	1
Definition and Staging of Chronic Kidney Disease.....	1
Composition of Medical Expert Panel.....	2
Methodology.....	3
Brief Overview of Evidence Report Methodology.....	3
The Medical Expert Panel Meeting and Recommendation Formulation.....	3
Medical Expert Panel Commentary on Findings of Evidence Report.....	3
Recommendations to the FMCSA from the Medical Expert Panel.....	4
Recommendation 1: Identification of Individuals with Chronic Kidney Disease.....	4
<i>Recommendation 2: Certification of Individuals with Stage 1, 2, or 3 CKD.....</i>	<i>7</i>
<i>Recommendation 3: Certification of Individuals with Stage 4 CKD.....</i>	<i>8</i>
<i>Recommendation 4: Certification of Individuals with Stage 5 CKD.....</i>	<i>9</i>
Recommendation 5: Specific Guidance—Individuals with Renal Transplants.....	10
Recommendation 6: Recommendations for Further Research.....	11
APPENDIX A: Findings of Evidence Report.....	12
APPENDIX B: Current Standards and Guidelines for Renal Disease.....	17

Introduction

The primary mission of the U.S. Department of Transportation's (DOT's) Federal Motor Carrier Safety Administration (FMCSA) is to reduce crashes, injuries and fatalities involving commercial motor vehicles, or CMV's, (including large trucks and buses) in the United States of America. One mechanism by which the FMCSA aims to meet this commitment is to ensure that individuals who drive commercial motor vehicle are physically qualified to do so. While physical qualification standards do exist and all commercial motor vehicle drivers must be certified by a qualified medical examiner as meeting these standards on a biennial basis, the standards have been criticized as being outdated. In addition, a number of disorders exist that are not addressed by the current standards. As a consequence, the FMCSA has embarked on a program whereby it will review all of its current physical qualification standards and begin the process of updating them as necessary by 2009.

At the present time there are no physical qualification standards pertaining directly to individuals with chronic kidney disease (CKD). The FMCSA determined that it was necessary to establish whether renal disorders were likely to have a deleterious impact on driver safety and, if it does, to determine how this might best be mitigated. Consequently, the FMCSA requested that Manila Consulting and its research team summarize the best available evidence on the impact that CKD may have on driver safety. In addition, the agency asked Manila Consulting to convene an expert panel to provide recommendations to the agency as to whether and, under what conditions, individuals with kidney disease may be considered physically qualified to drive a commercial motor vehicle.

This report serves the purpose of summarizing the considerations and recommendations of a panel of three experts from the field of nephrology (henceforth termed the Medical Expert Panel, or MEP) who examined the FMCSA's current guidelines for medical examiners pertaining to obstructive renal disease.

Scope of Recommendations Document

The MEP considered the impact of CKD on CMV driver safety. The impact of acute kidney disease is beyond the scope of the present recommendations document.

Definition and Staging of CKD

Throughout this recommendations document we have used the classification and classification systems proposed by the National Kidney Foundation (Table 1 and Table 2 respectively).

Table 1. Definition of CKD

Criteria	Definition
1	Kidney damage ≥ 3 months as defined by structural or functional abnormalities of the kidney, with or without decreased GFR, manifest by either: <ul style="list-style-type: none">• Pathological abnormalities;• Markers of kidney damage including abnormalities in the composition of the blood or urine, or abnormalities in imaging tests.
2	GFR < 60 mL/min/1.73 m ² for ≥ 3 months with or without kidney damage

Table 2. Stages of CKD

Stage	Description	Glomerular Filtration Rate (GFR)	Prevalence in US Population
1	Renal damage (protein in urine) and normal GFR. Involves mildly diminished renal function, with few overt symptoms	≥90 mL/min/1.73 m ²	5.9 million (3.3%)
2	Renal damage and mild decrease in GFR. Kidney damage is defined as pathologic abnormalities or markers of damage, including abnormalities in blood or urine test or imaging studies	60-89 mL/min/1.73 m ²	5.3 million (3.0%)
3	Renal damage and moderate decrease in GFR	30-59 mL/min/1.73 m ²	7.6 million (4.3%)
4	Renal damage and severe decrease in GFR	15-29 mL/min/1.73 m ²	400,000 (0.2%)
5	Renal Failure (also known as ESRD). Involves severe illness and requires some form of renal replacement therapy (dialysis or renal transplant). Stage 5 CKD is also called end-stage renal disease (ESRD).	≤15 mL/min/1.73 m ²	300,000 (0.2%)

Source: The National Kidney Foundation Disease Outcomes Quality Initiative (NKF-K/DOQI) Clinical Practice Guidelines for Chronic Kidney Disease

Composition of MEP

Members of the MEP charged with making recommendations on whether the current guidelines for renal disease need to be updated are listed in Table 1.

Table 1. Members of the MEP

Name	Current Position
Dr. Stephen Z. Fadem	Stephen Z. Fadem, MD, FACP, FASN (Texas) is Clinical Professor of Medicine at Baylor College of Medicine. He is also Vice-President of the Board of Directors for Chronic Kidney Disease and on the Medical Advisory Board of the American Association of Kidney Patients. He is a graduate of the University of Oklahoma College of Medicine and completed his internal medicine residency at The University of Texas. He lectures frequently on dialysis management, preventive nephrology, vascular calcification, anemia, patient education, chronic kidney disease education, computer technology and computer security. Dr. Fadem founded the Houston Kidney Center (HKC). The HKC Integrated Service Network, now a part of DaVita, is comprised of six dialysis facilities. The DaVita Medical Center Facility is now one of the largest dialysis units in the United States. Dr. Fadem has been nationally recognized by receiving the American Association of Kidney Patient's Peter Lundin Award and the National Kidney Foundation's Distinguished Service Award.
Dr. Mark Unruh	Mark Unruh, MD, MSc (Pennsylvania) is Assistant Professor of Medicine at the University of Pittsburgh and also serves as the University's Sub-Specialty Education coordinator for the Renal-Electrolyte Division. He received his medical degree from the University of Chicago and served his residencies at the University of Pennsylvania and at Tufts-New England Medical Center in Massachusetts. Dr. Unruh's research interests include the care and treatment of individuals with chronic kidney disease, focusing on the link between sleep disorders and daytime functioning among individuals with chronic illness. In addition, his research group is examining the interaction of nighttime medical therapies such as dialysis on sleep quality. He has written over 30 articles and book chapters and received grant support from the National Institutes of Health, National Kidney Foundation and American Society of Nephrology.
Dr. Linda A. Szczech	Lynda A. Szczech, MD, MSCE (North Carolina) is Associate Professor of Medicine at Duke University Medical Center. She is also the Director of nephrology research at Duke Clinical Research Institute. Dr. Szczech has extensive experience in nephrological research and clinical epidemiology. She holds a medical degree from Jefferson Medical College in Philadelphia and earned a Master's degree in Clinical Epidemiology from the University of Pennsylvania School of Medicine. She is the author of numerous peer-reviewed publications on renal disease, especially its effects on HIV+ patients. Dr. Szczech is the recipient of the 1996 Kidney Fund Clinical Scientist in Nephrology Award and the National Research Service Fellowship Award. Dr. Szczech's clinical and research interests include the epidemiology of chronic kidney disease, the interaction between cardiac and renal disease, and HIV-related renal diseases.

Methodology

Brief Overview of Evidence Report Methodology

The recommendations of the MEP presented in this report were informed in part on the interpretation and assimilation of information presented in a comprehensive evidence report summarizing the best evidence that is currently available in the literature. This evidence report titled, “Chronic Kidney Disease and Commercial Motor Vehicle Driver Safety,” was developed following a systematic search for evidence accessible through several electronic databases. The electronic databases included (but were not limited to) Medline, PubMed (pre Medline), EMBASE, PsycINFO, CINAHL, and the Cochrane Library (through September 12, 2007). All searches were supplemented by hand searches of the published literature (e.g. bibliographies of identified relevant articles) and “gray literature” resources (e.g., Web searches).

The MEP Meeting and Recommendation Formulation

On January 16, 2008, the FMCSA, Manila Consulting, the ECRI Institute, and the three members of the MEP convened a one-day conference. The goals of this meeting included the following:

- To review the existing FMCSA guidelines for medical examiners on the certification and recertification of individuals who have, or are suspected of having, renal disease.
- To discuss the available evidence in the evidence report and other sources on the consequences to public safety of certifying individuals with renal disease medically fit to drive a CMV.

In developing their recommendations to the FMCSA, members of the MEP were guided by three central principles. These are:

- Recommendations pertaining to physical qualification standards (or guidance to medical examiners) should be based on scientific evidence whenever possible¹.
- Recommendations pertaining to physical qualification standards (or guidance to medical examiners) should be concise and explicit.
- Recommendations pertaining to physical qualification standards (or guidance to medical examiners) should be actionable.

This document summarizes the recommendations derived from this process.

MEP Commentary on Findings of Evidence Report

The MEP agreed with the findings of FMCSA’s evidence report titled, “Chronic Kidney Disease and Commercial Motor Vehicle Driver Safety.” The executive summary of this evidence report

¹ Recommendations from the MEP, for which no supporting evidence was identified and which are thus based on expert opinion alone, are identified as such.

can be found in Appendix A.

Recommendations to the FMCSA from the MEP

The MEP noted that at the present time the FMCSA does not have any physical qualifications standards that speak specifically to CKD. In addition, the MEP also noted that the FMCSA does not provide any guidance to medical examiners on certifying individuals with this disorder. The MEP believes that, while evidence is sparse, some individuals with CKD do constitute an additional risk to road safety. In light of this, the MEP made several specific recommendations to the FMCSA. These are presented below.

Recommendation 1: Identification of Individuals with CKD

The MEP recommends that the FMCSA's instruct its medical examiners to determine the kidney function status of all potential commercial motor vehicle drivers. Specifically the MEP made the following recommendation:

- Ideally, all individuals applying for medical certification to drive a CMV should have a serum creatinine test with calculation of the Modification of Diet in Renal Disease (MDRD) Glomerular Filtration Rate (GFR) in order to determine whether CKD is present and, if present to determine the stage of the disorder. The MDRD GFR, also known as the eGFR is readily available from standard labs. It can also be easily determined online from either of the following websites: <http://nephron.org>, <http://mdrd.com>, <http://kidney.org>, <http://www.nkdep.nih.gov>.
- At the very least, all individuals with risk factors for CKD should have a serum creatinine test with calculation of the GFR in order to determine whether CKD is present. Specific risk factors identified by the MEP included the following:
 - Individuals with a known history of kidney disease
 - Individuals with a family history of kidney disease
 - Individuals aged over 65 years of age
 - Individuals with diabetes
 - Individuals with high blood pressure
 - Individuals with proteinuria.

Justification

Chronic renal disease (CRD), its co-morbidities, complications, and treatments, have a complex interrelationship which potentially increase the risk of an individual with the disorder experiencing a motor vehicle crash. While this possibility is not supported by direct evidence from crash studies, indirect evidence does suggest that individuals with CKD may represent a threat to road safety.(Noble et al., 2007) Several studies have demonstrated that individuals with

CKD demonstrate impaired neurocognition.(Madero et al. 2008; Noble et al., 2007; Madan et al., 2006; Kurella et al., 2004) There is also some evidence, albeit weak, suggesting that individuals with CKD are at high risk for sleep disordered breathing,(Noble et al. 2007; Markou et al., 2006), a condition that has been shown to be associated with an increased risk for a motor vehicle crash.(Tregear et al., 2007)

Because CKD may have a deleterious impact on road safety that may increase as kidney function deteriorates, the MEP considered it important that individuals with the disorder be identified and the extent of their kidney failure disorder quantified. Two approaches to this were considered. The first approach was to suggest that all individuals who are applying for medical certification to drive a CMV be required to have a serum creatinine test with calculation of the Modification of Diet in Renal Disease (MDRD) Glomerular Filtration Rate (GFR) in order to determine whether CKD is present and, if present to determine the stage of the disorder.

The MEP discussed in some detail the feasibility of requiring that a serum creatinine test become a mandatory part of the medical examination for CMV drivers. They also discussed the fact that the U.S. Preventive Health Services Task Force does not recommend urinalysis or measurement of serum creatinine in otherwise seemingly healthy adults. Given this, it might be hard to justify making a GFR determination a mandatory part of the medical examination for CMV drivers. However, the MEP opined that that active testing for the disorder is necessary in healthy adults because many individuals will have marked renal insufficiency yet remain unaware of their condition. Evidence from a large population-based study (NHANES) suggests that approximately twenty-four percent of individuals found to have CKD were not be aware that they had the disorder (Coresh et al., 2005).

The MEP noted that one might reasonably argue that it is only individuals with less severe forms of disease that are unaware of their condition. However, this does not appear to be the case. Another analysis of data from NHANES found that 70% of patients with stage 2, 78% of patients with stage 3, and 55% of patients with stage 4 CKD were not aware that they had kidney disease.(Nikolas et al., 2004) An analysis of evidence from another large study demonstrated that of the individuals in their study who were found to have a stage-3 and stage-4 CKD, 75.3% and 42.4% respectively did not have a diagnosis and were otherwise unaware of their condition.(Singh et al., 2005) In another study, 92% of individuals with stage-3 CKD, 75% of individuals with stage 4 CKD, and 29% of individuals with stage-5 CKD were unaware that they had kidney disease.(Hsu et al., 2006)

As stated above, the MEP discussed the practicality of demanding that all CMV drivers have their GFR measured as part of the medical certification process. It was decided that reasonable individuals may argue against screening all CMV drivers for evidence of CKD. Consequently, a second recommendation was proposed. This contingency recommendation limits the requirement for a GFR measurement to only those individuals who are considered to be at risk for chronic kidney disease. According to evidence-based guidelines from the National Kidney Foundation risk factors for CKD include susceptibility factors and initiation factors. In addition, because it can be difficult to detect the onset of chronic kidney disease, some risk factors for faster progression may appear to be to susceptibility or initiation factors (Table 3).

Table 3. Types and Examples of Risk factors for CKD

Table 39. Types and Examples of Risk Factors for Chronic Kidney Disease

	Definition	Examples
Susceptibility factors	Increase susceptibility to kidney damage	Older age, family history
Initiation factors	Directly initiate kidney damage	Diabetes, high blood pressure, autoimmune diseases, systemic infections, urinary tract infections, urinary stones, lower urinary tract obstruction, drug toxicity
Progression factors	Cause worsening kidney damage and faster decline in kidney function after initiation of kidney damage	Higher level of proteinuria, higher blood pressure level, poor glycemic control in diabetes, smoking

From the K/DOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification

Supporting References

Coresh J, Byrd-Holt D, Astor BC, Briggs JP, Eggers PW, Lacher DA, Hostetter TH. Chronic kidney disease awareness, prevalence, and trends among U.S. adults. 1999 to 2000. *J Am Soc Nephrol*. 2005 Jan; 16 (1):180-8.

Hsu CC, Hwang SJ, Wen CP, Chang HY, Chen T, Shiu RS, Horng SS, Chang YK, Yang WC. High prevalence and low awareness of CKD in Taiwan: a study on the relationship between serum creatinine and awareness from a nationally representative survey. *Am J Kidney Dis*. 2006 Nov;48(5):727-38.

Kurella M, Chertow GM, Luan J, Yaffe K. *J. Am Geriatr Soc*. Cognitive impairment in chronic kidney disease. 2004 Nov;52(11):1863-9

Madan P, Kalra OP, Agarwal S, Tandon OP. Cognitive impairment in chronic kidney disease. *Nephrol Dial Transplant*. 2007 Feb;22(2):440-4. Epub 2006 Oct 5.

Madero M, Gul A, Sarnak MJ. Cognitive function in chronic kidney disease. *Semin Dial*. 2008 Jan-Feb;21(1):29-37.

Markou N, Kanakaki M, Myrianthefs P, Hadjiyanakos D, Vlassopoulos D, Damianos A, Siamopoulos K, Vasiliou M, Konstantopoulos S. Sleep-disordered breathing in nondialyzed patients with chronic renal failure. *Lung*. 2006 Jan-Feb;184(1):43-9.

National Kidney Foundation. *K/DOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification*. Published in 2002. see: http://www.kidney.org/professionals/kdoqi/guidelines_ckd/toc.htm

Nickolas TL, Frisch GD, Opotowsky AR, Arons R, Radhakrishnan J. Awareness of kidney disease in the US population: findings from the National Health and Nutrition Examination Survey (NHANES) 1999 to 2000. *Am J Kidney Dis*. 2004 Aug;44(2):185-97.

Noble M, Reston J, Tiller M, Tregear SJ. *Chronic Kidney Disease and Commercial Motor Vehicle Driver Safety*. FMCSA 2007.

Singh A, Oppong-Manu P, Mody S, et al. *The Renal Detection and Referral Study (RADAR Study): Applying eGFR measurement in detecting chronic kidney disease (CKD) in a managed care setting*. *Renal Week 2005; November 8-13, 2005; Philadelphia, PA. Abstract TH-PO926*.

Recommendation 2: Certification of Individuals with Stage 1, 2, or 3 CKD

The MEP opined that the mere presence of CKD does not, in of itself, provide grounds for restricting the driving privileges of all individuals with the disease. Some individuals with early CKD may be certified as physically qualified to drive a CMV. Specifically the MEP made the following recommendations:

- Provided that an individual is not precluded from being certified as physically qualified to drive a CMV for other reasons (e.g. because of issues related to cardiovascular disease, diabetes, etc), individuals with stage-1, 2, or 3 CKD may be considered as physically qualified to drive a CMV.
- Individuals with stage-1 or stage-2 CKD should be re-evaluated every 2 years as part of the normal re-certification process.
- Individuals with stage-3 CKD should be re-certified on an annual basis.

Justification

Currently there is no evidence (either direct or indirect) to suggest that individuals with stage-1, -2, or -3 CRD are at an increased risk for a motor vehicle crash.(Noble et al., 2005) The MEP noted that clinical signs and symptoms of CKD do not usually appear until the disease reaches stage 4, when changes in water or electrolyte balance, or endocrine or metabolic problems become clinically evident. Given the lack of evidence that individuals with early CKD are a safety risk the MEP unanimously agreed that restriction of driving privileges among this population of individuals would be inappropriate.

Kidney function progressively declines in approximately 85% of patients with CKD. (NKF KDOQI Guidelines, 2002; Hunsicker et al., 1997) This progressive decline has been attributed to a variety of mechanisms, including failure to resolve the initial injury and onset of self-perpetuating injury, ultimately leading to the typical pathologic features of the “end-stage” kidney and kidney failure. Data from the MDRD Study during an average 2-year follow-up show that the average rate of decline in GFR was approximately 4 mL/min/year and was not related to the baseline level of GFR.(Hunsicker et al.,1997) Evidence from other studies suggests that the rate of GFR decline is highly variable among patients, ranging from slowly progressive over decades, to rapidly progressive over months.(NKF KDOQI Guidelines, 2002) Consequently, individuals with stage-3 CKD require closer monitoring than individuals with stage-1 and 2 disease.

In addition to disease progression, the inherent and independent risks of patients with kidney disease having cardiovascular disease make it imperative to monitor this population of patients closely.

Supporting References

Hunsicker LG, Adler S, Caggiula A, England BK, Greene T, Kusek JW, Rogers NL, Teschan PE: Predictors of the progression of renal disease in the Modification of Diet in Renal Disease Study. Kidney Int 51:1908-1919, 1997.

National Kidney Foundation. *K/DOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification*. Published in 2002. see: http://www.kidney.org/professionals/kdoqi/guidelines_ckd/toc.htm

Noble M, Reston J, Tiller M, Tregear SJ. *Chronic Kidney Disease and Commercial Motor Vehicle Driver Safety*. FMCSA 2007.

Recommendation 3: *Certification of Individuals with Stage 4 CKD*

The MEP unanimously agreed that some individuals with Stage-4 CKD may be considered as qualified to drive a CMV. Specifically, the MEP stated the following:

- An individual with stage-4 CKD who has a normal EKG and a blood pressure that is less than 140 mm Hg systolic and 90 mm Hg diastolic may be certified as being physically qualified to drive a CMV for a period not to exceed 6 months whereupon the individual must present for re-certification.
- An individual with stage 4 CKD who has a normal EKG but whose blood pressure falls within the range of 140-180 mm Hg systolic or 90-110 mm Hg diastolic may be certified as medically qualified to drive a CMV for a period not to exceed 3 months whereupon the individual must present for re-certification.
- An individual with stage 4 CKD who has an abnormal EKG, or an echocardiogram that reveals left ventricular hypertrophy, or has blood pressure that is greater than or equal to 180 mm Hg systolic or 110 mm Hg diastolic, cannot be considered as being physically qualified to drive a CMV.

Justification

The MEP noted that while there is no direct evidence to suggest that individuals with stage 4 CKD are at increased risk for a motor vehicle crash,(Noble et al., 2007) there is evidence, albeit sparse, to suggest that some individuals with this degree of kidney disease may be at an increased risk for cognitive(Hailpurn et al., 2007; and sleep disturbances.(Markou et al., 2006) Whether the deficits observed in this population are severe enough to impact driver safety is not known but the MEP argued that it is at least plausible that driving ability may be impaired in some individuals.

While it may be plausible that some individuals with stage-4 CKD may demonstrate deficits in cognitive function and normal sleep patterns that might impact driving ability, the primary reason that the MEP recommends that the FMCSA restrict driving privileges among individuals in this population was the consequence of the fact that such individuals are at a particularly high risk for sudden incapacitation or death.

CKD is an independent risk factor for coronary artery disease, left ventricular hypertrophy and sudden death, even before dialysis. The American Heart Association published a statement in 2003 recommending that patients with CKD are in the “highest risk group” for subsequent cardiovascular disease.(Sarnak et al., 2003) This is also true of left ventricular hypertrophy,

which ranges from 8 to 40% in patients with CKD not on dialysis(Levin, 2003). In patients with CKD, no diabetes, the risk of atherosclerosis is 35.7%, of congestive failure 30.7% and death 17.7%. In patients with CKD and diabetes, the risk is worse, atherosclerosis 49.1%, congestive heart failure 52.3%, and death 19.9% (Foley et al., 2005) In an epidemiological study from Japan LVH was present in 40% of patients studied. 22.7% in Stage 3 and 43.6% in Stage 4.(Kimura et al., 2007)

Supporting References

Foley RN, Murray AM, Li S, et al.: Chronic kidney disease and the risk for cardiovascular disease, renal replacement, and death in the United States Medicare population, 1998 to 1999. J Am Soc Nephrol 16: 489-495, 2005

Hailpern SM, Melamed ML, Cohen HW, Hostetter TH. Moderate chronic kidney disease and cognitive function in adults 20 to 59 years of age: Third National Health and Nutrition Examination Survey (NHANES III). J Am Soc Nephrol. 2007 Jul;18(7):2205-13.

Kimura T, Iio K-i, Obi Y and Hayashi T: [Left ventricular hypertrophy in predialysis chronic kidney disease impact of cardiomuscular stress markers]. Nippon Jinzo Gakkai Shi 49: 1007-1013, 2007.

Levin A: Clinical epidemiology of cardiovascular disease in chronic kidney disease prior to dialysis. Semin Dial 16: 101-105, 2003.

Madan P, Kalra OP, Agarwal S, Tandon OP. Cognitive impairment in chronic kidney disease. Nephrol Dial Transplant. 2007 Feb;22(2):440-4.

Markou N, Kanakaki M, Myrianthefs P, Hadjiyanakos D, Vlassopoulos D, Damianos A, Siamopoulos K, Vasiliou M, Konstantopoulos S.Sleep-disordered breathing in nondialyzed patients with chronic renal failure. Lung. 2006 Jan-Feb;184(1):43-9.

Sarnak MJ, Levey AS, Schoolwerth AC, et al.: Kidney disease as a risk factor for development of cardiovascular disease: a statement from the American Heart Association Councils on Kidney in Cardiovascular Disease, High Blood Pressure Research, Clinical Cardiology, and Epidemiology and Prevention. Circulation 108: 2154-2169, 2003.

Recommendation 4: Certification of Individuals with Stage 5 CKD

The MEP unanimously agreed that individuals with kidney failure should not be considered as qualified to drive a CMV. Specifically, the MEP stated the following:

- Individuals who require renal replacement therapy (excluding renal transplant) and those with stage 5 CKD who are not receiving renal replacement (dialysis or renal replacement) therapy cannot be considered as fit-for-duty and should be disqualified from operating a CMV.

Justification

Aside from the logistical issues related to long distance driving and maintaining compliance with dialysis regimens there are several reasons why the MEP recommends the disqualification of all individuals with Stage 5 CKD from driving a CMV.

While there is currently no direct evidence demonstrating that individuals with stage 5 CKD are at increased risk for a motor vehicle crash, indirect evidence consistently demonstrates that, on average, individuals with renal failure exhibit cognitive impairments across several domains that are thought to be associated with decreased driving performance.(Noble et al., 2007) Several other studies have demonstrated an association between renal failure, dialysis, and disturbed sleep.(Noble et al., 2007) In addition, dialysis has been shown to be associated with several conditions that potentially preclude the safe operation of a CMV. Neurological complications that are associated with dialysis include dialysis dementia, disequilibrium syndrome, cerebrovascular accidents, hypertensive encephalopathy, Wernicke’s encephalopathy, hemorrhagic stroke, intracranial hypertension, and aggravation of pre-existing atherosclerosis. Hemodialysis patients may also experience muscle atrophy and related weakness and impaired movement that may impede an individual’s ability to safely operate a CMV.

In addition to sleep disorders and cognition changes, and as well the risk of sudden cardiac death associated with left ventricular hypertrophy and cardiovascular disease, dialysis *per se* causes changes to the heart. Hypotension, transient myocardial ischemia and the potential for arrhythmias may accompany this procedure. It will be impossible to control the timing of the dialysis treatment and the activity of driving, and thus, the MEP strongly recommends that patients undergoing dialysis not be certified as physically qualified to operate CMV’s for the purposes of interstate commerce.(Mohi-ud-din et al., 2005; Santoro et al., 2008; Selby and McIntyre, 2007)

Supporting References

Mohi-ud-din K, Bali HK, Banerjee S, Sakhujia V and Jha V: Silent myocardial ischemia and high-grade ventricular arrhythmias in patients on maintenance hemodialysis. Ren Fail 27: 171-175, 2005.

Noble M, Reston J, Tiller M, Tregear SJ. Chronic Kidney Disease and Commercial Motor Vehicle Driver Safety. FMCSA 2007.

Santoro A, Mancini E, London G, et al.: Patients with complex arrhythmias during and after haemodialysis suffer from different regimens of potassium removal. Nephrol Dial Transplant, 2008.

Selby NM and McIntyre CW: The acute cardiac effects of dialysis. Semin Dial 20: 220-228, 2007.

Recommendation 5: Specific Guidance—Individuals with Renal Transplants

The MEP recommended that the FMCSA consider adopting the following guidelines for people who have undergone renal transplants:

- Individuals who have undergone renal transplant with successful kidney transplantation may operate a CMV 90 days post operatively provided that they have been cleared as fit-for-duty by their transplant physician.
- With the exception of differences in recertification periods, individuals who have undergone successful renal transplantation should be assessed as per recommendation 1 through 4 above.
- All individuals who have undergone successful renal transplantation should be re-certified at

3 months, 6 months and 12 months postoperatively. Thereafter, individuals should be re-certified on an annual basis.

Justification

Although the management of maintenance immunosuppression varies from center to center, it is common practice to taper therapy after the first month. By the end of the first year, most patients should be on stable doses of therapy.

Due to the higher risk of infection, it is advisable that patients not return to active driving until initial therapy has been tapered or until after the physician feels their condition is stable. (Hricik et al., 1994; Schiff et al., 2007; Ciancio et al., 2004; Gaston et al., 2006; Chan et al. 2001). Most employed recipients of a kidney transplant should be able to return to work at one year. (van der Mei et al., 2007) Close follow-up during the first year is prudent. We suggest at three months, six months. The rationale should be that at the end of the first three months the patient should be approaching maintenance therapy, and at the end of six months should be stable on therapy. At the end of one year, it is likely that transplant recipients will have resumed previous job duties.

Supporting References

Chan L, Gaston R and Hariharan S: Evolution of immunosuppression and continued importance of acute rejection in renal transplantation. Am J Kidney Dis 38: S2- 9, 2001.

Ciancio G, Burke GW, Gaynor JJ, et al.: A randomized long-term trial of tacrolimus and sirolimus versus tacrolimus and mycophenolate mofetil versus cyclosporine (NEORAL) and sirolimus in renal transplantation. I. Drug interactions and rejection at one year. Transplantation 77: 244-251, 2004.

Gaston RS: Current and evolving immunosuppressive regimens in kidney transplantation. Am J Kidney Dis 47: 3-21, 2006.

Hricik DE, Almawi WY and Strom TB: Trends in the use of glucocorticoids in renal transplantation. Transplantation 57: 979-989, 1994.

Schiff J, Cole E and Cantarovich M: Therapeutic monitoring of calcineurin inhibitors for the nephrologist. Clin J Am Soc Nephrol 2: 374-384, 2007.

van der Mei SF, van Son WJ, van Sonderen ELP, de Jong PE, Groothoff JW and van den Heuvel WJA: Factors determining social participation in the first year after kidney transplantation: a prospective study. Transplantation 84: 729-737, 2007.

Recommendation 6: Recommendations for Further Research

The MEP recognizes that there is a dearth of data pertaining to CKD and driver safety. In particular, the association between CKD and CMV crash (with a particular focus on the impact of the stage of CKD) needs to be examined. Given the difficulty associated with obtaining crash data from individuals with CKD, another avenue of potentially fruitful investigation would be to examine the impact of CKD (all stages) on simulated driving performance.

APPENDIX A: Findings of Evidence Report

This appendix summarizes the findings of the Evidence Report titled, “Renal Disease and Commercial Motor Vehicle Driver Safety (Expedited Review).” The purpose of this evidence report was to address several key questions posed by the FMCSA. Each of the key questions was developed by the FMCSA such that the answers would provide information the Agency believed would be useful in updating its current medical examination guidelines. The four key questions addressed were:

Key Question 1: Are individuals with renal disease at an increased risk for a motor vehicle crash?

Key Question 2: Are medications used to treat individuals with renal disease associated with an increased risk of motor vehicle crash among pre-dialysis patients?

Key Question 3: Are dialysis and accompanying drug treatments associated with an increased risk of motor vehicle crash?

Key Question 4: Are renal transplantation and accompanying drug treatments associated with an increased risk of motor vehicle crash?

Identification of Evidence Bases

Separate evidence bases for each of the key questions addressed by the evidence report were identified through a comprehensive search of the literature, examination of abstracts of identified studies to determine which articles would be retrieved, and selection of the actual articles that would be included in each evidence base.

A total of seven electronic databases (Medline, PubMed [pre Medline], EMBASE, PsycINFO, CINAHL, TRIS, the Cochrane library) were searched (through April 30, 2007). In addition, we examined the reference lists of all obtained articles to identify relevant articles not identified by our electronic searches. We also did hand searches of the “gray literature.” Admission of an article into an evidence base was determined by formal retrieval and inclusion criteria determined a priori.

Grading the Strength of Evidence

Quality assessment of the evidence took into account not only the quality of the individual studies that comprise the evidence base for each key question; we also considered the interplay between the quality, quantity, robustness, and consistency of the overall body of evidence.

Analytic Methods

The set of analytic techniques used in the evidence report was extensive. Random- and fixed-effects meta-analyses were used to pool data from different studies. Differences in the findings of studies (heterogeneity) were identified using the Q-statistic and I^2 Sensitivity analyses, aimed

at testing the robustness of our findings included the use of cumulative fixed- and random-effects meta-analysis. The presence of publication bias was tested for using the “trim and fill” method.

Presentation of Findings

In presenting the findings of the evidence synthesis, a clear distinction was made between qualitative and quantitative conclusions and a separate strength-of-evidence rating was assigned to each of conclusion format. The strength-of-evidence ratings assigned to the different types of conclusions are defined in [Table 5](#)

Table 5. Strength of Evidence Ratings for Qualitative and Quantitative Conclusions

<i>Strength of Conclusion</i>	<i>Interpretation</i>
<i>Qualitative Conclusion</i>	
<i>Strong evidence</i>	Evidence supporting the qualitative conclusion is convincing. It is highly unlikely that new evidence will lead to a change in this conclusion.
<i>Moderate</i>	Evidence supporting the qualitative conclusion is somewhat convincing. There is a small chance that new evidence will overturn or strengthen our conclusion. ECRI Institute recommends regular monitoring of the relevant literature for moderate-strength conclusions.
<i>Acceptable</i>	Although some evidence exists to support the qualitative conclusion, this evidence is tentative and perishable. There is a reasonable chance that new evidence will either overturn or strengthen our conclusions. ECRI Institute recommends frequent monitoring of the relevant literature.
<i>Unacceptable</i>	Although some evidence exists, the evidence is insufficient to warrant drawing an evidence-based conclusion. ECRI Institute recommends frequent monitoring of the relevant literature.
<i>Quantitative Conclusion (Stability of Effect-size Estimate)</i>	
<i>Highly stable</i>	The estimate of treatment effect in the conclusion is stable. It is highly unlikely that the magnitude of this estimate will change substantially as a result of the publication of new evidence.
<i>Moderately stable</i>	The estimate of treatment effect in the conclusion is somewhat stable. There is a small chance that the magnitude of this estimate will change substantially as a result of the publication of new evidence. ECRI Institute recommends regular monitoring of the relevant literature.
<i>Low stability</i>	The estimate of treatment effect included in the conclusion is likely to be unstable. There is a reasonable chance that the magnitude of this estimate will change substantially as a result of the publication of new evidence. ECRI Institute recommends frequent monitoring of the relevant literature.
<i>Unstable</i>	Estimates of the treatment effect are too unstable to allow a quantitative conclusion to be drawn at this time. ECRI Institute recommends frequent monitoring of the relevant literature.

Evidence-Based Findings

The findings of our analyses of the data pertaining to the four key questions addressed in the evidence report are summarized below.

Key Question 1: Are individuals with renal disease at an increased risk for a motor vehicle crash?

Current direct evidence from crash studies does not demonstrate that individuals with renal disease are at an increased risk for a crash. Indirect evidence, albeit weak, does suggest that it is plausible that individuals with renal disease may be at increased risk for a motor vehicle crash (Strength of Conclusion: Acceptable).

Direct Evidence – Crash Studies: Our searches identified two direct crash risk studies with a total of 94 individuals with renal disease. It is unclear how similar the drivers in these studies are to CMV drivers because few characteristics of the drivers are reported; however, it does not appear that CMV drivers are represented. Driving exposure was not adequately controlled for in either study. For this and additional reasons, these studies were both rated as low in quality. One retrospective cohort study reported on the crash rate among individuals with chronic renal disease compared with the rate among community controls. The other study, a case-control study, reported on the proportion of individuals with renal disease among a cohort of individuals who crashed compared with the proportion of drivers with renal disease among a cohort of individuals who did not crash. Neither of these studies provided evidence in support of the contention that individuals with renal disease are at an increased risk for a motor vehicle crash. On the contrary, both studies actually found that individuals with renal disease appear to be at a reduced risk for a crash.

Indirect Evidence – Studies of Neurocognitive Function: Eight studies with a total of 489 patients assessed neurocognitive impairment of people with renal disease. Overall the evidence base was of low quality. Differences among the studies included varied types of study designs, controls selected, and outcomes reported. The eight studies reported outcomes on a total of 18 neurocognitive measurements in four domains: general neurocognition, attention and concentration, visuospatial skill, and executive function. There was no consensus between studies to definitively conclude that people with renal disease have neurocognitive impairment. However, there is a sufficient quantity of evidence that on multiple outcome measures with different groups of patients tested in different study designs that renal disease is associated with impaired neurocognition. Therefore, the possibility that people with renal disease experience neurocognitive impairment cannot be dismissed.

Indirect Evidence – Studies of Sleep-Related Outcomes: Only one study with 46 patients addressed this outcome. The study was of low quality and generalizability to the CMV driver population was uncertain. The authors found that the prevalence of severe sleep disordered breathing among enrolled patients with renal disease was four times that of the controls from a general population, but no significant difference was found on other outcomes important to safe operation of a motor vehicle, including daytime sleepiness. However, previous systematic reviews have associated sleep disordered breathing with an actual increase in motor vehicle crash. Therefore, this evidence suggests that people with renal disease are at a greater risk of motor vehicle crash than people without.

Key Question 2: Are medications used to treat individuals with renal disease associated with an increased risk of motor vehicle crash among pre-dialysis patients?

No conclusions regarding the effect of medications on crash risk in pre-dialysis renal disease patients can be drawn at the present time.

Our searches, including both electronic and hand searches, did not identify any studies that assessed the association of medications in pre-dialysis renal disease patients on direct or indirect crash risk.

Key Question 3: Are dialysis and accompanying drug treatments associated with an increased risk of motor vehicle crash?

There is currently no direct evidence regarding the association between dialysis and the risk for a motor vehicle crash. However, indirect evidence indicates that it is plausible that drivers with end stage renal disease (ESRD) treated with dialysis and related medications may be at an increased risk of motor vehicle crash (Strength of Conclusion: Acceptable).

Direct Evidence – Crash Studies: No studies were identified by our searches.

Indirect Evidence – Studies Neurocognitive Function: Thirteen studies with 980 patients with unclear generalizability to CMV drivers were identified. Overall, this evidence base was of low quality. The included studies employed a variety of study designs and different control populations, limiting their comparability and compatibility for statistical analysis. Furthermore, studies infrequently reported the same outcomes. For analysis, we subdivided the studies by comparisons performed. No clear trend emerged from these 13 studies to definitively conclude that patients treated with dialysis do or do not have neurocognitive impairment compared with controls. However, a substantial number of test results suggest that patients treated with dialysis do have neurocognitive impairment in domains associated with an increased risk of motor vehicle crash. Findings also suggest that ESRD patients on hemodialysis may be more impaired than patients not on dialysis, and that patients on hemodialysis may be more impaired the day before dialysis than the day after.

Indirect Evidence – Studies of Sleep-Related Outcomes: Three studies with a total of 70 patients were identified for this evidence base. Each of these three studies addressed different outcomes and therefore had to be considered in isolation. The findings of two studies point to an association between sleep disorders and renal disease, indirectly suggesting an increased risk of motor vehicle crash among dialysis patients. The findings of one of those studies also suggest that overnight (nocturnal) dialysis may alleviate sleep apnea. The findings of the third study suggest that different dialysis buffers may alleviate symptoms.

Key Question 4: Are renal transplantation and accompanying drug treatments associated with an increased risk of motor vehicle crash?

Presently, there is no direct evidence regarding the association between renal transplantation and

motor vehicle crash risk. However, indirect evidence does suggest the possibility that renal transplant recipients may be at a lower risk for motor vehicle crash than individuals with ESRD treated with dialysis (Strength of Conclusion: Acceptable).

Direct Evidence – Crash Studies: No studies were identified by our searches.

Indirect Evidence – Neurocognitive Function: Two low quality studies that enrolled a total of 43 renal transplant recipients met the inclusion criteria for this key question and reported on neurocognitive function. One included study observed significant improvements in neurocognitive function among renal transplant recipients across several domains. The second included study also observed some small improvements in neurocognitive function but these improvements were not statistically significant. Given the small size of this study, the lack of a statistically significant finding is not surprising and this finding may be an example of a type-II statistical error. Neither of these studies specifically enrolled individuals from a population of CMV drivers. Consequently, the generalizability of the findings of these two studies to CMV drivers is unclear.

Indirect Evidence - Sleep-Related Outcomes: One low quality study that enrolled 841 renal transplant recipients met the inclusion criteria for this key question and reported on a sleep-related outcome. The generalizability of this study to CMV drivers is unclear. The study findings suggest that a substantial portion of renal transplant recipients may be at risk for sleep apnea, and therefore at an increased risk of motor vehicle crash. However, a smaller proportion of renal transplant recipients were at risk for sleep apnea compared with similar individuals on dialysis, suggesting that the risk of motor vehicle crash among transplant recipient may be lower among transplant recipients than dialysis patients.

APPENDIX B: Current Standards and Guidelines for Renal Disease

Current Medical Fitness Standards and Guidelines for CMV Drivers in the U.S.

FMCSA regulations, found in 49 Code of Federal Regulations (CFRs) 301 through 399, cover businesses that operate CMVs in interstate commerce. FMCSA regulations that pertain to fitness to drive a commercial vehicle are found in 49 CFR 391 Subpart E. Only motor carriers engaged purely in intrastate commerce are not directly subject to these regulations. However, intrastate motor carriers are subject to state regulations, which must be identical to, or compatible with, the federal regulations in order for states to receive motor carrier safety grants from FMCSA. States have the option of exempting CMVs with a gross vehicle weight rating of less than 26,001 lbs. Currently, there are no regulations that directly address CMV drivers with renal disease.

Current Medical Qualification Guidelines

Currently, FMCSA does not provide guidelines to medical examiners specific to the certification of individuals with renal disease as being fit to drive a CMV.

Relevant Medical Fitness Standards and/or Guidelines from Other Transportation Agencies in the U.S.

Current relevant medical fitness standards and/or guidelines for other transportation modes in the U.S. are summarized in 4. Included in the table are pertinent rules and guidance for pilots, railroad workers, and merchant mariners.

Table 4. Standards and guidelines for renal from U.S. government transportation safety agencies

FAA* (all classes of airmen)	Railroad†	Merchant Mariner‡
<p>GPO ACCESS</p> <p>Title 14: Aeronautics and Space</p> <p>67.113 General medical condition.</p> <p>The general medical standards for a first-class airman medical certificate are:</p> <p>(a) No established medical history or clinical diagnosis of diabetes mellitus that requires insulin or any other hypoglycemic drug for control.</p> <p>(b) No other organic, functional, or structural disease, defect, or limitation that the Federal Air Surgeon, based on the case history and appropriate, qualified medical judgment relating to the condition involved, finds—</p> <p>(1) Makes the person unable to safely perform the duties or exercise the privileges of the airman certificate applied for or held; or</p> <p>(2) May reasonably be expected, for the maximum duration of the airman medical certificate applied for or held, to make the person unable to perform those duties or exercise those privileges.</p> <p>(c) No medication or other treatment that the Federal Air Surgeon, based on the case history and appropriate, qualified medical judgment relating to the medication or other treatment involved, finds—</p> <p>(1) Makes the person unable to safely perform the duties or exercise the privileges of the airman certificate applied for or held; or</p> <p>(2) May reasonably be expected, for the maximum duration of the airman medical certificate applied for or held, to make the person unable to perform those duties or exercise those privileges.</p> <p>§ 67.401 Special issuance of medical certificates.</p> <p>(a) At the discretion of the Federal Air Surgeon, an Authorization for Special Issuance of a Medical Certificate (Authorization), valid for a specified period, may be granted to a person who does not meet the provisions of subparts B, C, or D of this part if the person shows to the satisfaction of the Federal Air Surgeon that the duties authorized by the class of medical certificate applied for can be performed without endangering public safety during the period in which the Authorization would be in force. The Federal Air Surgeon may authorize a special medical flight test, practical test, or medical evaluation for this purpose. A medical certificate of the appropriate class may be issued to a person who does not meet the provisions of subparts B, C, or D of this part if that person possesses a valid Authorization and is otherwise eligible. An airman medical certificate issued in accordance with this section shall expire no later than the end of the validity period or upon the withdrawal of the Authorization upon which it is based. At the end of its specified validity period, for grant of a new Authorization, the person must again show to the satisfaction of the Federal Air Surgeon that the duties authorized by the class of medical certificate applied for can be performed without endangering public safety during the period in which the Authorization would be in force.</p> <p>(b) At the discretion of the Federal Air Surgeon, a Statement of Demonstrated Ability (SODA) may be granted, instead of an Authorization, to a person whose disqualifying condition is static or nonprogressive and who has been found capable of performing airman duties without endangering public safety. A SODA does not expire and authorizes a designated aviation medical examiner to issue a medical certificate of a specified class if the examiner finds that the condition described on its face has not adversely changed.</p>	<p>The railroads have no specific medical standards addressing renal disorders.</p>	<p>Potentially disqualifying conditions listed in the Physical Evaluation Guidelines for Merchant Mariner's Documents and Licenses included any disease or constitutional defect which would result in gradual deterioration of performance of duties, sudden incapacitation or otherwise compromise shipboard safety, including required response in an emergency situation. Renal guidelines and standards include the following:</p> <p>GENITOURINARY (potentially disqualifying condition):</p> <p>Chronic renal failure</p> <p>GENERAL INFORMATION FOR MERCHANT MARINER'S DOCUMENTS, LICENSES, AND STCW CERTIFICATES</p> <p>REQUIRED MEDICAL INFORMATION</p> <p>A medical waiver from the Officer In Charge, Marine Inspection (OCMI) is required whenever a Merchant Mariner Physical Examination Report (CG-719K) reveals a medical condition that may affect your ability to perform the duties of the license or MMD applied for. Please provide a signed medical history statement from your doctor under his letterhead that includes the information below.</p> <p>STANDARD INFORMATION REQUIRED</p> <ol style="list-style-type: none"> 1. The date on which the diagnosis was made. 2. A complete list of medications (current and past), including dosage and possible side effects. 3. Any limitations in the performance of your professional duties. 4. A prognosis of the potential deterioration or correction of your condition.

(c) In granting an Authorization or SODA, the Federal Air Surgeon may consider the person's operational experience and any medical facts that may affect the ability of the person to perform airman duties including—

- (1) The combined effect on the person of failure to meet more than one requirement of this part; and
- (2) The prognosis derived from professional consideration of all available information regarding the person.

(d) In granting an Authorization or SODA under this section, the Federal Air Surgeon specifies the class of medical certificate authorized to be issued and may do any or all of the following:

- (1) Limit the duration of an Authorization;
- (2) Condition the granting of a new Authorization on the results of subsequent medical tests, examinations, or evaluations;
- (3) State on the Authorization or SODA, and any medical certificate based upon it, any operational limitation needed for safety; or
- (4) Condition the continued effect of an Authorization or SODA, and any second- or third-class medical certificate based upon it, on compliance with a statement of functional limitations issued to the person in coordination with the Director of Flight Standards or the Director's designee.

(e) In determining whether an Authorization or SODA should be granted to an applicant for a third-class medical certificate, 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.

(f) An Authorization or SODA granted under the provisions of this section to a person who does not meet the applicable provisions of subparts B, C, or D of this part may be withdrawn, at the discretion of the Federal Air Surgeon, at any time if—

- (1) There is adverse change in the holder's medical condition;
- (2) The holder fails to comply with a statement of functional limitations or operational limitations issued as a condition of certification under this section;
- (3) Public safety would be endangered by the holder's exercise of airman privileges;
- (4) The holder fails to provide medical information reasonably needed by the Federal Air Surgeon for certification under this section; or
- (5) The holder makes or causes to be made a statement or entry that is the basis for withdrawal of an Authorization or SODA under §67.403.

(g) A person who has been granted an Authorization or SODA under this section based on a special medical flight or practical test need not take the test again during later physical examinations unless the Federal Air Surgeon determines or has reason to believe that the physical deficiency has or may have degraded to a degree to require another special medical flight test or practical test.

(h) The authority of the Federal Air Surgeon under this section is also exercised by the Manager, Aeromedical Certification Division, and each Regional Flight Surgeon.

(i) If an Authorization or SODA is withdrawn under paragraph (f) of this section the following procedures apply:

- (1) The holder of the Authorization or SODA will be served a letter of withdrawal, stating the reason for the action;
- (2) By not later than 60 days after the service of the letter of withdrawal, the holder of the Authorization or SODA may request, in writing, that the Federal Air Surgeon provide for review of the decision to withdraw. The request for

review may be accompanied by supporting medical evidence;

(3) Within 60 days of receipt of a request for review, a written final decision either affirming or reversing the decision to withdraw will be issued; and

(4) A medical certificate rendered invalid pursuant to a withdrawal, in accordance with paragraph (a) of this section, shall be surrendered to the Administrator upon request.

(j) No grant of a special issuance made prior to September 16, 1996, may be used to obtain a medical certificate after the earlier of the following dates:

(1) September 16, 1997; or

(2) The date on which the holder of such special issuance is required to provide additional information to the FAA as a condition for continued medical certification

The following is a partial list of conditions that warrant denial or deferral to the Aeromedical Certification Division, AAM-300. All disqualifying defects are subject to further FAA consideration.

(See Item 48 for details concerning diabetes and Item 57 for other information related to the examination of urine).

A. Urinary System

1. Calculus: renal, ureteral, or vesical (see 11 below).
2. Hydronephrosis with impaired renal function.
3. Nephrectomy, if associated with hypertension, uremia, infection of the remaining kidney, or other evidence of reduced renal function in the remaining kidney.
4. Nephritis: acute or chronic.
5. Nephrocalcinosis.
6. Nephrosis.
7. Polycystic kidney disease.
8. Pyelitis or pyelonephritis.
9. Pyonephrosis.
10. Tumors or malignancies, including prostatic carcinoma, require further evaluation.
11. Retained stones are disqualifying for issuance of a medical certificate. The Examiner should either deny or defer issuance and transmit the completed FAA Form 8500-8 to the Aeromedical Certification Division. Complete studies to determine the possible etiology and prognosis are essential to favorable FAA consideration. Determining factors include site and location of the stones, complications such as compromise in renal function, repeated bouts of kidney infection, and need for therapy. Any underlying disease will be considered. The likelihood of sudden incapacitating symptoms is of primary concern. (See Item 18.j.)
12. Congenital lesions of the kidney are often benign, and certification of applicants with ectopic and horseshoe kidney, agenesis (unilateral), and even hypoplasia and dysplasia is possible.
13. Cystostomy and neurogenic bladder require evaluation by a specialist and deferral of certification to the Aeromedical Certification Division, AAM-300.
14. Glycosuria requires special evaluation. (Also see Items 48 and 57 for glycosuria associated with diabetes).
15. Renal dialysis and transplant are cause for denial. FAA certification may be possible after complete recovery from surgery and in limited circumstances involving dialysis.

Guide for Aviation Medical Examiners

Decision Considerations

Aerospace Medical Dispositions

Item 41. Genitourinary System - General Disorders

Disease/Condition	Class	Evaluation Data	Disposition
Congenital lesions of the kidney	All	Submit all pertinent medical information and status report	If the applicant has an ectopic, horseshoe kidney, unilateral agenesis, hypoplastic, or dysplastic and is asymptomatic – Issue Otherwise – Requires FAA Decision
Cystostomy and Neurogenic bladder	All	Requires evaluation, report must include etiology, clinical manifestation and treatment plan	Requires FAA Decision
Renal Dialysis	All	Submit a current status report, all pertinent medical reports to include etiology, clinical manifestation, BUN, Ca, PO ⁴ , Creatinine, electrolytes, and treatment	Requires FAA Decision

Guide for Aviation Medical Examiners

Decision Considerations

Disease Protocols

Renal Transplant

An applicant with a history of renal transplant must submit the following if consideration for medical certification is desired:

1. Hospital admission, operative report and discharge summary
2. Current status report including:
 - The etiology of the primary renal disease
 - History of hypertension or cardiac dysfunction
 - Sequela prior to transplant
 - A comment regarding rejection or graft versus host disease (GVHD)
 - Immunosuppressive therapy and side effects, if any
 - The results of the following laboratory results: CBC, BUN, creatinine, and electrolytes

Guide for Aviation Medical Examiners

<p>Special Issuances</p> <p>AME Assisted - All Classes Renal Calculi</p> <p>AME Assisted Special Issuance (AASI) is a process that provides Examiners the ability to re-issue an airman medical certificate under the provisions of an Authorization for Special Issuance of a Medical Certificate (Authorization) to an applicant who has a medical condition that is disqualifying under Title 14 of the Code of Federal Regulations (14 CFR) part 67.</p> <p>An FAA physician provides the initial certification decision and grants the Authorization in accordance with 14 CFR § 67.401 The Authorization letter is accompanied by attachments that specify the information that treating physician(s) must provide for the re-issuance determination. If this is a first time issuance of an Authorization for the above disease/condition, and the applicant has all of the requisite medical information necessary for a determination, the Examiner must defer and submit all of the documentation to the AMCD or RFS for the initial determination.</p> <p>Examiners may re-issue an airman medical certificate under the provisions of an Authorization, if the applicant provides the following:</p> <p>An Authorization granted by the FAA;</p> <ul style="list-style-type: none"> A statement from your treating physician regarding the location of the retained stone(s), estimation as to size of stone, and likelihood of becoming symptomatic; and A current report of appropriate imaging study (IVP, KUB, Ultrasound, or Spiral CT Scan) and provide a metabolic work-up, both performed within last 90 days. <p>The Examiner must defer to the AMCD or Region if:</p> <ul style="list-style-type: none"> If the treating physician comments that the current stone has a likelihood of becoming symptomatic; If the retained stone(s) has moved when compared to previous evaluations; or If the stone(s) has become larger when compared to previous evaluations. <p>AME Assisted - All Classes Renal Carcinoma</p> <p>AME Assisted Special Issuance (AASI) is a process that provides Examiners the ability to re-issue an airman medical certificate under the provisions of an Authorization for Special Issuance of a Medical Certificate (Authorization) to an applicant who has a medical condition that is disqualifying under Title 14 of the Code of Federal Regulations (14 CFR) part 67.</p> <p>An FAA physician provides the initial certification decision and grants the Authorization in accordance with 14 CFR § 67.401 The Authorization letter is accompanied by attachments that specify the information that treating physician(s) must provide for the re-issuance determination. If this is a first time issuance of an Authorization for the above disease/condition, and the applicant has all of the requisite medical information necessary for a determination, the Examiner must defer and submit all of the documentation to the AMCD or RFS for the initial determination.</p> <p>Examiners may re-issue an airman medical certificate under the provisions of an Authorization, if the applicant provides the following:</p> <ul style="list-style-type: none"> An Authorization granted by the FAA; and 		
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<p>A current status report performed within 90 days that must include all the required follow-up items and studies as listed in the Authorization letter and that confirms absence of recurrent disease.</p> <p>The Examiner must defer to the AMCD or Region if:</p> <ul style="list-style-type: none"> There has been any recurrence of the cancer; or Any new treatment is initiated. 		
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*Source of information for FAA Regulations and Guidelines: http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/app_process/exam_tech/item41/amd/gd/

http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/app_process/exam_tech/item55/et/

http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/special_iss/all_classes/renal_cancer/

<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=214deb5c74f0994cf7d0d3d3fa584802&rgn=div8&view=text&node=14:2.0.1.1.5.5.1.1&idno=14>

‡Source of information for Federal Railroad Administration Guidelines: <http://www.fra.dot.gov/downloads/safety/hazmatch4.pdf>

±Source of information for Merchant Mariner Guidelines:

http://www.uscg.mil/hq/g-m/nvic/2_98/n2-98.pdf

http://www.uscg.mil/stcw/st-info-packs/General_Package.pdf

Relevant Medical Standards and/or Guidelines from Other Countries

Internationally, standards have been established to assess and determine the fitness of drivers operating CMVs. Regulatory standards and guidance pertaining to renal disorders and CMV driving have been developed in Australia, Canada, European Union, Malta, People's Republic of China, Singapore, Kingdom of Bahrain, United Kingdom, New Zealand, India, Ireland and Sweden.

Distinct worldwide policies by categories include:

UUKidney Transplant

- *Australia, Canada and Sweden* guidelines allow CMV drivers a license upon “successful” kidney transplant

UUSerious and Irreversible Renal Deficiency

- *European Union member states* will not issue or renew a CMV license

UUAdvanced Chronic Renal Failure

- *Australian* guidelines suggest a conservative/restrictive approach to allow CMV driving
- *United Kingdom* authorities will assess drivers individually

UUESRD

- *New Zealand* authorities propose regular assessments may be imposed
- If an individual possesses adequate cognitive and sensor motor ability, they are allowed to drive in *Canada*
- Dialysis is grounds for denial in *Sweden*

Hemodialysis

- CMV drivers will be assessed on an individual basis in the *United Kingdom*
- *Canadian* authorities suggest that hemodialysis is typically not a feasible treatment approach for a long-distance driver