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Requiring Total Abstinence from Alcohol Consumption and Testing for EtG

Technical Letter Report

February 2018

ME Lerchen
EP Kennedy
AC Dalton

Prepared for the U.S. Nuclear Regulatory Commission
under an Interagency Agreement with the U.S. Department of Energy
Contract DE-AC05-76RL01830

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Pacific Northwest National Laboratory
Richland, Washington 99352

Abstract

This report addresses clinical, scientific, regulatory, and legal considerations for requiring total abstinence from alcohol use for individuals employed in safety- and security-sensitive positions in regulated industries and professions. The report provides a conceptual framework for categorizing alcohol consumption and medical problems associated with drinking, and treatment options based on prevailing substance abuse professional opinions and practices. Based on discussions with experts from professional associations and certification authorities for substance abuse treatment and training programs, the report presents findings about professional opinions regarding treatment approaches and their scientific and empirical rationales. In addition, the report provides a discussion of alcohol metabolism and alcohol testing with regard to the validity and suitability of using ethyl glucuronide (EtG) testing for monitoring total abstinence compliance as well as potential challenges in accurately interpreting EtG results. The report offers an overview and discussion of the extent to which individuals with alcohol use disorders are protected by the extant laws and regulations and the current policies of regulatory and oversight agencies regarding workplace alcohol testing and abstinence requirements. The report concludes with summaries of the findings and a discussion of their implications for fitness-for-duty programs.

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The accuracy of the information and the views presented in this report are the responsibility of the authors and do not necessarily represent the opinion of the NRC or of any particular individuals or licensees.

Acronyms and Abbreviations

5-HIAA	5-hydroxyindole-3-acetic acid
5-HTOL	5-hydroxytryptophol
AA	Alcoholics Anonymous
AAAP	American Academy of Addiction Psychiatry
ADA	Americans with Disabilities Act
ADAAA	Americans with Disabilities Act Amendments Act
ALT	alanine amino transferase
APA	American Psychiatric Association
ARG	Alcohol Research Group
ASAM	American Society of Addiction Medicine
AST	aspartate amino transferase
AUD	alcohol use disorder
AUDIT	Alcohol Use Disorders Identification Test
BAC	blood alcohol concentration
BAT	breath alcohol technician
CAS	Center of Alcohol Studies
CBA	collective bargaining agreement
CDT	carbohydrate deficiency transferrin
CESAR	Center for Substance Abuse Research
CFR	Code of Federal Regulations
CIHS	Center for Integrated Health Solutions
DHHS	U.S. Department of Health and Human Services
DOJ	U.S. Department of Justice
DOL	U.S. Department of Labor
DOT	U.S. Department of Transportation
DSM	Diagnostic and Statistical Manual of Mental Disorders
DUI	driving under the influence
DWI	driving while intoxicated
EAP	employee assistance programs
EEOC	U.S. Equal Employment Opportunity Commission
EtG	ethyl glucuronide
EtS	ethyl sulfate
FAA	U.S. Federal Aviation Administration
FAEE	fatty acid ethyl esters
FFD	fitness for duty
FMCSA	Federal Motor Carrier Safety Administration

FMLA	Family and Medical Leave Act
FRA	Federal Railroad Administration
FSPHP	Federation of State Physician's Health Programs
FTA	Federal Transit Administration
GC-MS	gas chromatography-mass spectrometry
GGT	gamma-glutamyl transferase
GTOL	5-HTOL-glucuronide
HRSA	Health Resources and Services Administration
IC&RC	International Certification Reciprocity Consortium
LC-MS	liquid chromatography-mass spectrometry
LC-MS/MS	liquid chromatography-tandem mass spectrometry
MCV	mean corpuscular erythrocyte volume
mL	milliliter(s)
MMPI	Minnesota Multiphasic Personality Inventory
MRO	Medical Review Officer
NADAAC	National Association for Alcohol and Drug Abuse Counselors
NASADAD	National Association of State Alcohol and Drug Abuse Directors
NBCC	National Board for Certified Counselors, Inc. and Affiliates
NCADD	National Council on Alcoholism and Drug Dependence, Inc.
NCC	National Certified Counselors
ng	nanogram
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIH	National Institutes of Health
NRC	U.S. Nuclear Regulatory Commission
PEth	phosphatidyl ethanol
PHMSA	Pipeline and Hazardous Materials Safety Administration
PHP	physician health program
PNNL	Pacific Northwest National Laboratory
SAE	substance abuse expert
SAMHSA	Substance Abuse and Mental Health Services Administration
SAMHSA-HRSA	Substance Abuse and Mental Health Services Administration, Health Resources and Services Administration (HRSA)
SAP	substance abuse professional
SME	subject matter expert
STT	screening test technician
TAP	technical assistance publication
USCG	U.S. Coast Guard
USC	United States Code

Contents

Figures

Tables

1.0 Introduction

1.1 Background

Excessive consumption of alcohol has short- and long-term behavioral and health effects. In the short-term, drinkers may experience symptoms such as impairment of speech, motor skills, memory, and concentration as well as confusion; longer-term effects may include the development of alcohol use disorders (AUDs), other health problems (e.g., diseases of the brain, heart, lung, liver, and pancreas), and elevated risk of certain cancers (NIAAA n.d.).

Excessive alcohol consumption impairs individuals' ability to perform safety- and security-sensitive functions.[1] To ensure that persons performing these functions are free from the influence of drugs and alcohol and are fit for duty, various Federal agencies (e.g., the U.S. Nuclear Regulatory Commission [NRC] and Department of Transportation [DOT]) have established regulations to prohibit being under the influence while on duty, require workplace drug and alcohol testing, and stipulate sanctions for individuals violating these regulations (e.g., Title 10 of the *Code of Federal Regulations* (CFR) Part 26 and 49 CFR Part 40).

The NRC's requirements in 10 CFR Part 26 do not prohibit alcohol consumption when the use of alcohol occurs at a time and in a manner that does not affect on-the-job performance. However, if alcohol testing determines that an individual is or may have been impaired on the job, 10 CFR Part 26 requires nuclear power plant licensees to ensure that a qualified professional (1) performs an assessment of the individual's alcohol use before the individual is permitted to resume work and (2) develops a treatment plan, if warranted. In some instances, the treatment plan requires the individual to cease all alcohol use, as verified with testing in addition to that required under the rule. Some individuals and organizations have questioned whether a total abstinence approach is justifiable and whether the additional tests required by some treatment plans are valid outside the scope of treatment monitoring. Therefore, the NRC requested staff of the Pacific Northwest National Laboratory (PNNL) review the research literature and state-of-practice related to these topics.

1.2 Purpose and Research Questions

Workplace drug and alcohol regulations include provisions for workplace testing as well as sanctions for violations of requirements. Further, individuals with an AUD have other potential legal protections (e.g., the Americans with Disabilities Act [ADA]). Within this complex regulatory and legal landscape, questions might arise concerning the applicability and limits for testing, AUD treatment provisions and protections, and the rights and responsibilities of the individuals regarding employment sanctions. In exploring these issues, the NRC staff tasked the project team to summarize the scientific, clinical, regulatory, and legal information available to answer the following questions:

[1] See http://www.samhsa.gov/workplace/legal/federal-laws/safety-security-sensitive for a list of Federal agencies that have established specific drug-testing requirements for industries that perform public safety and national security roles.

1. What is the "gold standard" in AUD treatment? Is total abstinence a reasonable treatment goal for patients performing jobs that are important for public health and safety?
2. Is ethyl glucuronide (EtG) an appropriate biomarker for alcohol testing? Is its use scientifically defensible for AUD treatment and workplace alcohol-testing programs?
3. How do workplace drug- and alcohol-testing regulations (e.g., 10 CFR Part 26) apply to workplace total abstinence requirements and EtG testing?
4. What are the rights and responsibilities for licensees and personnel addressing employment conditions and disputes associated with alcohol-related problems in the workplace?

1.3 Methods Overview

The objective of this report is to provide pertinent scientific, clinical, regulatory, and legal information to help address the research questions. Our methodology for collecting the information presented in this report is described below.

- The project team reviewed literature on alcohol use, abuse, and treatment to understand the requirements and implementation of treatment standards and guidance from the U.S. Department of Health and Human Services (DHHS) and its agencies (e.g., Substance Abuse and Mental Health Services Administration [SAMHSA] and the National Institute on Alcohol Abuse and Alcoholism [NIAAA]).
- We interviewed subject matter experts (SMEs) specializing in substance abuse research and treatment, and documented their perspectives regarding circumstances in which total abstinence is a reasonable workplace requirement for individuals who perform safety- or security-sensitive jobs.
- We reviewed and compared scientific literature on alcohol metabolism and use of EtG as a means for monitoring compliance with abstinence requirements.
- We reviewed drug- and alcohol-testing programs and policies for the NRC and DOT, the courts, and physician health programs (PHPs)[2] to gain a better understanding of how these programs are implemented with respect to AUD treatment programs with particular attention devoted to alcohol abstinence and monitoring.
- Finally, the project team reviewed laws, regulations, and other requirements that might be relevant to alcohol abuse in the workplace and analyzed these regarding the rights and responsibilities of employees who have AUDs and their employers, and compliance with these requirements in workplace alcohol testing and fitness-for-duty (FFD) programs.

AUD is one of many addictive substance use disorders involving the use of a variety of illegal (e.g., heroin, marijuana, and methamphetamines) and legal substances (SAMHSA 2011). This report focuses on alcohol use and abuse. Substance abuse—involving illegal drugs (e.g., heroin, marijuana, and methamphetamines) and illicit or inappropriate use of legal drugs (e.g., prescription and over-the-counter drugs)—is outside the scope of this report.

[2] PHPs have been established to help and treat physicians with substance abuse and mental health issues. PHPs are described in detail in Section 4.4.

1.4 Report Structure

This report is organized into seven chapters, including this Introduction. Chapter 2 discusses the framework for categorizing problems arising from increasing levels of alcohol consumption based on clinical research literature and prevailing clinical practices. Chapter 2 also presents current AUD treatment guidance from DHHS and its agencies, and findings from interviews with SMEs in substance abuse treatment, substance abuse training programs, and certification programs. Chapter 3 provides an overview of alcohol metabolism, an overview of available test methods for alcohol consumption, and a discussion of the validity and suitability of using EtG to monitor alcohol abstinence compliance. Chapter 4 identifies and discusses NRC and DOT workplace drug- and alcohol-testing regulations pertaining to total abstinence and EtG testing. Chapter 4 also presents findings about how EtG testing is used for monitoring alcohol abstinence by criminal and family courts as well as in PHPs. Chapter 5 provides a discussion of the extant laws and regulations regarding workplace drug and alcohol use, legal protections for individuals who have an AUD, and legal cases involving employment dispute resolution through third-party arbitration. In Chapter 6, the research questions are answered and the findings are summarized in a discussion of how the clinical, scientific, regulatory, and legal evidence intersects the questions surrounding requirements for total alcohol abstinence in the workplace as a condition of unescorted access and implications for FFD programs. Finally, Chapter 7 contains a list of references cited in this report.

2.0 Alcohol Use Disorders: Framework and Standards for Diagnosis and Treatment

Alcohol consumption is pervasive in the United States. According to the 2015 National Survey on Drug Use and Health (SAMHSA 2016), almost 86 percent of adults (18 and older) reported they had consumed alcohol sometime in their life, about 70 percent in the last year, and 56 percent in the previous month. For some of these people, drinking can be a problem. In the 2015 survey, about one quarter of the adult population indulged in binge drinking and seven percent had engaged in heavy drinking in the past month. Of the adult population, 15.1 million (6.2 percent) had an AUD; roughly two-thirds of these were men and one-third women.[3]

2.1 Framework: Levels of Drinking and Alcohol Use Disorder

Drinking patterns are classified into three levels based on frequency and amount of consumption: moderate, binge, and heavy drinking, see Table 2-1.

Table 2-1. Drinking Levels and Definitions

Level of Drinking	Definition	Source
Moderate	Up to one alcoholic drink[(a)] per day for women and up to two alcoholic drinks per day for men.	DHHS and U.S. Department of Agriculture[(b)]
Binge	Five or more alcoholic drinks on the same occasion on at least one day in the past 30 days.	SAMHSA[(c)]
	A pattern of drinking that brings blood alcohol concentration (BAC) levels to 0.08 g/dL. This typically occurs after four alcoholic drinks for women and five alcoholic drinks for men in a two-hour period.	NIAAA[(d)]
Heavy	Five or more drinks on the same occasion on each of 5 or more days in the past 30 days.	SAMHSA[(c)]

(a) According to the *Dietary Guidelines for Americans 2015–2020*, one alcoholic drink-equivalent contains 14 g of pure alcohol, which is equal to 12 fluid ounces of regular beer (5 percent alcohol), 5 fluid ounces of wine (12 percent alcohol), or 1.5 fluid ounces of 80 proof distilled spirits (40 percent alcohol), Office of Disease Prevention and Health Promotion, Department of Health https://health.gov/dietaryguidelines/2015/guidelines/
(b) https://health.gov/dietaryguidelines/2015/guidelines/appendix-9/
(c) https://www.samhsa.gov/disorders/substance-use
(d) https://www.niaaa.nih.gov/alcohol-health/overview-alcohol-consumption/moderate-binge-drinking

Increasing levels of drinking raise the risk for individuals to experience alcohol-related problems. According to NIAAA (n.d. b), low-risk drinking refers to drinking no more than three drinks in one day or no more than seven drinks per week for women, and no more than four drinks in a day or no more than 14 drinks per week for men. NIAAA research indicates that among individuals who drink within these limits, only about two percent have an AUD (*id.*). Drinking above these limits puts drinkers at an elevated risk for AUD.

[3] NIAAA has published an alcohol fact sheet providing more selected statistics from the lengthy SAMHSA survey report at: https://pubs.niaaa.nih.gov/publications/AlcoholFacts&Stats/AlcoholFacts&Stats.pdf.

To establish whether an individual has an AUD, specific diagnostic criteria must be met. The Diagnostic and Statistical Manual of Mental Disorders (DSM) developed by the American Psychiatric Association (APA) is considered the most authoritative source for diagnosing mental disorders. It is widely used by clinicians; mental health and other professionals such as psychiatrists, psychologists, counselors, therapists, nurses, and social workers; researchers; government agencies; and health insurance professionals (Institute of Medicine 2006; APA n.d.). The DSM provides standard classifications of mental disorders and offers formal diagnostic criteria for a wide range of psychiatric disorders including AUD.

The levels of drinking and at-risk drinking specified by NIAAA and SAMHSA and the diagnostic criteria in the DSM provide a framework for understanding drinking behavior and the threshold beyond which alcohol consumption can, and does, become a problem. Figure 2.1 depicts the prescreening process for physician use in diagnosing AUDs along with drinking level categories and identification of at-risk drinkers. The DSM diagnostic criteria are discussed in Section 2.2.2.

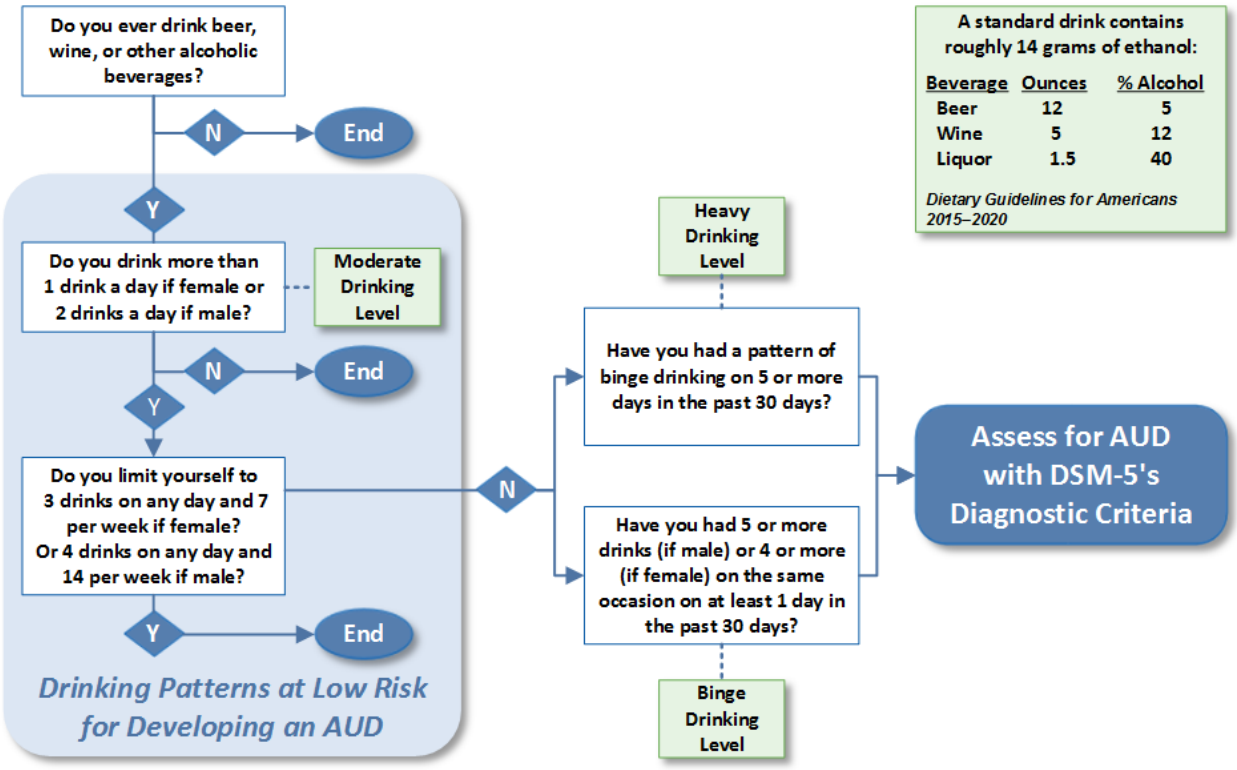

Figure 2.1. Process for Prescreening for AUD and Identifying At-Risk Drinking

Symptoms of AUD include continued alcohol use despite negative consequences, growing tolerance for alcohol, alcohol cravings, loss of control over drinking, and withdrawal symptoms (SAMHSA 2015a). A significant caveat in diagnosing AUD is that there must be evidence of repetitive symptoms or problems that impair an individual's health and physical, mental, and social functions. An AUD is diagnosed when "the recurrent use of alcohol … causes clinically and functionally significant impairment, such as health problems, disability, and failure to meet major responsibilities at work, school, or home" (SAMHSA 2015a). One-time problematic drinking, although putting the health and safety of the drinker and others at risk, does not automatically lead to a diagnosis of AUD. For instance, if an individual is charged with driving

while intoxicated (DWI) or driving under the influence (DUI) and reports no symptoms of AUD, a diagnosis of AUD might not be established without additional evidence.

2.2 AUD Treatment Standards: Guidelines from DHHS Agencies

Alcohol abuse is an expensive and disruptive problem. Several DHHS agencies and professional organizations have addressed what constitutes abuse, who has an AUD, and what are appropriate treatment approaches. The following subsections describe the positions of SAMHSA and NIAAA, agencies within DHHS, regarding alcohol abuse and AUD diagnosis and treatment along with the findings of interviews with substance abuse experts (SAEs) regarding AUD treatment standards.

2.2.1 The DHHS and Its Agencies

The DHHS enhances and protects the health and well-being of all Americans. It fulfills that mission by providing for effective health and human services and fostering advances in medicine, public health, and social services. The DHHS funds research to better understand the causes and impacts of alcohol abuse on human health. It develops programs and initiatives for abuse prevention, treatment, and research dissemination to reduce the impact of substance abuse on the behavioral and mental health of individuals. The DHHS and its agencies have published guidance, technical assistance publications, and protocols for treating substance abuse problems and improving treatment effectiveness. They have also developed educational and training resources for professionals and communities in need of substance abuse expertise for prevention and treatment. DHHS organizations doing this work are:

- The SAMHSA is a DHHS agency that leads public health efforts to advance the behavioral health of the nation. SAMHSA's mission is to reduce the impact of substance abuse and mental illness on American communities.

- The NIAAA is one of the 27 institutes and centers that compose the National Institutes of Health (NIH). The NIH, a part of DHHS, is the nation's medical research agency. NIAAA supports and conducts research on the impact of alcohol use on human health and well-being. It is the largest funder of alcohol research in the world.

2.2.2 AUD Treatment Guidelines Issued by SAMHSA and NIAAA

The NIAAA published a clinician's guide on AUD diagnosis and treatment that recommends a four-step clinical approach to screening at-risk drinkers and individuals who may have AUD (NIAAA 2005):

1. Prescreen for at-risk drinking: The clinician asks an individual questions regarding the frequency and amount of his/her alcohol consumption to determine if at-risk drinking is present.
2. AUD assessment: If an individual is an at-risk drinker based on Step 1, the clinician uses DSM[4] diagnostic criteria to determine whether an AUD is present.
3. Advise and assist (brief intervention): The clinician concludes diagnosis, communicates medical findings to the patient, makes treatment recommendations, considers additional

[4] Although the AUD treatment guide was based on DSM-IV, its basic workflow remains relevant for screening and diagnosing AUD using DSM-5.

evaluation by another healthcare professional, and provides medication and/or other medical interventions to treat/alleviate symptoms.

4. Follow-up: If the patient chooses to receive treatment, the clinician provides continued support by documenting alcohol use and reviewing goals during each visit to monitor treatment compliance. The clinician also helps coordinate care with other healthcare professionals and addresses other coexisting conditions as needed.

As noted in Section 2.1, the DSM is the most authoritative source on diagnosing a wide variety of mental disorders by healthcare professionals and practitioners specializing in substance abuse and addiction treatment. The DSM was used in the NIAAA's guide for screening for and identifying individuals who have an AUD. The previous DSM (DSM-IV) had defined two categories of disorders—those with alcohol abuse and those with alcohol dependence—and specific criteria for each, with alcohol dependence being more severe. In DSM-5, the current edition of the DSM issued in 2013, alcohol abuse and alcohol dependence were combined into one disorder—AUD. Further, based on 11 diagnostic criteria in DSM-5, AUD was classified into 3 categories: mild, moderate, and severe. Table 2-2 presents the DSM-IV and DSM-5 criteria.

When DSM-IV was in use, meeting any one of the alcohol abuse criteria would indicate the presence of alcohol abuse, and meeting any three of the alcohol dependence criteria would indicate the presence of alcohol dependence. In DSM-5, an AUD is diagnosed if symptoms for at least 2 of the 11 criteria are present. In DSM-5, an AUD is considered to be mild if two or three symptoms are present, moderate if four to five symptoms are present, and severe if six or more symptoms are present (NIAAA 2016; APA 2013). The criterion in DSM-IV pertaining to legal consequences due to driving was excluded in DSM-5 and a new criterion regarding alcohol cravings was added as an AUD diagnostic measure.

Once diagnosed with an AUD, specific options for an individualized treatment plan are identified. Because AUD causes and symptoms are complex, treatment options are varied. In a SAMHSA technical assistance publication (TAP), existing treatment options were reviewed and grouped into two categories: (1) biologically based treatment including pharmacotherapeutic treatment (e.g., use of medications such as disulfiram, naltrexone, and acamprosate) and acupuncture/ transcutaneous electrical nerve stimulation; and (2) behaviorally or psychosocially based treatment, including residential or inpatient treatment (e.g., inpatient hospitalization and therapeutic communities) and outpatient treatment (SAMHSA 1994, 2015b). A variety of treatment components, such as individual self-help programs (e.g., the Alcoholics Anonymous 12-step program), individual counseling, group therapy, family therapy, behavior modification, and aversive conditioning, can be used in any of the treatment options.

With regard to recommended treatment goals, especially concerning abstinence versus controlled drinking, NIAAA (2005a) recommendations include the following:

- Abstinence is preferred for drinkers who have certain medical or physical conditions (e.g., pregnancy), are taking a contraindicated medication, have a medical or psychiatric disorder that can be exacerbated by drinking, or have an AUD.
- For heavy drinkers without AUDs, professional judgment should be used to determine whether abstaining from drinking or cutting down on drinking is appropriate, based on family history of substance abuse, age, injuries due to drinking, and co-occurring disorders (e.g., sleep disorder or sexual dysfunction).

Table 2-2. Comparison of DSM-IV and DSM-5 Criteria

	DSM-IV		DSM-5
	In the past year, have you:		**In the past year, have you:**
Any one = Alcohol Abuse	Found that drinking—or being sick from drinking—often interfered with taking care of your home or family? Or caused job troubles? Or school problems?	**1**	Had times when you ended up drinking more, or longer, then you intended?
	More than once got into situations while or after drinking that increased your chances of getting hurt (e.g., driving, swimming, using machinery, walking in dangerous areas, or having unsafe sex)?	**2**	More than once wanted to cut down or stop drinking, or tried to, but couldn't?
	More than once got arrested, been held at a police station, or had other legal problems because of your drinking?[(a)]	**3**	Spent a lot of time drinking? Or being sick or getting over other aftereffects?
	Continued to drink even though it was causing trouble with your family or friends?	**4**	Wanted a drink so badly that you couldn't think of anything else?[(b)]
Any 3 = Alcohol Dependence	Had to drink much more than you once did to get the effect you wanted? Or found that your usual number of drinks had much less effect than before?	**5**	Found that drinking—or being sick from drinking—often interfered with taking care of your home or family? Or caused job troubles? Or school problems?
	Found that when the effects of alcohol were wearing off, you had withdrawal symptoms, such as trouble sleeping, shakiness, restlessness, nausea, sweating, a racing heart, or a seizure? Or sensed things that were not there.	**6**	Continued to drink even though it was causing trouble with your family or friends?
	Had times when you ended up drinking more, or longer, then you intended?	**7**	Given up or cut back on activities that were important or interesting to you, or gave you pleasure, in order to drink?
	More than once wanted to cut down or stop drinking, or tried to, but couldn't?	**8**	More than once got into situations while or after drinking that increased your chances of getting hurt (such as driving, swimming, using machinery, walking in dangerous areas, or having unsafe sex)?
	Spent a lot of time drinking? Or being sick or getting over other aftereffects?	**9**	Continued to drink even though it was making you feel depressed or anxious or adding to another health problem? Or afterwards experienced a memory blackout?
	Given up or cut back on activities that were important or interesting to you, or gave you pleasure, in order to drink?	**10**	Had to drink much more than you once did to get the effect you wanted? Or found that your usual number of drinks had much less effect than before?
	Continued to drink even though it was making you feel depressed or anxious or adding to another health problem? Or afterward experienced a memory blackout?	**11**	Found that when the effects of alcohol were wearing off, you had withdrawal symptoms, such as trouble sleeping, shakiness, restlessness, nausea, sweating, a racing heart, or a seizure? Or sensed things that were not there.

(a) This criterion is not included in DSM-5.

(b) This criterion is new to DSM-5.

Source: NIAAA (2016)

- Compared to controlled drinking, the NIAAA states that abstinence is "the safest strategy … [and] has a greater chance of long-term success."
- If patients who have an AUD are unwilling to abstain, they might be willing to cut down on their drinking.
- If cutting down is the initial strategy but the patient fails to stay within limits, abstinence is recommended.

To ensure patients receive the appropriate level of care and achieve treatment goals, the following five practices are recommended as part of treatment strategies to enhance treatment effectiveness (SAMHSA 1994; Messalle 1992):

- Use appropriate diagnostic instruments and processes to determine the nature of the problem and an individual patient's need for treatment;
- Match/align a patient's need with treatment plans to ensure that the patient's "personality, background, mental condition, and the extent and duration of substance abuse determined by assessment" are taken into consideration to customize the treatment plan;
- Provide comprehensive services beyond the specific alcohol treatment to help address the patient's complex health, financial, legal, psychological, and other needs;
- Prevent relapse by assessing the triggers such as specific events, people, circumstances, location, and activities that could cause patients to relapse; and
- Hold treatment programs accountable by evaluating treatment success, treatment program integrity, and treatment outcome including patients' success in abstinence and social adjustment, and behavioral changes such as crime reduction.

The DHHS agencies provide online resources for treating AUD and other disorders. For example, resources available at SAMHSA include treatment improvement protocols such as *Incorporating Alcohol Pharmacotherapies into Medical Practice* (SAMHSA 2009), which provides clinical guidelines for using medications in AUD treatment. The SAMHSA-Health Resources and Services Administration (HRSA) Center for Integrated Health Solutions provides a host of online resources for AUD screening, such as DSM-5 online assessment measures, AUDIT, AUDIT-C (short form of the AUDIT instrument), and CAGE.[5,6] The center also provides NIAAA's computer-based tools for cost-effective assessment of and intervention to address AUDs. These include a web-based training course and resources from non-governmental organizations (e.g., the University of Washington's substance use screening and assessment database).[7]

[5] AUDIT is a 10-item screening tool to assess alcohol consumption, drinking behaviors, and alcohol-related problems. The AUDIT acronym stands for the Alcohol Use Disorders Identification Test. https://www.drugabuse.gov/sites/default/files/files/AUDIT.pdf

[6] CAGE is a four-question survey used to identify potential alcohol dependence. The CAGE acronym stands for the four areas identified: felt need to **C**ut back, **A**nnoyance by critics, **G**uilt about drinking, and **E**ye-opening morning drinking. https://psychology-tools.com/cage-alcohol-questionnaire/

[7] SAMHSA-HRSA (Health Resources and Services Administration) Center for Integrated Health Solutions: http://www.integration.samhsa.gov/clinical-practice/screening-tools#drugs

2.2.3 Summary on AUD Diagnosis and Treatment

Reducing the impact of alcohol abuse on American communities is an important goal of the DHHS and its agencies, SAMHSA and NIAAA. These agencies have funded research and programs to better understand, prevent, and treat disorders associated with alcohol abuse. They have also developed guidelines and technical publications for screening, diagnosing, and treating individuals who have AUDs to help clinicians and other professionals specializing in substance abuse treatment to make appropriate diagnoses and develop tailored treatment plans that best serve the needs of individual patients.

The NIAAA clinician's guide does not recommend a one-size-fits-all approach to AUD treatment. Instead, the agency suggests that the treatment plan and the level of care should be compatible with the patient's individualized circumstances such as his/her personality, background, mental conditions, and family/social relationships to provide a holistic treatment for AUD. In the NIAAA clinician's guide, the DSM diagnostic criteria developed by the APA are an important component of the AUD screening and diagnosis workflow. The guide also identifies groups of individuals for whom total abstinence should be recommended, and observes that abstinence is the "safest strategy" with better long-term outcomes for AUD patients.

2.3 Interviews with Substance Abuse Subject Matter Experts

To supplement the findings of the literature review, interviews were conducted with SMEs specializing in substance abuse treatment to gather their professional perspectives on alcohol use, diagnosis, treatment standards, and testing. The purpose of SME input was to understand whether there is a "gold standard" in AUD treatment and whether total abstinence is an industry-wide preferred treatment option/goal. The inputs from the SMEs also include their professional insights into assessment, treatment, post-treatment, and monitoring processes. This section summarizes the methods used and the results of these interviews.

2.3.1 Expert Interviews: Purpose and Methods

Eleven in-depth semi-structured interviews were conducted with substance abuse SMEs to understand how and under what circumstances these SMEs diagnose and recommend near-term and long-term treatment for individuals who have problems with alcohol use. An additional goal of the interviews was to gather professional perspectives on the practice of requiring total abstinence from alcohol use and the circumstances that warrant the recommendation of total abstinence as part of the treatment and post-treatment maintenance requirements.

Expert interviewing is a qualitative, non-probabilistic, purposeful sampling technique used to gain knowledge from individuals who have expertise in a particular subject (Patton 2002).[8] Individuals interviewed are selected because of their knowledge and their ability to answer specific research questions. Purposeful sampling is ideal when the goal is to gather "information-rich cases for study in-depth" rather than "empirical generalizations" (Patton 2002, p. 203). One disadvantage of non-probabilistic purposive sampling is that it is not possible to defend the representativeness of the sample. However, for the purposes of this report, the goal was not to quantitatively evaluate consensus among experts—as is common with survey instruments—but to qualitatively present a range of professional perspectives on total abstinence requirements in the workplace.

[8] According to Patton (2002), purposeful sampling is also known as judgment or purposive sampling.

A series of semi-structured and open-ended questions were developed to elicit the SMEs' input on understanding differences, if any, in an individual's path into a treatment program (e.g., self-referral or workplace requirement), methods for diagnosing alcohol problems including category of diagnosis, requirements for abstinence and effectiveness of treatment, alcohol compliance testing, post-treatment abstinence requirements, and professional standards and guidelines regarding alcohol treatment programs. (See Appendix A for a complete list of questions.) Snowball, or chain-referral, sampling, was also used. This is another non-probabilistic sampling method that relies on asking the SMEs being interviewed to use their professional network to refer and identify other experts to interview (Patton 2002:237-238).

2.3.2 Description of Substance Abuse Organizations Contacted and Substance Abuse Experts Interviewed

The project team developed a preliminary list of 15 substance abuse organizations as a means to identify SMEs to interview (a list of these organizations and their associated mission is provided in Appendix A). The list of substance abuse organizations included two Federal agencies, five research organizations, five professional organizations, and three SAE certification organizations. The team made initial contacts with representatives from these organizations by e-mail and telephone. All interviews were conducted over the telephone.

Four of the 15 initial contacts resulted in an interview with an affiliated substance abuse treatment expert; these were: SAMHSA, National Council on Alcoholism and Drug Dependence, International Certification Reciprocity Consortium (IC&RC), and American Academy of Healthcare Providers in the Addictive Disorders. Four provided six referrals: the American Academy of Addiction Psychiatry (AAAP) provided three referrals; the Center for Substance Abuse Research provided one referral; the IC&RC provided one referral and the Alcohol Research Group provided one referral. Five of the six referred experts were interviewed. Of the five, one provided three additional referrals, of which one was interviewed, and one provided one referral, who was also interviewed. Thus, 11 interviews were conducted between May 3 and June 13, 2016. Of those, 10 were extensive interviews (see Table 2-3). The interviewees represented a broad spectrum of experience in treatment of both substance abuse and addiction. The majority of the interviewed SMEs are practicing clinicians, some of whom are affiliated with treatment centers or affiliated with universities and actively involved in research; others are practicing Medical Review Officers (MROs). One interviewee is affiliated with a Federal agency and actively involved in training SAEs.

Table 2-3. Results of Contacts Made with Substance Abuse Organizations that Resulted in an Interview and/or Referral

Substance Abuse Organizations Interviewed or Providing a Referral	Results	Referral
Federal Agencies		
1. Substance Abuse and Mental Health Services Administration (SAMHSA)-Health Resources and Services Administration (HRSA), Center for Integrated Health Solutions run by the National Council for Behavioral Health	Interviewed Aaron Williams, MA, Director of Training and Technical Assistance for Substance Abuse on May 3, 2016.	No referral provided.

Table 2-3. (contd)

Substance Abuse Organizations Interviewed or Providing a Referral	Results	Referral
Professional Organizations		
2. National Council on Alcoholism and Drug Dependence, Inc. (NCADD)	Interviewed Dr. Mel Pohl (member of NCADD's Medical Scientific Committee) and Medical Director at Las Vegas Recovery Center on May 4, 2016.	No referral provided.
3. American Academy of Addiction Psychiatry (AAAP)	Spoke with Executive Director Kathryn Cates-Wessel on May 13, 2016 who provided contact information for three experts: Larry Westreich, MD Tom Kosten, MD, PhD Kevin Sevarino, MD, PhD	Three referrals provided and interviewed.
	Interviewed Dr. Larry Westreich, MRO, consultant to Major League Baseball and a private clinician on May 26, 2016.	Dr. Westreich provided three referrals of which Dr. Louis Baxter was interviewed.
	Interviewed Dr. Thomas Kosten, professor, and Jay H. Waggoner, Endowed Chair in the Menninger Department of Psychiatry and Behavioral Sciences at Baylor College of Medicine in Houston, Texas on May 31, 2016.	No referral provided.
	Interviewed Dr. Kevin Sevarino, active clinician, serving as Medical Director attending for the VA Connecticut Healthcare System Newington Mental Health Firm on May 31, 2016.	No referral provided.
	Interviewed Dr. Louis Baxter, President, Chief Executive Officer, and Executive Medical Director for the Professional Assistance Program of New Jersey and Certified MRO, consultant to the National Football League and the National Basketball Association on June 14, 2016.	No referral provided.
	Interviewed Alan Davis, a PhD. Candidate at Bowling Green State University who has conducted surveys regarding acceptability of non-abstinence goals on May 4, 2016.	One referral provided (Dr. Rosenberg) and interviewed.

Table 2-3. (contd)

Substance Abuse Organizations Interviewed or Providing a Referral	Results	Referral
Certification Organizations		
4. International Certification Reciprocity Consortium (IC&RC)	Interviewed Dr. David Turpin, Chair of Credentialing Services for IC&RC and private clinician on May 3, 2016.	IC&RC provided one additional referral (Alan Davis) who was interviewed.
	Interviewed Dr. Harold Rosenberg, Professor at Bowling Green State University clinical psychologist who co-authored paper with Alan Davis on acceptability of non-abstinence goals on May 25, 2016.	No referral provided.
5. American Academy of Healthcare Providers in the Addictive Disorders	Interviewed Dr. John Fitzgerald, private clinician and Certified Addiction Specialist on May 11, 2016.	No referral provided.
Research Organizations		
6. Center for Substance Abuse Research	Spoke with Director Eric Wish on April 14, 2016 who provided contact information for Dr. Robert DuPont, President of the Institute for Behavior and Health.	One referral provided and interviewed.
	Spoke briefly with Dr. Robert DuPont, President of the Institute for Behavior and Health on April 28, 2016.	One referral provided but not interviewed.
7. Alcohol Research Group	E-mailed with Diane Schmidt, Communications Specialist who reached out to researchers on staff. Staff provided contact information for Genevieve Ames of Pacific Institute for Research and Evaluation.	One referral provided but not interviewed.

2.3.3 Interview Analysis and Results

In the approximately one-hour interviews, the interviewer asked questions from the list of interview questions (Appendix B) while a scribe took notes. Time constraints limited the number of questions asked of each SME. As a result, each was asked a different subset of the interview questions tailored to the SME's expertise. However, all interviews included discussion of diagnosis and assessment, treatment, perspectives on non-abstinence goals, perspectives on requirements for total abstinence in the workplace and circumstances surrounding those requirements, and professional organizations/guidelines. Once interviews were completed, summary notes for each interview were generated and reviewed by the interviewer. Interview responses were categorized by topics covered in the questions and by additional topics that

emerged in the responses. A total of 10 major topic categories were identified; these are listed below and followed by more detailed discussion:

- path into treatment,
- diagnostic tool(s),
- diagnostic categories/criteria,
- reliability of diagnostic tool(s),
- treatment types and relationship of diagnosis to treatment,
- circumstances requiring total abstinence,
- circumstances where total abstinence may not be necessary or required,
- alternatives to abstinence and perspectives on non-abstinence goals,
- testing and monitoring, and
- professional organizations.

2.3.3.1 Path into Treatment

Most experts agreed that treating professionals' decisions about an individual's treatment are based on what is best for the patient and are not affected by whether they are in a treatment program as a workplace requirement or by self-selection. However, the reason an individual is in treatment can play a role in the patient's motivation (i.e., internal or external) to remain abstinent. In workplace situations, some employers have specific requirements that the treating professional is required to consider when choosing treatment options.

2.3.3.2 Diagnostic Tool

All experts interviewed referred to the DSM as the primary tool used to make an initial assessment about an individual's alcohol use (see Section 2.2.2 for DSM criteria).

According to experts interviewed, the DSM AUD criteria are the accepted means for establishing an AUD in a legal context as well as for medical insurance reimbursement purposes. All acknowledged that the DSM is one tool that is routinely used, but other tools are necessary to fully evaluate an individual and establish the extent of his/her AUD and any other co-occurring conditions such as other addictions or mental health disorders (also known as dual-diagnoses). Experts identified several screening tools used in addition to the DSM. These include the Addiction Severity Index, Substance Abuse Screening Inventory, the NIH's Alcohol Use Disorders Identification Test (AUDIT), Minnesota Multiphasic Personality Inventory (MMPI), T-ACE, and CAGE (see http://pubs.niaaa.nih.gov/publications/arh28-2/78-79.htm for a more detailed description of these tools).

Additional evaluation and assessment tools may also be used. These may include clinical interviewing (i.e., Structured Clinical Interview for DSM disorders [First et al. 2016]) to collect information about the individual's psychosocial history, personal development, childhood and family, and the individual's case history. Blood tests and other medical tests might also be used as physical indicators of recent and long-term alcohol use (see Section 3.1).

The experts identified other key variables for distinguishing between an individual with an AUD and an individual who made a one-time poor judgment after binge drinking. These include an assessment of the severity of the addiction, the length of time using, family history of AUD, history of trauma, a comprehensive evaluation of the individual's situation, self-report, and family input.

2.3.3.3 Diagnostic Categories/Criteria

As described in Section 2.2, the SMEs confirmed that the DSM-5 is considered the authoritative set of diagnostic criteria. However, they also referred to alternative definitions of an alcoholic. One definition presented is someone who repeatedly uses alcohol despite adverse consequences in various aspects of their lives (i.e., social, emotional, work-related, personal, and family life) and is unable to control his or her drinking. The SMEs also mentioned the American Society of Addiction Medicine (ASAM) definition of addiction, as follows:

> … a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors.
>
> Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death.[9]

As an alternative to the disease model described by ASAM, some SMEs defined addiction using a functional analysis model where the analysis and diagnosis focus on the role/function alcohol plays in the individual's life. Within this framework, the focus is on the reasons an individual is addicted and their associated addictive behaviors.

The SMEs also mentioned that the impetus to seek treatment, whether voluntary or mandated (e.g., due to being impaired on the job or getting a DUI), is a good indication that there is a problem indicative of an AUD. The SMEs agreed that it is possible for an individual to have exercised poor judgment when he or she tested positive for alcohol on the job or within the context of a DUI without the positive test result indicating a disorder. Most SMEs stated that these cases are rare, however, and more likely in someone who is young (below 25 years old). In most instances, this type of incident indicates a chronic alcohol problem rather than a one-time lapse in judgment. It is also possible for individuals who do not have an AUD to be able to control their drinking. However, all SMEs agreed that the hallmark of an individual with an AUD is the inability to stop or control their drinking; thus, controlled drinking is not a viable recommendation for treatment.

2.3.3.4 Reliability of the Diagnostic Tool

Most experts expressed concern about the accuracy and reliability of using the DSM as a stand-alone tool for assessing AUD. Most stated that it is a good screening tool, but find some of the criteria to be problematic. They noted that under the DSM-IV, depending on the number of diagnostic criteria met, diagnoses were differentiated—an individual could be diagnosed as having "alcohol abuse" or "alcohol dependence" with the former being less severe than the latter. Under the DSM-5, as long as an individual meets any 2 of the 11 criteria, the diagnosis would be a single disorder, AUD, with three sub-classifications—mild, moderate, and severe—based on the number of criteria met. Despite this broad-brush approach to labeling the

[9] http://www.asam.org/quality-practice/definition-of-addiction

disorder, individuals who have AUDs will have different treatment needs, depending upon the severity of the disorder.

Experts specifically expressed concern about the revised diagnostic criteria in DSM-5 for a number of reasons. For one, the criteria are not mutually exclusive and some have considerable overlap. As a result, if there is a significant overlap between two criteria, meeting one criterion could potentially mean meeting the other, thus leading to an AUD diagnosis. For example, Criterion 3 (drinking—or being sick from drinking—often interferes with taking care of your home or family, or caused job troubles, or school problems) and Criterion 6 (continues to drink even though it is causing trouble with your family or friends) describe two similar conditions that could result in an individual simultaneously meeting both criteria, and hence being diagnosed as having an AUD. Further, the DSM-5 diagnostic criteria are weighted equally in the diagnosis, which might override meaningful nuances in terms of how they relate to the diagnosis. For example, due to equal weights across the criteria, no distinction is made between someone who faces adverse consequences due to drinking but still has the ability to stop drinking on his/her own volition versus someone whose drinking is such that he/she is unable to stop, and adverse consequences occur as a result. Additionally, the DSM-5 is limited to assessing behaviors within the past 12 months. If this restriction is overlooked and historical behavior prior to the 12-month time frame is used in a clinical evaluation, incorrect diagnosis regarding the severity of the disorder would be possible. Finally, responses to some of the criteria rely heavily on self-reporting, which would require substantiation and corroboration from other information sources. Some experts stated that they augment the individual's self-reports with additional information (e.g., from the spouse, employer, or family) to confirm the diagnosis.

The DSM serves to label individuals, but labeling can mask important information (e.g., history of the problem, motivation and commitment to change, prognosis for recovery, and coping skills) needed to develop an individualized treatment plan. To understand how to best treat individuals with an AUD, all SMEs stressed the importance of using additional screening and evaluation tools (in tandem with the DSM) to make an individualized assessment to allow a firm diagnosis of an AUD, but also to understand the foundation of the problem, evaluate any co-occurring addictions, and develop an individualized treatment plan. Two of the SMEs interviewed are certified MROs with experience screening individuals for AUD within a workplace context. These SMEs indicated that individualized assessment is necessary to comply with the ADA, to clearly establish whether an individual has an AUD, and to be able to make reasonable recommendations for treatment (see Section 5.1 on the ADA).

2.3.3.5 Treatment Types and Relationship of Treatment to Diagnosis

The SMEs made it clear that abstinence is not a type of treatment, but rather a goal of treatment. Most treatment programs and SMEs recommend total abstinence as part of their programs. Alternative treatments, when not recommending total abstinence or if the individual does not have an AUD, include alcohol education, assessing readiness for change, working to set goals for reduced drinking based on client's input, self-monitoring, and cue-exposure therapy (see Rosenberg 2002).

Several SMEs referred to ASAM's placement criteria[10] when selecting a treatment program or service for individuals with an AUD. ASAM's treatment criteria provide a spectrum of treatment options that are dependent upon the severity of the alcohol dependence. They include early intervention, outpatient services, and inpatient services ranging from residential inpatient

[10] See http://www.asam.org/quality-practice/guidelines-and-consensus-documents/the-asam-criteria/about

services to medically managed intensive inpatient services including detox. Within the context of these services, patients would receive group and individual therapy. Variables affecting selection of treatment include the following:

- individual differences and goals of the individual,
- severity of dependence,
- specific requirements within a work context,
- patient factors (e.g., time away from work, cost, and availability of resources),
- individual context and needs (e.g., history or trauma, depression, or abuse),
- individual motivation and resilience, and
- mental health history.

Most SMEs stressed the importance of developing an individualized care plan. Several other therapeutic paradigms that would be recommended based on the results of the individualized assessments and evaluation of the patient's antecedent problems include, but are not limited to, the following:

- 12-step programs,
- dialectical behavioral therapy,
- cognitive behavioral therapy,
- acceptance and commitment theory,
- mindful meditation,
- contingency management,
- addiction medications (Campral, Naltrexone, Antabuse),[11]
- psychotherapy,
- alcohol education,
- treatment of anxiety and depression,
- yoga,
- motivational interviewing,
- community reinforcement approach, and
- psychoeducation.[12]

2.3.3.6 Circumstances Requiring Total Abstinence

The SMEs provided an extensive list of circumstances in which total abstinence should be required. These circumstances include the following:

- The individual meets the definition of an AUD/dependent (loss of control and continues to drink despite adverse consequences).
- The individual presents mild AUD, for which the preferred recommendation would still be abstinence as a preventative measure to protect the long-term health of the individual.
- The individual presents denial and craving, which are symptoms of an AUD; thus they are not going to want to abstain. This is a good indication that the individual needs to abstain.
- The individual is self-motivated and wants to totally abstain.

[11] See http://pubs.niaaa.nih.gov/publications/10report/chap08c.pdf

[12] According to Lukens and McFarlane (2004), psychoeducation is an evidence-based treatment modality that integrates psychotherapeutic and educational interventions focused on empowering and working collaboratively with individuals who have a mental health condition by helping them better understand and adjust to living with their condition.

- The individual's work requires abstinence or abstinence is court-ordered (e.g., a DUI).
- The individual performs safety- and/or security-sensitive work and thus must be held to a higher standard.
- The individual's history suggests abstinence is necessary but it is important to also focus on treating the whole person (i.e., emotional, mental health and physical needs, level of resilience, ability to cope).
- The individual presents a threat to him/herself (i.e., suicidal) or others.
- The individual has severe health problems.
- The individual has had multiple relapses, endangers his/her own and others' physical well-being, or has impaired relationships in school, social settings, work, family, etc.
- The individual has job performance problems in the workplace, especially for a safety- and/or security-sensitive job.
- The individual presents a pattern of, or inability to control, alcohol use.

Two SMEs indicated that they would not recommend abstinence to their patients outright if the patient was not interested in abstaining. Both indicated that within a clinical setting, the goal is to build a therapeutic alliance and a trusting relationship with their patient, allowing them to assess the patient's motivation for change and letting the patient decide if they can try controlled drinking. Of these two SMEs, one did believe that abstinence was necessary if the patient had an AUD; however, their respect for the patient outweighed their desire to force abstinence on an unwilling patient—particularly in the context of the therapeutic relationship.

With the exception of the two SMEs described above who are proponents of non-abstinence goals, most SMEs were in agreement that abstinence was necessary for individuals with an AUD. Within the context of the work setting, SMEs were in agreement that total abstinence should be required if an individual has an AUD—hence the importance of the individualized assessment—but job setting and related risk of position also play a role. For example, for personnel working in safety- or security-sensitive positions, it was even more important to require an individual with an AUD to be totally abstinent. Several SMEs mentioned the PHP as an example of a workplace-treatment program for physicians predicated on total abstinence, which requires routine monitoring to test for total abstinence over the course of 5 years (see DuPont et al. 2009, 2008; McLellan et al. 2008). PHPs are discussed further in Section 4.4.

2.3.3.7 Circumstances Where Total Abstinence May Not Be Necessary or Required

The SMEs provided the following responses regarding circumstances where total abstinence would not be required or necessary:

- Because alcohol is legal, one has to establish whether an individual has an AUD. If the individual does not have an AUD, he or she may only require a brief intervention and a discussion about what drove the behavior.
- If use is not problematic and not causing an individual to be unable to meet the demands of his or her job.
- If an individual is a "one-time" problem drinker and does not have an AUD.
- If within the context of a therapeutic relationship an SAE can work with the individual to try controlled drinking.

2.3.3.8 Alternatives to Abstinence and Perspectives on Non-Abstinence Goals

Alternative non-abstinence based programs include controlled drinking, moderation management, smart recovery, and harm reduction. According to most SMEs, the perspective on non-abstinence goals for alcohol is changing compared to what it was 25 years ago (see Davis and Rosenberg 2013). Some believe that this is changing because of the shift in types of individuals entering the addiction field. In the past, many individuals with addiction issues themselves became SAEs and most went through Alcoholics Anonymous (AA) programs, which strongly advocate abstinence. But with the exception of the two SMEs who support non-abstinence goals within the context of a clinical setting, most SMEs interviewed were not supportive of non-abstinence goals. According to the other nine SMEs, abstinence is still the dominant approach, but more clinicians have increased their open-mindedness about treating individuals with respect and supporting their pursuit of alternative goals (e.g., controlled drinking). Two of those interviewed were supportive of non-abstinence goals and one did not recommend non-abstinence goals but was still willing to work with individuals on non-abstinence goals.

2.3.3.9 Testing and Monitoring

The SMEs had a variety of experience with and perspectives on EtG testing. The most important takeaway from this input is that most of the SMEs who were familiar with EtG testing are aware of incidental exposure and do not interpret a test level of 500 ng/mL or lower as positive. Also, both MROs interviewed expressed the opinion that it is important that the medical professional interpreting EtG test results be qualified in order to defend interpretations against claims of positives due to incidental exposure or false positives (e.g., fermented glucose from individuals with diabetes or individuals with a urinary tract infection; see Section 3.3.2) in a legal setting. They stated that it is also important that the medical professional interpreting EtG test results have some familiarity with the individual and the circumstances surrounding the individual when interpreting lower EtG levels and that the MRO use this additional information to augment his or her interpretation of lower EtG levels. Some SMEs indicated that monitoring was important and could motivate an individual to remain abstinent. For people who do not have a problem, monitoring will not pose a problem; however, for those that do have a problem, their problem will manifest because of their inability to control their drinking. Two of the SMEs indicated monitoring could undermine the therapeutic relationship and is therefore not therapeutically useful. SMEs also mentioned the following monitoring tests:

- Soberlink®, a wireless mobile breathalyzer used to remotely and randomly assess impairment;
- Carbohydrate deficiency transferrin (CDT), used to detect heavy drinking (expensive but fairly accurate); and
- Psychomotor testing to test executive function, which can provide additional information when conducting impairment testing. This kind of testing would be important for individuals who have high tolerance levels and are able to function at high BAC levels, but are still impaired.

2.3.3.10 Professional Organizations

SMEs were asked if there was any one entity that establishes professional guidelines for SAEs and treatment professionals and if abstinence was recommended as part of treatment. All SMEs indicated that the DSM is the most authoritative reference used by mental health

professionals when diagnosing an AUD and that most professional organizations representing SAEs uniformly recommend some form of abstinence for treatment. There are a variety of professional organizations that focus on alcohol and addiction distinguished by various mental health disciplines (e.g., social worker, psychiatrist, addiction treatment counselor, substance abuse professional, mental health practitioner) and each provides a discipline-specific focus on substance abuse training and treatment guidelines. SMEs provided the following list of professional organizations affiliated with addiction expertise:

- American Academy of Addiction Psychiatry (AAAP),
- American Board of Addiction Medicine (ABAM),
- American Psychological Association (APA),[13]
- American Society of Addiction Medicine (ASAM),
- Employee Assistance Program (EAP) associations,
- National Association for Alcohol and Drug Abuse Counselors (NADAAC),
- National Institute on Alcohol Abuse and Alcoholism (NIAAA),
- Substance Abuse and Mental Health Services Administration (SAMHSA),
- States (licensure and certification), and
- Department of Veterans Affairs (which has the highest standards for implementing evidence-based practices).

2.3.4 Summary on Subject Matter Expert Interviews

The interviews resulted in findings that complement those revealed in the literature review regarding the process and diagnostic tools used for conducting assessments and treatment types. They added clarification regarding the reliability of diagnostic tools and their relationship to treatment recommendations, circumstances requiring total abstinence, and the interrelationships of requirements for total abstinence within the context of an employer where job performance has the potential to place the public at risk and how that influences workplace policy. They also corroborated the literature review findings about the sensitivity of EtG testing and the importance of interpretation (see Section 3.0). A summary of the clarifying and pertinent themes that emerged as a result of the interviews is provided below:

- the importance of assessment and how it ties to treatment and recommendations including total abstinence;
- the importance of using the DSM as the authoritative standard for diagnosing and AUD thereby providing a legally defendable and medically sound basis for diagnosis, and equally important the need to conduct additional evaluation to individualize treatment;
- the need to be able to demonstrate influence on job performance in order to recommend total abstinence;
- the need to have offered treatment in response to an AUD diagnosis in accordance with the ADA;

[13] The American Psychological Association shares the acronym APA with the American Psychiatric Association. In all other instances in this report, APA refers to the American Psychiatric Association.

- the concept that risk plays a role in workplace policy when recommending total abstinence; and
- the concept that total abstinence is not an unreasonable requirement in a safety- and/or security-sensitive job if a person has been evaluated to have an AUD and has had performance issues or tested positive for alcohol on the job.

Because there are issues surrounding interpretation of EtG levels under 500 ng/mL, experts interpreting EtG results should use caution and need to be knowledgeable about the limitations of EtG testing when interpreting results. In situations where EtG testing results in levels at or under 500 ng/mL, the consensus was that experts should also evaluate additional information (i.e., individual inquiry, medical, mental health, and substance use history) to establish whether it is possible that the EtG results are indicative of accidental exposure rather than alcohol ingestion.

3.0 Testing for Alcohol Consumption and Abstinence Compliance

Detection of alcohol[14] and its metabolites in an individual's specimen provides empirical evidence of that individual's alcohol use or exposure. Factors important in testing for alcohol use include the following:

- length of time ethanol or an ethanol metabolite has a detectable presence,
- whether test data can be attributed to alcohol consumption, and
- how well the test data represent the individual's consumption of alcohol.

3.1 Alcohol Metabolism and Metabolic Products Used in Testing

Testing for recent alcohol consumption is relatively straightforward and is accomplished by direct determination of BAC or its estimation from breath. However, ethanol is only found in test matrices until metabolized.[15] A number of ethanol's metabolites are detectable for considerably longer and can be used in detection and monitoring programs for providing evidence of alcohol consumption over a longer window of detection.

3.1.1 Overview of Ethanol Metabolism

Alcohol is most commonly ingested as a beverage or in food; however, it can also be absorbed directly into the blood through respiration of alcohol vapors (Skipper et al. 2009; Arndt et al. 2014b). Alcohol is not absorbed in detectable quantities through the skin unless the skin is damaged with open wounds or abrasions (Skipper et al. 2009; Arndt et al. 2014a).

After ingestion, alcohol absorption into the blood stream begins immediately as it passes through the stomach and into the small intestine; about 95–98 percent of the ingested alcohol will be absorbed (Helander and Beck 2005). The resulting BAC is dependent on a number of factors including the amount of alcohol, rate of drinking, gender, food in the stomach, weight, chronic alcohol consumption, and genetic factors related to absorption, elimination, and metabolic breakdown (Zakhari 2006). About 5 percent of ingested alcohol is eliminated unchanged via urine, sweat, and breath (Maenhout et al. 2013).

Alcohol metabolizes through several pathways as shown in Figure 3.1. As alcohol is absorbed into the blood stream from the digestive system, it is initially transported directly to the liver where it undergoes a two-stage oxidation process called first pass metabolism. During this and subsequent passes through the liver, ethanol is metabolized in two steps to yield acetaldehyde and then acetate. A small percentage of ethanol metabolizes via other pathways to EtG or ethyl sulfate (EtS) and additional, very minor metabolic pathways that yield phosphatidyl ethanol (PEth) and fatty acid ethyl esters (FAEE).

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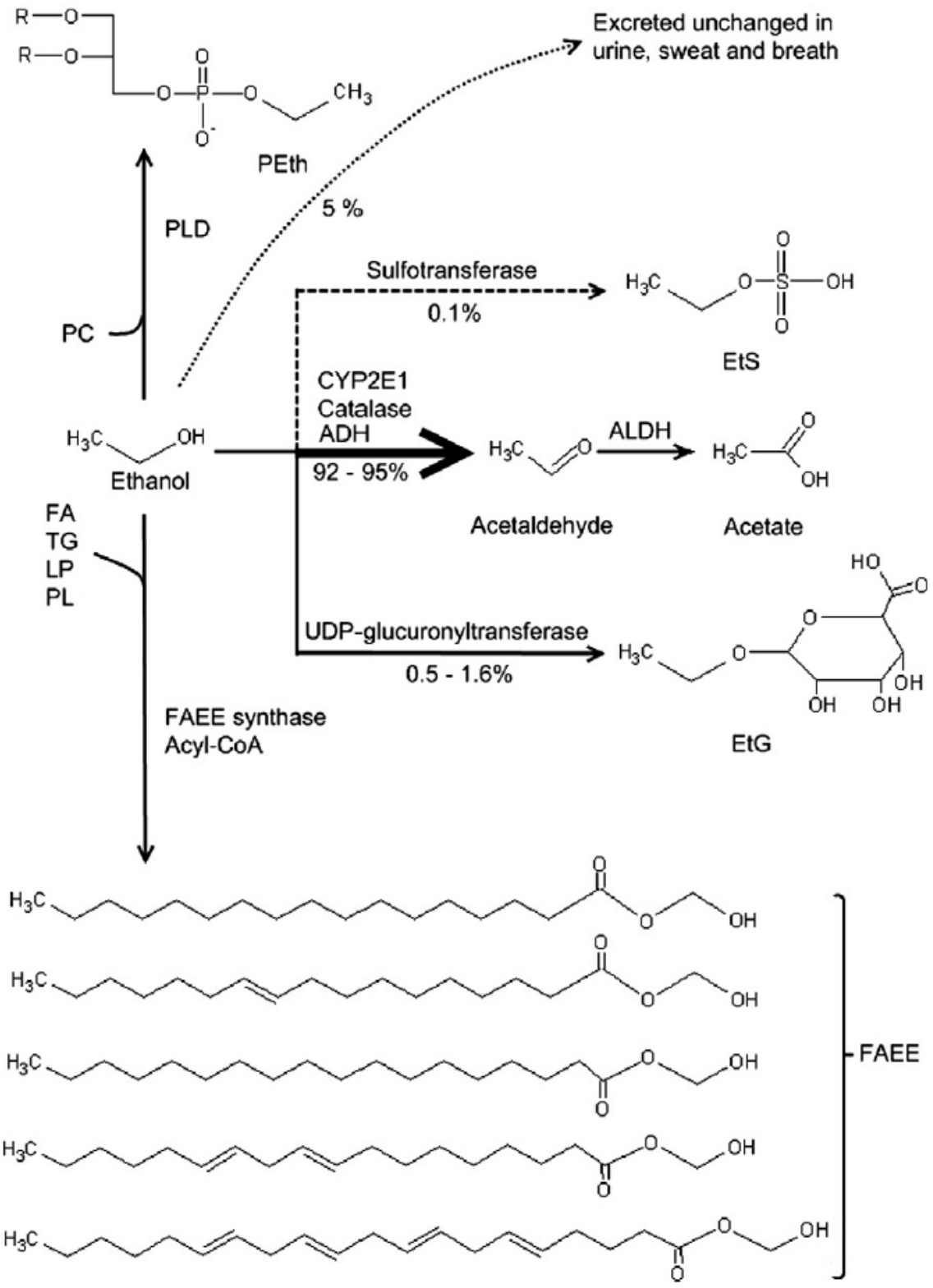
[14] In the context of metabolism and testing, it is sometimes important to distinguish ethanol from other alcohols (e.g., iso-propanol). In these cases, the term ethanol is used; otherwise, the term alcohol is used consistent with the rest of this report.

[15] Ethanol is metabolized at about 0.01 BAC per hour (the rate varies somewhat due to factors such as gender, weight, and whether food is in the stomach). For an individual with a starting BAC of 0.1, the BAC will be reduced to 0.07 within two hours and to 0.01 after six hours. See https://pubs.niaaa.nih.gov/publications/aa35.htm and https://www.mayomedicallaboratories.com/test-info/drug-book/alcohol.html for more information.



(Reprinted from Clinica Chimica Acta 415:322–329, Maenhout T.M, M.L. De Buyzere, and J.R. Delanghe, Non-Oxidative Ethanol Metabolites as a Measure of Alcohol Intake, Copyright 2013, with permission from Elsevier.)

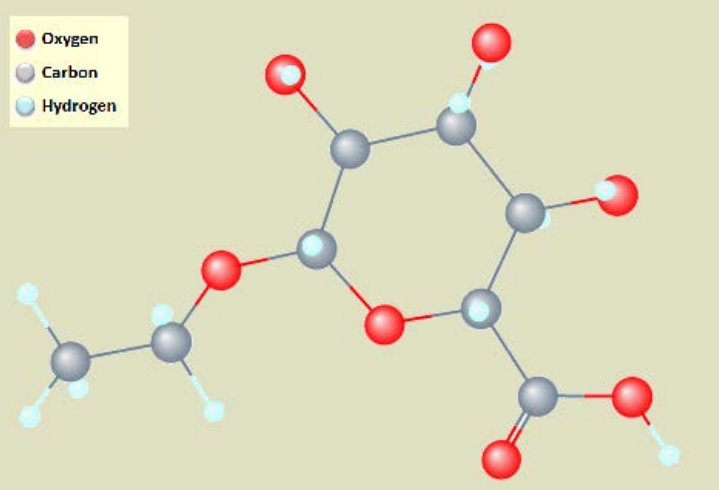
Figure 3.1. **Ethanol Metabolism.**

Both acetaldehyde and acetate contribute to cell and tissue damage (Zakhari 2006).[16] Metabolization of alcohol to aldehyde is mediated primarily by alcohol dehydrogenase (a small fraction of aldehyde is also produced via pathways mediated by cytochrome P450 2E1 and catalase) (Zakhari 2006; DHHS 2007). Acetaldehyde is quickly metabolized to acetate via a process mediated by aldehyde dehydrogenase. The resulting acetate metabolizes as an energy source that is broken down to carbon dioxide and water. The relative rates for these metabolic pathways depend on the individual's genetic variants for their forms of alcohol dehydrogenase and acetaldehyde dehydrogenase (Zakhari 2006; DHHS 2007).

3.1.2 Direct Biomarkers of Ethanol

Biomarkers are physiological indicators of exposure to, or ingestion of, a particular substance. Direct biomarkers are metabolites resulting directly from a substance. In the case of ethanol, the direct biomarkers are its metabolic products: EtG, EtS, PEth, and FAEEs.

Ethyl glucuronide (EtG) is generated by metabolism of ethanol by UDP glucuronyltransferase in the liver; this minor metabolic pathway consumes about 0.1 percent of the ethanol (see Figure 3.2) (Helander and Beck 2005). Glucuronidation assists in removal of chemicals, including many frequently prescribed drugs, from the body by making them more soluble in water. Plasma concentrations for EtG typically peak 2 to 3 hours after maximum BACs are reached (Maenhout et al. 2013).



(National Center for Biotechnology Information, PubChem Compound Database; CID=18392195, **https://pubchem.ncbi.nlm.nih.gov/compound/18392195** (accessed Nov. 9, 2015)).

Figure 3.2. Three Dimensional Conformer of Ethyl Glucuronide.

Ethyl sulfate (EtS) is formed by sulfate conjugation through the action of cytosolic sulfotransferase, another metabolic pathway for removal of small toxic chemicals. EtS is produced at lower rates than EtG (Helander and Beck 2005; Høiseth et al. 2008). Plasma concentrations for EtS typically peak one to 2 hours after maximum BACs are reached (Maenhout et al. 2013).

[16] Acetaldehyde is a probable human carcinogen. National Center for Biotechnology Information. PubChem Compound Database; CID=177, https://pubchem.ncbi.nlm.nih.gov/compound/177 (accessed April 29, 2016).

Phosphatidylethanol (PEth) is a minor metabolite formed in cell membranes only when ethanol is present (Maenhout et al. 2013). PEth has a longer half-life in the body (approximately 4 days) than EtG or EtS and is indicative of more sustained drinking or withdrawal from sustained drinking. For alcohol-dependent donors with newfound sobriety, PEth may be observed for up to 14 days. A single instance of high alcohol consumption does not result in observable PEth (Maenhout et al. 2013).

Fatty acid ethyl esters (FAEEs) are formed in a minor enzyme-mediated metabolic pathway occurring in almost all tissues. The FAEEs are formed from free fatty acids as well as from triglycerides, lipoproteins, and phospholipids. FAEE concentrations closely parallel BACs and can accumulate in organs and fatty tissues including the brain, pancreas, myocardium, and adipose tissues. FAEEs have a half-life of about 16 hours and may be detectable 24 hours after ethanol ingestion (or up to 99 hours after drinking cessation for heavy drinkers) (Maenhout et al. 2013).

3.1.3 Indirect Biomarkers of Ethanol

Indirect biomarkers are metabolic products resulting from conditions that arise from exposure or use of a substance. In the case of alcohol, many of the indirect biomarkers are attributable to its damaging effects on the liver. For reliable detection of indirect alcohol biomarkers indicative of alcohol consumption, an individual will typically have a history of sustained, heavy drinking (Maenhout et al. 2013). Because these biomarkers result from a condition rather than as a direct metabolic product, they may be elevated for reasons unrelated to alcohol consumption (SAMHSA 2012; Maenhout et al. 2013). Researchers and policy makers in this topical area repeatedly caution that direct biomarker panels are preferable and that the donor population should be informed regarding common products to avoid (Albermann et al. 2012; Maenhout et al. 2013). Although these are metabolites of alcohol, they are typically not used for evaluating alcohol consumption as discussed in Section 3.1.4. Indirect biomarkers of alcohol include the following:

- **Elevated liver enzymes** include gamma-glutamyl transferase (GGT), alanine amino transferase (ALT), and aspartate amino transferase (AST).
- **Mean corpuscular erythrocyte volume** (MCV) can be elevated due to enlarged red blood cells caused by alcohol consumption. MCV may be indicative of alcohol-related causes in about 65 percent of cases with known limitations for donors with malnutrition, liver diseases, hematological (blood) diseases, increased immature red blood cells (reticulocytosis), or hypothyroidism (Maenhout et al. 2013).
- **Carbohydrate-deficient transferrin** (CDT) is a useful biomarker in early alcohol withdrawal; however, measurements vary broadly and care must be taken in interpreting clinical values and accounting for false positives (Maenhout et al. 2013).
- **Relative ratio of serotonin metabolites** shifts with alcohol consumption. The relative production 5-hydroxyindole-3-acetic acid (5-HIAA) is reduced and more 5-hydroxytryptophol (5-HTOL) is produced. The urinary metabolite of 5-HTOL is 5-HTOL-glucuronide (GTOL), which can be directly measured. Elevated ratios of either 5-HTOL/5-HIAA or GTOL/5-HIAA are indicators of alcohol consumption (Høiseth et al. 2008).

3.1.4 Alcohol Biomarkers as Abstinence Indicators

None of the direct or indirect biomarkers for alcohol are viewed as being definitive for establishing an individual's alcohol consumption (Cabarcos et al. 2015). However, in 2012

SAMHSA issued a revision to a previous advisory that detailed the relative merits of both direct and indirect biomarkers for alcohol consumption and identified EtG/EtS as suitable for abstinence monitoring (Table 3-1). The substance abuse treatment community quickly took note of SAMHSA's updated positive stance on EtG's utility for abstinence monitoring (e.g., Cary 2012).

Table 3-1. Characteristics of Several Alcohol Biomarkers (reproduced from SAMHSA 2012)

Biomarker	Type of Drinking Characterized	Sensitivity/ Specificity+	Examples of Possible Sources of False Positives	General Comments
Aspartate Amino Transferase (AST), Alanine Amino Transferase (ALT)	Unknown, but heavy and lasting for several weeks	Moderate/Moderate (somewhat lower sensitivity than GGT as screen for heavy drinking)	See GGT. Excessive coffee consumption can lower values.	Primarily reflects liver damage that is often related to alcohol. ALT seems less sensitive than AST. Ratios of AST to ALT greater than 2 may suggest liver damage that is alcohol-related. Performs best in adults ages 30 to 60 years.
Carbohydrate-Deficient Transferrin (CDT)	Probably at least 5 drinks/ day for approximately 2 weeks	Moderate/High (as screen for alcohol dependence)	Rare genetic transferring variant, primary biliary cirrhosis, chronic end-stage liver disease, fulminant hepatitis C. Values are also altered due to smoking or obesity.	Equal to, or possibly slightly better than GGT, but much more specific. Biomarker of relapse to heavy drinking following a period of abstinence. Likely less sensitive for women and younger people.
Ethyl Glucuronide (EtG), Ethyl Sulfate (EtS	Perhaps as little as a single drink	High/High (as indicator of relapse)	Extraneous alcohol exposure, such as alcohol in medications, hygiene products, cosmetics, foods, etc., can elevate values of biomarkers.	As direct analytes of nonoxidative breakdown of alcohol, highly sensitive. Probably little gender, age, or ethnicity effect. New, but promising biomarkers; more research is warranted.
Gamma-Glutamyl Transferase (GGT)	Probably at least 5 drinks/day for several weeks	Moderate/Moderate (as screen for heavy drinking)	Liver and biliary disease, smoking, obesity, diabetes, and medications inducing microsomal enzymes.	Most commonly used traditional biomarker. Primarily reflects liver damage that is often related to alcohol consumption. Performs best in adults ages 30 to 60 years.
Mean Corpuscular Volume (MCV)	Unknown, but heavy and lasting up to several months	Moderate/Moderate (sensitivity somewhat below GGT as screen for heavy drinking)	Hemolysis, bleeding disorders, anemia, folate deficiency, hypothyroidism, hyperglycemia, and medications reducing folate.	Poor biomarker for relapse because of sluggish response to drinking. Higher sensitivity in women than men. Performs best in adults ages 30 to 60 years.
Phosphatidyl Ethanol (PEth)	Possibly 3 or 4 drinks/day for several days	High/High (additional research is needed)	None likely but still unknown due to paucity of research.	Probably little gender, age, or ethnicity effect. Linear dose-response relationship with recent drinking levels. A new but promising biomarker; more research is warranted.

Note: Low represents values approximately 40 percent or less and high represents values usually above 70 percent.

How well a biomarker represents an individual's consumption or exposure to the drug of concern is dependent on that biomarker's test data specificity (low false positives) and sensitivity (low false negatives). EtG has high specificity because it is produced only after exposure to or use of ethanol (Jatlow and O'Malley 2010). EtG has high sensitivity because EtG test methods have very low levels of quantitation and detection (Cabarcos et al. 2015). Thus, donors with positive EtG results are presumed to have recently used or been exposed to alcohol because there are few other reasons for the testing to have yielded a positive result (Høiseth et al. 2008).

EtS is produced along with EtG but at lower concentrations and, where present with EtG, indicates metabolized alcohol rather than sample deterioration (Jatlow and O'Malley 2010). EtS is a natural constituent of wine and may be seen at relatively elevated levels after wine consumption (Maenhout et al. 2013; Høiseth et al. 2008). The time window for EtG and EtS detection (nominally one to two days but up to three days for heavy drinking) also supports abstinence monitoring because it provides earlier detection of alcohol consumption than other non-ethanol biomarkers (SAMHSA 2012). EtG reaches peak concentrations in blood about three to four hours after exposure to or use of alcohol and EtS reaches peak concentrations after one to two hours (Høiseth 2007; Albermann et al. 2012; Maenhout et al. 2013).

3.2 Testing for Alcohol and EtG

The following subsections focus on testing for alcohol and EtG, the alcohol biomarker of interest for this report. Other metabolites (EtS and creatinine) may be important in understanding EtG test data because they can reveal confounding metabolic factors and potential sample adulteration or substitution (Bergstrom et al. 2003; Helander and Beck 2005).

3.2.1 Test Matrices

Test matrices are the body fluids or tissues used for testing and include urine, blood, oral fluids, breath, and hair or other tissues (ASAM 2013). Test matrices are characterized by their window of detection where alcohol or its metabolites would be expected to be present in sufficient quantity to yield true positive results relative to alcohol consumption or exposure. Actual windows of detection depend on additional factors, including the nature of the drug or metabolite; dose and frequency of use; the donor's mass, metabolism, health, and tolerance; and the amount of other fluids consumed and exercise undertaken (ASAM 2013).

Urine is the typical test matrix for EtG and EtS, both of which may be detected in urine for about 24 hours after light, casual drinking (one or two drinks), about twice as long after heavier consumption, and may be detected for up to 3 days after binge or heavy drinking (Jatlow and O'Malley 2010; SAMHSA 2012; ASAM 2013). Urine is a suitable test matrix for EtG and EtS because both are water soluble, sensitive to testing, and their concentrations can be compared to each other or to creatinine to rule out dilution (Albermann et al. 2010). Urine is infrequently used for alcohol testing because it is more complicated than breath (Jones 2002). Detection of alcohol in urine provides information about recent alcohol exposure or use, but the concentration in urine is difficult to correlate with BAC (SAMHSA 2012; ASAM 2013).

Blood is an infrequently used test matrix in workplace FFD programs because drawing blood is invasive and poses potential health risks to the donor. Alcohol's window of detection for blood is typically shorter than for urine and oral fluids (ASAM 2013).

Breath is the standard matrix for alcohol testing. Alcohol's window of detection for breath testing is limited to the time just before the testing (up to 12 hours for heavy drinking) because detection is only possible when alcohol is in the body. Pursuant to 10 CFR 26.83, breath or oral fluids may be used for initial tests for alcohol but evidential-grade breath testing is required for confirmatory tests. When used for abstinence monitoring, frequent testing of breath alcohol (e.g., twice daily) is typical (Leickly et al. 2015).

Oral fluids may be used for initial alcohol testing under 10 CFR 26.83. Alcohol's window of detection for oral fluids is generally 12 to 48 hours as long as alcohol remains in the individual's system (ASAM 2013). EtG concentrations in oral fluids are generally lower and the window of detection is shorter than for EtG concentrations in blood (Høiseth et al. 2010). EtG concentrations from oral fluids do not correlate as well to alcohol use or exposure as EtG measured in blood (Høiseth et al. 2010).

Hair, nails, or other tissues are repository matrices that can accumulate alcohol metabolites (but not alcohol), thus indicating exposure to or use of alcohol over time (approximately 90 days for a 1.5-inch hair sample) (ASAM 2013; SAMHSA 2012; Politi et al. 2006). The window of detection for hair and other repository matrices makes them unsuitable for monitoring abstinence. However, there is consensus that EtG from hair could be used for understanding long-term (three to six months) alcohol consumption patterns despite the fact that standardized sample preparation and test methods are yet to be established (Crunelle et al. 2014; ASAM 2013; Politi et al. 2006). In some testing, hair data has correlated with ethanol consumption if normalized to body weight and after effective sample preparation (e.g., washing to remove lipids, pulverization, and effective EtG extraction with solvents and sonication) (Politi et al. 2006). However, confounding factors include length of sample, pigmentation, source location (e.g., scalp), alcohol consumption profile, and individual metabolism, gender, and genetics (Crunelle et al. 2014). Further, EtG incorporation into hair is poor, the uptake mechanism is not known, and the observed concentration is reduced by washing, exposure to bleach or dyes, and chemical processing (Cabarcos et al. 2015; ASAM 2013; SAMHSA 2012).

3.2.2 EtG Sample Handling

EtG test methods use urine sample matrices, which must be handled in a manner that limits potentially inaccurate results from degradation or post-sampling production of EtG prior to testing. When stored at 4°C, urine samples for EtG are stable for five weeks and urine samples for EtS are stable for more than three weeks (Maenhout et al. 2013). EtG urine samples stored at room temperature are subject to degradation, but EtS samples are not (Helander and Beck 2005; Helander et al. 2010; Jatlow and O'Malley 2010). (See Section 3.3.2 for further discussion.)

3.2.3 EtG Test Methods

Test methods include immunoassay for initial testing of EtG and chromatographic separation and detection by mass spectrometry for confirmatory testing of EtG and testing of EtS. These techniques are described below, including their application to EtG testing.

Immunoassay: A technique based on competitive binding between an antibody and an antigen that is targeted toward a specific drug or drug metabolite. Immunoassay testing is qualitative because it is designed to classify substances as either present or absent in a specimen based on a predetermined cutoff threshold. Many structurally similar drugs may cross-react with an immunoassay reagent, also giving a positive result. Specimens that are found to be positive by

immunoassay must be further tested using a different analytical method (ASAM 2013; SAMHSA 2012). Positive immunoassay EtG results must be confirmed by chromatography-mass spectrometry to rule out potential false positives due to cross-reaction with other non-ethanol glucoronated metabolites from exposure to, or daily use of hygiene products (e.g., shampoo and deodorant), household cleaning products, or industrial chemicals (Arndt et al. 2014a; ASAM 2013). In clinical settings, EtG detection by immunoassay correlates well with detection by chromatography-mass spectrometry methods at higher cutoff levels (500 ng/mL) (Jatlow and O'Malley 2010; Leickly et al. 2015). There is no immunoassay test for EtS (Leickly et al. 2015; ASAM 2013).

Gas chromatography-mass spectrometry (GC-MS): An analytic technique that is used to separate and identify a compound based on its molecular structure and properties. GC-MS typically involves extraction of the analyte from the biological matrix prior to analysis. The analyte is separated from other analytes or adulterants via gas chromatography and then identified as a unique compound (rather than as a member of a pharmacological class of compounds) via mass spectrometry. GC-MS is a sensitive method for EtG with detection levels well below 500 ng/mL. Values below 500 ng/mL were noted by the SMEs interviewed in this study as not being interpreted as positive (see Sections 2.3.3.9 and 3.3).

Liquid chromatography-mass spectrometry (LC-MS): An analytic technique used to separate and identify a compound based on its molecular structure and properties. Liquid chromatography is used to separate different components in a specimen and mass spectrometry is used to specifically identify the components. Tandem LC-MS (LC-MS/MS) typically does not involve extraction of the analyte from the biological matrix prior to analysis. LC-MS/MS uses a separation technique with two mass spectrometers placed in tandem to detect an analyte's secondary fragmentation ions from its characteristic precursor ions. The two-stage mass fragmentation process significantly improves analyte identification when coupled with liquid chromatographic separation. The LC-MS/MS instruments require high skill levels and are expensive. Further, relatively few laboratories offer the technology (Jatlow and O'Malley 2010; ASAM 2013). LC-MS/MS is a sensitive method for EtG with detection levels well below 500 ng/mL. Values below 500 ng/mL were noted by the SMEs interviewed in this study as not being interpreted as positive (see Sections 2.3.3.9 and 3.3).

3.3 Interpreting EtG Test Results

Detection of EtG is specific and is found only after an individual has had alcohol in his/her system. However, interpreting EtG test results is complicated, as noted in the 2012 SAMHSA advisory which states that although: "… EtG can be measured at very low concentrations …, the source of EtG cannot always be determined."

3.3.1 Cutoff Levels

Specimens that have no EtG detected indicate no alcohol use or exposure in the past day and no heavy drinking in the past 2 to 3 days (Jatlow and O'Malley 2010; SAMHSA 2012). Test results with EtG detected should be interpreted with caution below 1000 ng/mL because incidental exposure to common foodstuffs and other products containing alcohol may be responsible (see Sections 2.3.3.9 and 3.3.2).

Abstinence programs use varied cutoff values for EtG detection and there are no established cutoff values for EtS (Albermann et al. 2012; Jatlow et al. 2014). Cutoff values for EtG and EtS are a subject of ongoing research into dose, metabolism, genetics, windows of detection, and other factors affecting their detected concentration in a particular specimen. A significant

portion of these efforts is going into finding reproducible dose-response relationships that may reasonably be expected from alcohol consumption and that are not affected by inadvertent exposure to alcohol, metabolic suppression, or sample degradation.

Although the 2012 SAMHSA advisory stated that further research is necessary before setting EtG cutoff values, it also presented conclusions based on observations from researchers. Table 3-2 presents SAMHSA's conclusions alongside researcher and clinician observations from additional sources. It is important to note that the research community distinguishes between treatment needs for clinical testing and stringent controls needed for workplace forensic testing (McDonnell 2015). As a general rule, the research community views higher cutoff values as limiting the potential for false positives and lower cutoff values as better for monitoring failures in abstinence (Jatlow et al. 2014, McDonell et al. 2015). SAMHSA cutoff values follow this with the 2012 guidance stating detection of EtG greater than 1,000 ng/mL to be indicative of alcohol consumption while lower values may be due to drinking or "extraneous exposure."

Table 3-2. SAMHSA (2012) EtG Cutoff Value Ranges

SAMHSA Ranges for Cutoff Values for EtG in Urine	Per SAMHSA, Detection in this Range Indicates	Researcher and Clinician Observations
>1,000 ng/mL "high" positive	Heavy drinking[(a)] on the same day or previously (e.g., previous day or two). Light drinking the same day.	Noted as a possible EtG cutoff level used by testing laboratories (Reisfield et al. 2011).
500 to 1,000 ng/mL "low" positive	Previous heavy drinking (previous 1 to 3 days). Recent light drinking (e.g., past 24 hours). Recent intense "extraneous exposure" (within 24 hours or less).	Relatively recent, heavy consumption of alcohol (Jatlow and O'Malley 2010; Leickly et al. 2015). Detection >500 ng/mL for EtG and >100 ng/mL for EtS largely removes questions about incidental exposure (ASAM 2013; Jatlow and O'Malley 2010). Using a cutoff level of 500 ng/mL reduces sensitivity substantially (to 50% from 100% positive detect for 100 or 200 ng/mL cutoff values 12 hours after a low dose) (Jatlow et al. 2014).
100 to 500 ng/mL "very low" positive	Previous heavy drinking (1 to 3 days). Previous light drinking (12 to 36 hours). Recent "extraneous" exposure.	>100 ng/mL by LC/MS/MS indicates light drinking in the previous 24 hours (Jatlow and O'Malley 2010). 100-500 ng/mL is suitable for distinguishing excessive consumption from abstinence and social drinking behavior (Maenhout et al. 2013). Higher cutoff levels may result in under-detection and few studies have examined EtG at low cutoff levels (i.e., 100 and 250 ng/ml) (Leickly et al. 2015). Drinking of almost any amount would be detected at a 100 or 200 ng/mL level for samples collected within 12 hours (Jatlow et al. 2014).
<100 ng/mL	Not listed by SAMHSA; presumably negative.	<100 ng/mL may be possible, but lead to misleading results (Jatlow and O'Malley 2010) 100 ng/mL may be the lowest sensitivity offered by a testing laboratory (Wojcik and Hawthorne 2007; Jatlow and O'Malley 2010).

(a) SAMHSA defines heavy drinking as drinking five or more drinks on the same occasion on each of five or more days in the past 30 days (SAMSHA 2015b) (see Section 2.1).

3.3.2 Mitigating Factors for Interpreting EtG Test Results

The metabolic pathways leading to direct and indirect alcohol biomarkers (see Sections 3.1.2 and 3.1.3), along with their windows of detection, inform test result interpretation. Metabolites other than EtG (e.g., EtS and creatinine) can help in interpreting test data because they can reveal confounding metabolic factors and potential sample adulteration, substitution, or degradation.

Sample storage conditions can elevate or reduce EtG due to bacteria. Reliable EtG detection in urine depends on specimen storage conditions. Urine specimens stored at room temperature are subject to degradation, including changes in EtG concentration (Helander and Beck 2005; Jatlow and O'Malley 2010). In the absence of other factors, EtG levels in urine specimens stored at 4°C are stable for 5 weeks (Maenhout et al. 2013). Other preservation methods do not necessarily prevent degradation. Specific examples include specimen storage at insufficiently cool temperatures (e.g., inside a refrigerator) or by the alternative preservation method of adding sodium fluoride (Maenhout et al. 2013).

Bacterial contamination with *Escherichia coli* in urine samples can lead to false-negative EtG results (Helander and Beck 2005; Maenhout et al. 2013). In controlled conditions for urine samples contaminated with *E. coli*, more than 90 percent of EtG decomposed after 4 days at 37°C and after 8 days at room temperature (Maenhout et al. 2013).[17]

False positive results may be obtained from urine samples containing glucose when the samples are not chilled. Glucose in the sample may be converted to alcohol and subsequently metabolized to EtG by yeast and bacteria (Jatlow and O'Malley 2010). Elevated levels of glucose in urine, as may be common for persons with diabetes, increase the risk of obtaining a false positive in a sample stored at room temperature.

Because EtS degradation is not observed in urine samples stored at room temperature (Helander and Beck 2005), concurrent testing for EtG and EtS can assist in result interpretation. Where EtG concentration is found to be relatively low compared to EtS, the specimen's EtG may have decomposed; likewise, where EtG concentration is high relative to EtS, EtG may have been produced after the sample was collected (Helander and Beck 2005; Maenhout et al. 2013). Proper sample handling is discussed in Section 3.2.2.

EtG excretion is affected by urinary dilution. As with other urinary analytes, individuals can intentionally dilute EtG and EtS by excessive liquids consumption and thus creatinine ratios may be important in evaluating test results (Maenhout et al. 2013; Helander and Beck 2005; Høiseth et al. 2008; Thierauf et al. 2010). In one clinical study on testing of dilute specimens, researchers compared EtG results with creatinine and identified specimens that would have had elevated EtG concentrations above cutoff values if the specimen was not dilute (Jatlow et al. 2014).

Incidental exposure to ethanol can result in elevated EtG. Unintentional ethanol uptake from a large variety of products may result in elevated EtG values. These include alcohol beverages (e.g., beer, wine, and liquor) but also mouthwash, hand sanitizers, and fermented products (e.g., non-alcoholic beer, kombucha, sauerkraut, and matured bananas) (Jatlow and O'Malley 2010; Maenhout et al. 2013). Alcohol in medications also produces EtG; however, the

[17] A characteristic of *E. coli* is the β-glucuronidase enzyme, which cleaves EtG; this enzyme is not typically present in other bacteria (Helander and Dah 2005).

overall exposure to alcohol from proper dosing of most medications should be negligible (Jatlow and O'Malley 2010). Exposure to and use of hand sanitizers leads to alcohol vapor absorption through inhalation and may result in false positive test results for EtG above 100 or even 500 ng/mL (Arndt et al. 2014b; Skipper et al. 2015; Maenhout et al. 2013; Jatlow and O'Malley 2010). In one study using a hand sanitizer containing both ethanol and propanol, empirical results included detection of propyl glucuronide in addition to EtG illustrating the potential for EtG false positive test results from immunoassay testing (Arndt 2014b).

Consumption of yeast and sugar can result in elevated EtG. In a small study, consumption of yeast and sugar led to measurable amounts of EtG and EtS; however, no ethanol was detected (Thierauf et al. 2010).

Donor metabolism, condition, and lifestyle can affect EtG production. The vagaries of human metabolism apply to ethanol; controlled clinical studies have observed that in samples tested for EtG and EtS both are typically present or not present, but under some conditions only one may be observed, particularly when it is present in low concentrations (Helander and Beck 2005). The relative production of EtG is controlled by metabolic pathways that have genetic polymorphism; that is, controlling for other factors, different individuals will produce different amounts of EtG given the same dose (Jatlow and O'Malley 2010). Further, the glucuronosyl and sulfotransferases mediating the production of EtG and EtS also competitively metabolize other compounds found in foods and drugs (including benign drugs such as acetaminophen), and the impact of these on EtG testing is the subject of ongoing research (Stachel and Skopp 2016, 2014; Halter et al. 2008). Elevated EtS relative to EtG may be due to wine consumption (Maenhout et al. 2013). Clinical studies indicate EtG and EtS elimination is slowed for individuals with kidney disease (Høiseth et al. 2009).

3.4 Summary

Detection of ethanol and its metabolites provides a window into alcohol use or exposure. Testing may be done for both alcohol impairment and abstinence. Impairment testing is done by measuring for BAC using direct tests for ethanol in breath or oral fluids; EtG is a metabolite produced over time and is not a good indicator of current BAC and thus impairment. Abstinence testing can be done with frequent breath monitoring for BAC; however, alternatives such as EtG offer an extended window of detection that provides longer intervals between tests. Factors for alcohol impairment testing using BAC and abstinence testing using EtG are summarized in Table 3-3.

Table 3-3. Factors in Ethanol and EtG Testing for Impairment and Abstinence

Testing Factor	Alcohol Impairment Using BAC	Alcohol Abstinence Using EtG
Length of time ethanol or an ethanol metabolite has a detectable presence.	Alcohol impairment is observed directly by testing for ethanol in oral fluids or breath because alcohol affects individuals only when it is present.	SAMHSA 2012 guidance states that EtG and EtS are suitable for abstinence monitoring for one to three days after alcohol consumption.
Test data attributed to alcohol consumption.	BAC is well correlated with impairment effects and there are cutoff values established in the regulations.	EtG is only produced from ethanol, thus it is very specific to alcohol use or exposure.
Test data represent the individual's consumption of alcohol.	Test methods for alcohol use oral fluids and breath matrices that give immediate and accurate results correlated to BAC.	The correlation between EtG test results and alcohol concentration is an active research area. It is clear that higher concentrations (most cases above 500 ng/mL and all cases above 1,000 ng/mL [SAMHSA 2012]) are due to alcohol consumption. However, questions remain for issues such as daily use hygiene products, differences in metabolism between individuals, and controlling for sample degradation.

4.0 EtG Testing in Abstinence Compliance and Treatment

Since SAMHSA issued the revised advisory in 2012, use of EtG for monitoring alcohol abstinence has increased (Cary 2012). However, rules for EtG testing are not established under NRC or DOT regulations, nor are there clear procedures or cutoffs for forensic use under DHHS/SAMHSA guidance (SAMHSA 2012). In contrast, EtG is in use for monitoring abstinence under many judicial programs and PHPs where there are no restrictions on how abstinence is monitored (DuPont et al. 2008; DuPont et al. 2008; Cary 2014).

4.1 NRC Requirements

The NRC has established alcohol-testing requirements and policies concerning alcohol use to ensure that individuals who are subject to the FFD rule are free from the influence of alcohol when they are performing their duties. The NRC's FFD rule also requires sanctions and controls for access authorization in the event of an alcohol-related FFD policy violation. The requirements regarding alcohol use and testing as well as whether EtG testing is permissible for individuals subject to these regulations are discussed below.

10 CFR Part 26, "Fitness for Duty Programs," establishes the requirements for FFD programs. These include requirements for FFD program personnel (e.g., the MRO, SAE, employee assistance program [EAP] personnel, and reviewing official); requirements for licensee testing facilities, testing laboratories, and collection sites; acceptable testing procedures and devices; processes for reporting test results; processes for determining FFD policy violations, and sanctions resulting from such violations. An overview of FFD personnel roles and their responsibilities regarding substance abuse problems is shown in Table 4-1.

Table 4-1. Roles and Responsibilities of NRC Drug- and Alcohol-Testing Programs

Role	Responsibilities
MRO	• reviews and interprets drug and alcohol test results • identifies evidence of test subversion • selects alternative specimens or tests or cancels test • determines FFD policy violations
SAE	• evaluates individuals who have violated the substance abuse provisions of an FFD policy • serves as a referral source to assist the individual's entry into an education and/or treatment program • makes recommendations concerning education, treatment, return to duty, follow-up drug and alcohol testing, and aftercare • evaluates treatment compliance and makes fitness determinations for individuals receiving treatment before making return-to-duty recommendations • if recommending abstinence from substance in the treatment plan, defines or describes what abstention means (e.g., no use or cutoffs)
EAP personnel	• offer confidential assessment, short-term counseling, referral services, and treatment monitoring to individuals with substance abuse problems • protect the identity and privacy of individuals seeking EAP assistance • report individuals to FFD program management if the individual poses or has posed an immediate hazard to self and others, or has been impaired by drugs or alcohol while on duty, or has a continuing substance abuse disorder that likely causes impairment on duty
Reviewing Official	• an individual designated by the licensee to review and evaluate information for the purposes of granting, maintaining, denying, or terminating access authorization

4.1.1 Alcohol-Testing Requirements

The FFD policy mandates a pre-duty five-hour alcohol abstinence period (10 CFR 26.27), which specifies that individuals who are subject to the rule are prohibited from consuming alcohol while on the job and within the 5 hours before their scheduled tour of duty.[18] Under 10 CFR Part 26, individuals are subject to pre-access, random, for-cause, post-event, and follow-up drug and alcohol tests (10 CFR 26.31(c)). Conditions for testing, test methods, matrices, metabolite cutoff values—including BAC values—and other procedural requirements are clearly defined. For-cause and follow-up tests are particularly pertinent to substance abuse: the former can be triggered by reasonable suspicion of substance abuse impairment on the job, and the latter as a means of verifying an individual's continued compliance with the requirements of substance abuse treatment.

Initial tests for alcohol may be performed on either breath or oral fluids; breath must be used for confirmatory tests (10 CFR 26.83(a)). Alcohol collectors must be trained, qualified, and meet knowledge requirements (10 CFR 26.85(b)).[19] For alcohol tests, specific collection methods and cutoff values have been established in 10 CFR Part 26, Subpart E. For an initial alcohol breath or oral fluid test, if the BAC is less than 0.02 percent, the result is negative; if the BAC is at or above 0.02 percent, a confirmatory breath test is required (10 CFR 26.99). If a confirmatory test is required, it must be performed as soon as possible, but no more than 30 minutes after the initial test (20 CFR 26.101(a)). The rule prohibits the use of other test matrices and methods.

Section 26.101 details the steps for performing a confirmatory breath test. If warranted by an individual's medical condition, the MRO has the discretion to recommend alternative evaluation processes per 10 CFR 26.31(d)(5)(i). The alternative process must be comparable to breath analysis for alcohol. The confirmatory test cutoff values depend on the duration of time an individual has been in work status, as shown in Table 4-2 (10 CFR 26.103).

Table 4-2. BAC Cutoff Values

BAC (%)	Duration of Being in a Work Status When Initial Test Was Concluded[(a)]	Confirmatory Test Results
≥ 0.04		Positive
≥ 0.03	At least 1 hour	Positive
≥ 0.02	At least 2 hours	Positive
≥ 0.01 and < 0.02	At least 3 hours or more	Negative[(b)]

(a) This time includes any breaks for rest, lunch, dental/doctor appointments, etc., and measures the duration of time from the start of work status to the initial alcohol test.
(b) The collector must declare the test result to be negative and inform FFD program management. The licensee must prohibit the donor from performing any duties subject to Part 26 until a determination of fitness is made.

[18] For individuals being called in to perform unscheduled work, 10 CFR 26.27 (C) (3) describes the process used by licensees to ensure these individuals are fit for duty.
[19] If an alcohol collector is not available, a medical professional, technologist, or technician can serve as collector if the conditions of 10 CFR 26.85(c) are met.

4.1.2 Policy Violations and Sanctions

The MRO reviews test results and determines, with donor input, whether a confirmed positive alcohol test is a positive, adulterated, substituted, dilute, or invalid drug test result and whether there has been a violation of FFD policy (10 CFR 26.185). The FFD policy requires minimum sanctions for FFD policy violations associated with test subversion attempts, onsite alcohol consumption while on duty, and confirmed positive tests due to offsite alcohol consumption (10 CFR 26.75). These different kinds of violations and their corresponding sanctions for alcohol use are listed in Table 4-3. The licensee may impose more stringent sanctions than those required under the rule (10 CFR 26.75(a); see also Section 5.1).

Table 4-3. FFD Policy Violations and Sanctions for Alcohol Use

FFD Policy Violation Regarding Alcohol Use	Minimum Sanctions
Any attempt to subvert the testing process (10 CFR 26.75(b))	• Immediate unfavorable termination of authorization • Permanent denial of authorization
Alcohol consumption onsite (10 CFR 26.75(c)) • within a protected area of any nuclear power plant • at a facility licensed to possess/use formula quantities of strategic special nuclear material • within a transporter's facility/vehicle • while performing duties under Subpart D	• Immediate unfavorable termination of authorization • A minimum five-year denial of authorization from the date of unfavorable determination
Any one resigning/withdrawing application of authorization *before* authorization is terminated or denied for a first violation (10 CFR 26.75(d))	• A minimum five-year denial of authorization from the date of unfavorable determination/denial
Confirmed positive test due to presumed offsite alcohol use: first violation (10 CFR 26.75(e)(1))	• Immediate unfavorable termination of authorization for at least 14 days
Confirmed positive test due to presumed offsite alcohol use: subsequent violation (10 CFR 26.75(e)(2))	• A minimum five-year denial of authorization
Any subsequent violation by individuals whose authorization was previously denied for 5 years (10 CFR 26.75(g))	• Immediate, permanent denial of authorization

10 CFR Part 26 also mandates management actions concerning possible impairment on the job from substance abuse (10 CFR 26.77). If an individual appears to be impaired on the job, the licensee must immediately prevent the individual from performing duties that subject the individual to 10 CFR 26 Subpart D. Alcohol tests are triggered if an observed behavior or physical condition creates a reasonable suspicion of possible alcohol abuse (10 CFR 26.77(b)(1)). If no behavioral or physical indication other than the smell of alcohol is observed, the rule permits the licensee to conduct an alcohol test without additional evaluations. The alcohol test result must be negative before the individual can be returned to duty.

4.1.3 Access Authorization with Potentially Disqualifying Information

The FFD access authorization regulations are part of NRC's requirements for access authorization.[20] Under 10 CFR 26.53(b), alcohol policy violations trigger FFD regulations for

[20] https://www.nrc.gov/reactors/operating/ops-experience/access-authorization.html

access authorization with potentially disqualifying information at 10 CFR 26.69. These regulations have clear requirements for subsequent access authorization, follow-up random testing, alcohol abstinence, and clinically appropriate treatment that differ somewhat depending on whether the positive alcohol result is a first, second, or third incident. For alcohol violations, the requirements of 10 CFR 26.69(b) require the licensee to reach favorable findings based on the individual's employment information, an SAE's determination of fitness, and required drug and alcohol testing prior to granting and for maintaining access authorization. Specific requirements related to access authorization and alcohol and substance abuse testing and treatment programs include those listed in Table 4-4. Required testing must be conducted and the results reviewed in accordance with the FFD policy (see Section 4.1.1). For alcohol abuse, the SAE makes fitness determinations that ensure individuals subject to the rule are unimpaired by and are fit for duty.[21] In some cases, an SAE may refer individuals for treatment.

4.1.4 FFD Requirements and EtG Testing

Alcohol testing under the FFD program must be done with either oral fluids or breath testing correlated to readings in BAC (Section 4.1.1). Under the current FFD regulation, there is no provision for EtG testing (10 CFR 26.31, drug and alcohol testing). However, given the revised SAMHSA advisory in 2012 and the subsequent increase in use of EtG testing for abstinence monitoring in treatment programs, there is some question on whether EtG testing could affect an individual's access authorization through other FFD requirements.

When an individual has violated the alcohol policy, the SAE may subsequently determine that a clinically appropriate alcohol treatment program is required for granting or maintaining access authorization for that individual. Such treatment programs vary in their implementation and in their requirements (see Section 2.0); however, a common feature of these programs is clinical monitoring for alcohol abstinence. Clinical monitoring of alcohol abstinence provides adequate indication of treatment plan compliance without the additional controls used in forensic testing (e.g., confirmation, split samples, chain of custody, etc.).[22] As noted by the SMEs interviewed for this study, EtG testing is used in clinical practice for monitoring (see Sections 2.3.3 and 3.3). Thus, it is possible for an individual to be required to be in an alcohol treatment program and for that treatment program to rely upon clinical EtG testing for monitoring abstinence compliance.

For access authorization under the FFD program, the licensee must ensure that for an individual required to be in a treatment program, that the individual is in compliance with or has successfully completed such treatment. Where the individual's treatment program compliance is monitored with clinical EtG testing, the FFD program may, by extension, also be reliant on that information. It should be recognized that Part 26 requires the licensee's designated reviewing official to review new potentially disqualifying information, including the circumstances associated with that information (10 CFR 26.69(d)(1)). Further, the reviewing official can conclude that a determination of fitness is required (10 CFR 26.69(d)(1)), which would be performed under FFD rules by an SAE (10 CFR 26.69(b)(4)(iii)). These requirements provide for licensee discretion and possible mitigation for potentially false positive clinical testing results from abstinence monitoring by EtG, however, it is unknown whether this happens (see also discussion in Section 5.4).

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[21] Pursuant to 10 CFR 26.189, "A determination of fitness must be made by a licensed or certified professional who is appropriately qualified and has the necessary clinical expertise, as verified by the licensee or other entity, to evaluate the specific fitness issues presented by the individual."

[22] See https://www.samhsa.gov/workplace/drug-testing for SAMHSA guidance on workplace forensic drug and alcohol testing.

Table 4-4. FFD Access Authorization Requirements for an Alcohol Policy Violation

Requirement for Access	Description	10 CFR Regulation
Determination of fitness	The SAE evaluates individuals who have violated the substance abuse provisions of an FFD policy and make recommendations concerning education, treatment, return to duty, follow-up drug and alcohol testing, and aftercare.	§26.187(g)(1) §26.189(b)
	The SAE conducts a determination of fitness and concludes the individual is fit.	§26.69(b)(4)
	After a first violation, the licensee ensures that clinically appropriate treatment and follow-up testing plans have been developed by an SAE.	§26.69(b)(4)(i)
	If there are breaks in authorization for a first-time offender preventing completion of required testing within 5 years, ensure that an SAE conducts a determination of fitness to assess whether follow-up testing is required.	§26.69(b)(6)(iii)
	After a second violation, ensure that follow-up testing and treatment from an SAE's determination of fitness are developed [implied].	§26.69(b)(4)(ii)
Maintaining authorization	Maintaining authorization with disqualifying information requires review of the circumstances by the licensee's reviewing official.	§26.69(d)(1)
	The licensee's reviewing official determines whether a determination of fitness is required.	§26.69(d)(2)
	If the licensee's reviewing official determines that maintaining authorization is warranted, the official implements recommendations for treatment and follow-up testing from the determination of fitness and ensures that the individual complies with and successfully completes the treatment plans.	§26.69(d)(3)
Treatment	The SAE shall serve as a referral source to assist the individual's entry into an education and/or treatment program.	§26.187(g)(2)
	Verify that the individual is in compliance with, and successfully completes, any follow-up testing and treatment plans.	§26.69(b)(4)(iii)
	The designated reviewing official implements recommendations for treatment and follow-up drug and alcohol testing from the determination of fitness and ensures that the individual complies with and successfully completes the treatment plans.	§26.69(d)(3)
	After a second violation, ensure that treatment from an SAE's determination of fitness is initiated.	§26.69(b)(4)(ii)
Alcohol abstinence	After a second violation, abstain from substance abuse from time authorization was terminated, up to five years.	§26.69(b)(3) §26.31(c)(4)
Testing	Within 10 business days before granting authorization, perform pre-access drug and alcohol testing and confirm test results are negative before granting authorization.	§26.69(b)(5)
	Ensure that the individual is subject to random testing after authorization is granted.	§26.69(b)(5)
	After a first violation, ensure that the individual is subject to unannounced testing (random and follow-up) for a minimum of 15 tests conducted at least quarterly for 3 calendar years[(a)] after the date the individual is granted authorization.	§26.69(b)(6)
	After a second violation, ensure that follow-up testing from an SAE's determination of fitness is initiated.	§26.69(b)(4)(ii)
	All drug and alcohol tests required under the FFD program conducted since authorization was terminated or denied indicate no further drug abuse, as determined by the MRO after review, or alcohol abuse, as determined by the result of confirmatory alcohol testing.	§26.69(b)(7)
	If an individual has confirmed positive, adulterated, or substituted test results from any drug, validity, or alcohol test required in this section, the licensee or other entity shall, at a minimum and as appropriate, deny or terminate authorization.	§26.69(f)

(a) If there is a break in authorization, the 15 tests may be completed over up to a 5-year period. If the time with authorization is insufficient for 15 tests, a determination of fitness to assess whether follow-up testing is required.

4.2 DOT Requirements

As mandated by the Omnibus Transportation Employee Testing Act of 1991, the DOT and its agencies are required to implement drug and alcohol testing for individuals who are subject to 49 CFR Part 40, which provides the overarching rules and requirements regarding workplace drug- and alcohol testing for the transportation industry.

49 CFR Part 40 specifies the types of alcohol tests, test matrices, test procedures, requirements for testing facilities, personnel (e.g., specimen collection personnel, screening test technician [STT], breath alcohol technician [BAT], MRO, and substance abuse professional [SAP]), laboratories, and testing equipment/devices. 49 CFR Part 40 also establishes rules and procedures for policy violation determination and return-to-duty evaluation for individuals who have violated DOT drug and alcohol rules. In addition to 49 CFR Part 40, DOT agencies have also established agency-specific regulations for specific classes of covered individuals, industries, and post-violation employer actions (see Appendix C, Table C.1).

Under 49 CFR Part 40, covered individuals are subject to six types of drug and alcohol testing: pre-employment, reasonable suspicion/cause, random, return-to-duty, follow-up, and post-accident. For alcohol testing, an alcohol screening test must be conducted by an STT or BAT using breath or saliva, and a confirmation test must be conducted by a BAT using breath.

49 CFR Part 40 prohibits individuals subject to the rule from using or possessing alcohol while assigned to perform or while performing duties that are covered by the rule. These individuals must not perform duties if they are impaired by alcohol or have a BAC of 0.04 or higher, and they must abstain from alcohol consumption within five hours prior to scheduled tours of duty (the abstinence period is eight hours for flight crew members and flight attendants). If a covered individual tests positive for alcohol, refuses to test, or violates DOT alcohol rules, 49 CFR Part 40 requirements state that the individual must be removed from performing duties immediately, and is not permitted to return to duty until a SAP completes a return-to-duty evaluation and the individual completes any treatment program prescribed by the SAP and tests negative for drugs and alcohol (i.e., BAC less than 0.02). See Table 2 in Appendix C for BAC values and individual actions for other agencies under the DOT.

For return-to-duty evaluations, the SAP makes face-to-face clinical assessments and evaluations to determine the extent of assistance required to help covered individuals resolve their substance use problems. The SAP also serves as a referral source for covered individuals for appropriate education or treatment programs and conducts a face-to-face follow-up evaluation to determine the individuals' completion of, and compliance with, initial evaluation and recommended treatment programs before allowing them to return to duty (DOT 2009).

The DOT SAP Guidance specifies that the SAP's evaluation should include "a standard psychosocial history; an in-depth drug and alcohol use history (with information regarding onset, duration, frequency, and amount of use; substance(s) of use and choice; emotional and physical characteristics of use; associated health, work, family, personal, and interpersonal problems); and a current mental status…the evaluation should provide a diagnosis, treatment recommendations, and a treatment plan to be successfully complied with prior to the individual becoming eligible for follow-up evaluation and subsequent return (if the employer desires) to safety-sensitive functions" (DOT 2009, p. 6).

The SAP provides a follow-up testing plan for the individual and recommendations for continuing education, treatment, and aftercare (49 CFR 40.291). SAPs have the sole

responsibility and authority in determining the follow-up testing frequency. For return-to-duty testing, individuals are subject to unannounced testing for drugs and/or alcohol minimally 6 times during the first 12 months of active duty. As determined by the SAP, the individual may be subject to unannounced testing for up to 60 months. Follow-up testing can be terminated by the SAP any time after 12 months, assuming all recommended tests have been completed during that time frame. No other party is authorized to challenge a SAP's initial evaluation except the SAP him/herself if modification is warranted in view of new information including information from treatment programs such as EtG test results.

4.3 Judicial Programs

EtG testing is widely used in drug/DUI courts and family courts, especially in cases involving substance use and abuse (e.g., DUI) and in custody disputes (Cary 2011; DeJesus 2016). In drug/DUI courts, drug testing is designed to deter future drug use; monitor abstinence compliance; identify relapse for early intervention; prioritize court resources; provide incentives, support, and accountability for DUI/drug offenders; and frame sanction decisions (Cary 2014). Family courts may order drug and alcohol testing if it is in the child's best interests and there is credible and independent corroboration of substance abuse (Mason and Valade 2015; New York City Bar n.d.; Burns et al. 2012).

4.3.1 EtG Testing in Criminal and Civil Courts

Due to its sensitivity to alcohol metabolites and a longer window of detection than that of the breathalyzer test, EtG testing is favored in many criminal courts for verifying alcohol abstinence compliance by individuals on bond or probation (Cary 2013). It is common practice for a judge to order an offender to receive probation instead of jail time. The conditions of probation often include alcohol abstinence or require an offender to participate in a treatment program that requires alcohol abstinence. During probation, positive EtG test results can be regarded as evidence of probation violations and result in extended probation or even incarceration.

In family courts, EtG testing could be ordered by a judge presiding over a custody dispute to ensure parents do not consume alcohol during parenting time or to monitor abstinence compliance if parents are not allowed to consume alcohol at any time. Test results can be linked with the allowed parenting time. That is, when an individual involved in such a dispute successfully passes the required tests, the court may then reinstate or alter favorably the parenting time for the individual (DeJesus 2016).

4.3.2 Basis for Permitting or Disallowing EtG Testing in Courts

As a court-ordered test and as an evolving testing method, EtG testing continues to be challenged in terms of its reliability and legal admissibility in spite of its wide acceptance in drug/DUI courts (DeJesus 2016; SAMSHA 2006 and 2012; Lawrence 2011).

Evidence suggests that wide acceptance of EtG testing in drug/DUI courts could be based on the belief that EtG testing satisfies the evidentiary admissibility requirements under the current Federal rule (i.e., Federal Rule of Evidence 702 regarding testimony by expert witnesses) and meets other prevailing legal standards (i.e., the Daubert standard and the Frye standard) (Meyer 2011; Hankey n.d.). Borne out of *Daubert v. Merrell Dow Pharmaceuticals* (1993), the Daubert standard affords broad discretion to trial judges and enables them to play the role of "gatekeepers" in determining the reliability of scientific knowledge as legal evidence. Judges

must consider whether the evidence can be objectively tested, has been subject to peer review and publications, has a known and acceptable rate of error when applied, and has been generally accepted in the scientific community (Walsh 1998). The Frye standard, set forth in *Frye v. United States* (1923), similarly states that scientific evidence is only admissible if it is generally accepted in the field or discipline to which it belongs (Moenssens 1984).

Drug court professionals and researchers have been closely monitoring research and SAMHSA's advisories on EtG (SAMHSA 2006, 2012; Cary 2012; Hankey n.d.). SAMHSA's 2012 revision to the advisory was believed to have provided added support for EtG's reliability in the scientific community without creating a "roadblock" for its use in drug courts (Cary 2012).

The broad acceptance of EtG testing in drug courts might also be attributable to the use of "client contracts"[23] that clearly enumerate substances (e.g., over-the-counter medication, food, and personal hygiene products) that might cause incidental exposure and positive test results. These contracts assign the responsibility for avoiding incidental exposure to the individual subject to EtG testing, and, therefore, help reduce the likelihood of false positive results. Further, several litigation outcomes concerning the role of EtG testing in determining probation violations confirmed judicial acceptance of the reliability and validity of EtG testing in making such decisions (e.g., *People v. Oehler* 2006; *Murphy v. Board of Parole and Post-Prison Supervision* 2011) (Lawrence 2011).

Despite the wide use of EtG testing in drug/DUI courts, the legal and regulatory basis for permitting EtG testing in family courts has not gone unchallenged. Recognizing the lack of substantive and procedural guidance for court-ordered testing, the California State Legislature (2016) addresses this gap in the Family Code Section 3041.5 (Judicial Council of California 2007). The Family Code stipulates that for any custody or visitation proceedings or any guardianship proceedings under the code, any court-ordered testing must be, along with other criteria, conducted in conformance with the DHHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (DHHS 2010). In *Deborah M v. Superior Court* (2005), the court decided that pursuant to Family Code Section 3041.5, only urine drug testing is permitted in custody and visitation proceedings for a parent who has been determined to have drug abuse problems, and that tests based on methods outside the existing DHHS Mandatory Guidelines (e.g., hair testing) are not allowed. Under the current DHHS Mandatory Guidelines, EtG testing, although a urine-based test, is not used in Federal workplace alcohol testing. However, the fact that EtG testing in family courts is not uncommon suggests considerable variability in States' regulations concerning the legal and regulatory basis for court-ordered testing (DeJesus 2016; Esposito 2014).

4.4 Physician Health Programs

PHPs were developed to prevent addicted and mentally ill physicians from potentially harming the public while being impaired. The PHP approach treats addiction like an illness emphasizing treatment and recovery (DuPont et al. 2008, 2009; FSPHP 2016). PHPs were developed in response to a seminal paper published in 1973 by the American Medical Association Council on Mental Health entitled "The Sick Physician: Impairment by Psychiatric Disorder, Including Alcoholism and Drug Dependence" (American Medical Association Council on Mental Health 1973).

[23] See www.ncjfcj.org/sites/default/files/exampleetgdrugcourtcontract.pdf for an example client contract.

As of 2016, 47 States had developed PHPs that operate within the parameters of State regulation and legislation. Across the United States, PHPs are overseen by the Federation of State Physician's Health Programs (FSPHP) (FSPHP 2016). Depending upon the State, PHPs have their own set of guidelines and are operated by various entities (e.g., State medical societies, corporations, non-profit organizations, and/or State licensing boards) (FSPHP 2016). All PHPs act on behalf of a State licensing board, and over half of them have "independent legal authority based on specific state laws" (DuPont et al. 2009:2).

Physicians participate in PHPs through self-reporting or by referral from State licensing boards, colleagues, hospital medical staff, law-enforcement officials, or family members, usually on the basis of concern about impaired performance (DuPont et al 2009; McClellan et al. 2008). By entering into signed contracts with participating physicians, PHPs provide active long-term care management including intervention, evaluation and diagnosis, oversight, and monitoring of addicted physicians. The signed contracts are binding and last 5 years for those diagnosed with alcohol dependence and 2 years for those diagnosed with alcohol abuse (DuPont et al. 2008). These contracts cover treatment requirements (e.g., outpatient or residential substance abuse treatment, monitoring, and ongoing professional support). Most PHPs also have a close relationship with the State licensing boards, which frequently accept PHP care in lieu of "… imposing disciplinary action for physicians, but with the stipulation that failure to adhere to the PHP's treatment recommendations and/or return to the use of alcohol or other drugs will lead to referral of the physician back to the licensing board for disposition" (DuPont et al. 2008:161). Most PHPs embrace the 12-step model for treatment with total abstinence being a common required treatment goal shared by all PHPs (DuPont et al. 2008). The treatment contracts typically specify alcohol abstinence monitoring consisting of intensive random alcohol testing at the beginning of the contract (e.g., weekly or twice weekly) that becomes less frequent toward the end (e.g., 20 times per year) (DuPont et al. 2008). The tests used include randomly scheduled urine drug-testing panels that commonly include ethanol and EtG (DuPont et al. 2008).

Positive test results and other noncompliant activities (e.g., failure to attend an AA meeting) result in a variety of sanctions against physicians. Depending upon the circumstances of the substance use, a positive test result could result in clinical and administrative actions that include recommendations for increased monitoring, re-evaluation, or reporting to the physician's licensing hospital or agency. Further, sanctions might arise if PHP contractual obligations are not successfully met by participating physicians (e.g., failing an alcohol test or not completing the treatment program as required). As a result, physicians could face limitations on practice, probationary agreements, and could be reported to the medical board to have their licenses suspended or revoked (DuPont et al. 2009).

Research suggests PHPs have demonstrated positive outcomes for helping physicians deal with AUDs. Of the 904 physicians included in a five-year study, McLellan et al. (2008) reported that five years after the start of their PHP contracts, 802 physicians remained in the study and of these, 79 percent were licensed without restriction, 3 percent retired or voluntarily left practice, 11 percent had their licenses revoked, 4 percent had died due to substance misuse, suicide, or other causes, and 3 percent had missing data.

Despite considerable success, PHPs have come under scrutiny as a result of ethical concerns associated with coercive requirements, lack of due process, and probationary responses to false positive EtG tests. For example, the five-year study by DuPont et al. (2009) has been criticized as being "methodologically flawed and rife with conflicts of interest" (Lanagan 2016). Some State PHPs have also come under scrutiny for questionable ethical practices as

demonstrated by the 2015 class action lawsuit filed against the Michigan PHP alleging "a coercive punitive process" where physicians were forced into medical treatment under threat of termination without due process (Lanagan 2015; Boyd 2015). In 2014, the State of North Carolina conducted a performance audit of North Carolina's PHP in response to multiple complaints from adversely affected physicians (Boyd 2015). The audit found that the State's PHP "lacked objective, impartial due process procedures for physicians who disputed its conclusions" (Boyd 2015). While the audit looked for abuse, but found no evidence, the potential for abuse was present and abuse could occur as a result of excessive influence by the PHP director and the lack of due process for disputing physicians (Wood 2014). Other concerns center on reporting all positive EtG tests, including those that may be false positive or those that do not indicate a relapse, by some PHPs to the licensing board (Boyd and Knight 2012). Even if these reports did not eventually result in sanctions against the medical professionals, they did place an undue and unnecessary emotional and economic burden on those who may be placed on probation while awaiting investigation results. This seems to contradict the FSPHP's own guidance stating that "EtG is not recommended to be used as a sole indicator of relapse. It must be correlated with clinical and ancillary data" (FSPHP 2007).

In conclusion, the PHP provides a model for programs that rely on total abstinence monitored by EtG testing to prevent impaired workers from inflicting harm upon the general public. The PHP has a zero-tolerance policy for alcohol-addicted physicians and many PHPs use EtG testing to monitor total abstinence compliance. A review of the concerns and grievances highlights potential pitfalls that may arise when incorporating total abstinence requirements that are monitored by EtG testing into a workplace drug and alcohol policy.

4.5 Summary

NRC and DOT have implemented drug- and alcohol-testing requirements for individuals in a wide range of industries/professions. These agencies provide clear requirements regarding the kinds of tests to be performed, conditions triggering testing, drugs subject to testing, specimen collection procedures, acceptable test devices, specimen collection, test matrices, cutoff values for metabolites and BAC values for alcohol testing, requirements for drug-testing laboratories, and credentials and responsibilities for the drug- and alcohol-testing program personnel as well as sanctions resulting from rule violations.

With regard to individuals who might have an AUD and/or are impaired on the job, the NRC and DOT rules give SAEs and SAPs the authority to assess the individuals and, if appropriate, refer them for treatment, which can include abstinence as a treatment goal along with compliance monitoring per the treatment program's requirements. In the context of the FFD rule, it is possible that an SAE may require an individual to be in a treatment program that uses EtG testing to monitor for abstinence compliance and test results could be used as evidence regarding whether the individual is complying with the SAE's treatment recommendation. The rule further requires the licensee to verify that individuals subject to a 5-year denial of authorization have abstained from substance abuse for at least the past 5 years. It is hypothetically possible that abstinence monitoring outside of testing under the FFD rule may be reliant on EtG testing. Thus, access authorization decisions under Part 26 could be based on EtG test results.

Despite ongoing challenges to EtG testing validity, the courts and healthcare professions are using EtG testing to monitor compliance with alcohol abstinence requirements. For these applications, EtG testing benefits derived from available inexpensive immunoassay tests and

the longer time window for detection are deemed to override those for alternative testing regimes based on breath. Acceptance of EtG testing for these purposes is not based on an explicit regulatory authority. Instead, for judicial programs, case law has established that this testing is acceptable and PHP programs rely on prevailing professional views within the pertinent scientific community and therapeutic professions.

5.0 Legal Considerations

This section provides an overview of legal protections and employment provisions for individuals with respect to alcohol consumption and AUDs, and discusses the applicability of these laws with respect to workplace drug- and alcohol-testing policies. Specifically, individuals who have AUDs may be entitled to protection under the ADA, the Americans with Disabilities Act Amendments Act (ADAAA), and the Family and Medical Leave Act (FMLA), and may resort to litigation and third-party arbitration to dispute employment grievances through unions and on the basis of their collective bargaining agreements (CBAs). In addition, this section discusses procedural due process protections for individuals subject to 10 CFR Part 26. The sections below provide a discussion of the ADA and ADAAA, FMLA, employment-related arbitration and due process pertinent to FFD programs and how these laws relate to individuals who have AUDs.

5.1 ADA Protection

The employment provisions in Title 1 of the ADA (42 U.S.C 12101 et seq.) and in ADAAA (2008) protect qualified individuals who have disabilities against employment discrimination on the basis of their disabilities in all employment practices (e.g., hiring, firing, scheduling, promotion, and disciplinary action).

5.1.1 AUD as a Covered Disability under the ADA

Under the ADA and ADAAA, individuals who have an AUD may be considered disabled and thus could have employment protections. The Equal Employment Opportunity Commission (EEOC), the Federal agency overseeing the application of Title I of the ADA, states that an alcoholic is an individual with a disability and is protected by the ADA if she or he is qualified to perform the essential functions of the job (EEOC 2002a). The EEOC also states that an individual who currently uses alcohol is not automatically disqualified from ADA protection (EEOC i.d.).

For an individual seeking ADA protection on the basis of an AUD, the impairment resulting from the individual's use of alcohol must meet the definition of a "disability" in 42 USC 12102 (1). The individual must also be deemed to be a "qualified individual" who has a disability. A qualified individual who has a disability is someone "… who, with or without reasonable accommodation, can perform the essential functions of the employment position that such individual holds or desires" (42 USC §12111(8)).

5.1.2 Employer and Employee Obligations and Responsibilities under the ADA

Employers have certain obligations and responsibilities under the ADA. The ADA and ADAAA require that, at the request of an employee who has a known disability, an employer should make reasonable accommodations for the employee unless doing so will result in an undue hardship to the employer (i.e., significant expense or difficulty for business operations) (42 USC §12111(10); EEOC 2002b). At an employee's request for reasonable accommodation, the employer should initiate an interactive process with the employee to determine what kind of an accommodation is needed and would be effective (EEOC 2002b). Examples of reasonable accommodations may include job restructuring, modifying work schedules to allow employees with disabilities to receive treatment, reassignment to a vacant position, acquiring or modifying

equipment or devices, and making the workplace readily accessible to and usable by people who have disabilities (42 USC §12111(9) (A)-(B), EEOC 2008). An employer may not discipline or terminate an employee who has a disability on the basis of poor job performance, if poor performance was caused by the employer's refusal to provide requested reasonable accommodation that did not impose undue hardship on the employer (EEOC 1992).

Employees with disabilities nonetheless need to conform to the performance and conduct standards of the workplace. They can be held to the same standards of performance and professional conduct as similarly situated employees without disabilities for performing essential job functions (EEOC 1992). Employees with disabilities should not be disciplined less severely than any other employee for the same conditions triggering disciplinary action (EEOC i.d.). An employee with a disability can be disciplined or denied employment if his or her alcohol use or alcohol addiction adversely affects job performance or violates professional conduct of the workplace (EEOC 2011).

5.1.3 Employer Discretion and Authority under the ADA

The ADA does not preclude an employer from exercising discretion and authority to terminate an employee with a disability due to poor performance or infraction of workplace professional conduct standards. *The EEOC Technical Assistance Manual* states an employer is free to "… discipline, discharge or deny employment to an alcoholic whose use of alcohol adversely affects job performance or conduct to the extent that s/he is not qualified" (EEOC 1992, p. 145). To illustrate this point, the EEOC provides the following example:

> "If an individual who has alcoholism often is late to work or is unable to perform the responsibilities of his/her job, an employer can take disciplinary action on the basis of the poor job performance and conduct. However, an employer may not discipline an alcoholic employee more severely than it does other employees for the same performance or conduct." (EEOC, i.d.).

The U.S. Commission on Civil Rights (2000) further clarified the employers' discretions pursuant to the ADA and in light of court cases:

- An employer is not required by the ADA to provide an alcohol rehabilitation program or to offer rehabilitation in substitution of disciplining an employee for alcohol-related misconduct or performance problems.
- The ADA differentiates between alcoholism as a covered disability from alcoholism-related misconduct. Court decisions have repeatedly upheld that employees cannot blame their misconduct on alcoholism and have it excused.
- Reasonable accommodation does not mean employers have to forgive misconduct *because* the misconduct resulted from alcoholism.
- An employer might not be obligated to provide an accommodation to an employee who has not asked for an accommodation and who denies having a disability.
- If evidence shows an employee's alcohol abuse treatment is "futile" or the employee has a "poor prognosis for recovery," an employer might not be required to provide leave to the employee.

5.1.4 ADA and Workplace Drug- and Alcohol-Testing

With regard to drug and alcohol use on the job, the ADA also made it clear that employers can

- prohibit the use of alcohol in the workplace;
- require employees not be under the influence of alcohol in the workplace;
- require employees to comply with the Drug-Free Workplace Act wherever applicable;
- hold employees with disabilities to the same employment qualification and performance standards for job performance and behavior as the employer holds other employees, even if any unsatisfactory performance or behavior is related to the drug use or alcoholism of such employee; and
- comply with NRC and DOT regulation regarding workplace drug- and alcohol-testing programs (42 USC §12114 (C)(1)-(5)).

5.1.5 ADA and Public Health and Safety

Certain industries have a heightened responsibility for protecting public health and safety. To enable employers in these industries to balance between the interests of protecting public health and safety objectives and the interests of employees with disabilities, the ADA permits employers to establish qualification standards to exclude individuals from posing direct threats to themselves and others under certain conditions. These conditions include (1) the qualification standards are job-related and are consistent with the business necessity of the employer; and (2) the risk cannot be eliminated or mitigated by reasonable accommodation (EEOC n.d.). The Department of Justice (DOJ) (2005) further states the employer's discretion in deciding whether to retain an employee with a disability:

- "The ADA permits employers to establish qualification standards to exclude individuals who pose a direct threat (i.e., a significant risk of substantial harm) to the health or safety of the individual or of others, if that risk cannot be eliminated or reduced below the level of direct threat by reasonable accommodation,
- An employer may not simply assume that a threat exists; the employer must establish through objective, medically supportable methods that there is significant risk that substantial harm could occur in the workplace, and
- By requiring employers to make individualized judgements based on reliable medical or other objective evidence rather than on generalizations, ignorance, fear, patronizing attitudes, or stereotypes, the ADA recognizes the need to balance the interests of people with disabilities against the legitimate interests of employers in maintaining a safe workplace" (DOJ, i.d.).

5.1.6 ADA and At-Will Employment

It is worth noting that the provisions of the ADA can create exceptions to the at-will doctrine where an employer can terminate an employment relationship without cause.[24] At-will termination of employment due to discrimination on the basis of age, race, gender, religion, disability, or veteran status or as an act of retaliation against employees violates laws such as

[24] That is, "an employer can terminate an employee at any time for any reason, except an illegal one, or for no reason without incurring legal liability. Likewise, an employee is free to leave a job at any time for any or no reason with no adverse legal consequences" (NCSL n.d.).

Title I of the ADA and the Age Discrimination in Employment Act of 1967 (Pub. L. 90-202), and thus is illegal.

5.1.7 Disability-Based Employment Discrimination and Total Abstinence Requirement

Whether or not personnel actions taken by employers concerning employees' disabilities and their employment status constitute discrimination on the basis of the employees' disabilities centers on whether a charge of discrimination meets the definition of discrimination in the ADA (42 USC §12112 (b)(1)-(7) and satisfies the necessary defenses laid out in ADA Section 103 (42 USC §12113).)

In an informal opinion letter published by the EEOC (2014a), the author provides a discussion in response to union grievances challenging the legality of total alcohol abstinence requirements as a condition of continued employment for a nuclear power plant's employees who were alcoholics or perceived to be alcoholics. The central questions of the discussion include (1) whether the qualification standards imposed by the employer (i.e., total alcohol abstinence requirements) would screen out employees with disabilities, and (2) whether the employer can show that such requirements are justifiable in terms of the business necessity or direct threat defenses stipulated in Title I of the ADA.

The EEOC letter explains that the ADA prohibits employers from using qualification standards to screen out individuals or a class of individuals with disabilities without demonstrating that the qualification standards are job-related and consistent with business necessity, and the direct threat cannot be eliminated by reasonable accommodation.

The EEOC letter points out that the total abstinence requirements seemed to act as an across-the-board exclusion applicable only to employees who were alcoholics regardless of whether or not they were impaired on the job. But the same requirements did not appear to be mandated for employees who have tested positive for alcohol on the job. This indicates that the total abstinence requirements might not be necessary for effective job performance or for ensuring that employees are trustworthy and reliable.

Further, the EEOC letter points out that the employer should demonstrate that the direct threat—employees being impaired on the job in the future and posing a direct threat due to their unescorted access to a nuclear power plant—can be mitigated or eliminated by implementing the total abstinence requirements among employees with alcoholism. The letter emphasizes that the determination of a direct threat must be based on individualized assessment of the employee's "present ability to safely perform the essential functions of the job … taking into account the most current medical knowledge and/or best available objective evidence." Determination of a direct threat should not be based on speculation about potential harm or based on generalization about the individual's disability. (For a list of recent EEOC significant employment discrimination litigation, see EEOC 2014b and 2016.)

5.2 Family and Medical Leave Act

The FMLA protects the rights of employees to take unpaid leave for up to 12 weeks during any 12-month period for reasons such as serious health conditions, childbirth, caring for the employee's family, and active military duty (Department of Labor [DOL] n.d.). According to the DOL, treatment for substance abuse may qualify as a serious health condition if the condition

meets the requirements for inpatient care and/or continuing treatment, and if the treatment is provided by healthcare providers. However, as clarified by the court's ruling in *Darst v. Interstate Brands Corporation* (2008), absence from work due to an employee's substance use rather than substance abuse treatment does not qualify the employee for FMLA leave. Under the FMLA, the employer is required to maintain the employee's current health plan coverage while the employee is on leave, and return the employee to the same or equivalent position upon the employee's return. However, FMLA does not preclude an employer from terminating an employee who is on FMLA leave if the cause of termination is legitimate and nondiscriminatory (e.g., poor performance). In *Picarazzi v. John Crane* (2011), the employee took FMLA leave for alcoholism treatment but was terminated while on leave due to a relapse from the treatment. The court concluded that the language of the Act does not dictate whether the employee should be under the care of a physician or rehabilitation service provider for each day of his leave, and hence the employer had no legitimate grounds to terminate the employee (EPS 2013).

5.3 Employment-Related Grievance Arbitration

Through the Steelworkers Trilogy,[25] the Supreme Court affirmed its preference for arbitration over litigation as an alternative means of resolving labor-management grievances (Gregory et al. 2010). The Court made it clear that the Court's role is not to judge the merits of an arbitrator's award, and that an award should be upheld and binding unless such an award fails to draw "… its essence from the collective bargaining agreement" (*Steelworkers v. Enterprise Car,* 363 U.S. 593 [1960]). In a review of Federal court decisions concerning arbitration appeals since the 1960s, LeRoy and Feuille (1991) report that, typically, grievance arbitration can be vacated due to lack of arbitrability per the CBA or due to problems arising from enforcing an award if enforcement conflicts with external laws or public policy.

Among the legal cases involving employment grievance arbitration involving alcohol use, some judicial decisions supported the intent of existing workplace drug and alcohol regulations designed to protect public safety and security. In *Delta Airlines vs. Airline Pilot Association International* (1988), the Airline Pilot Association alleged that Delta Airlines had no sufficient cause for discharging a pilot for being inebriated on the job, and submitted the dispute for arbitration. An award was granted to reinstate the pilot and to order Delta Airlines to pay for the pilot's substance abuse treatment. The court sided with Delta Airlines by highlighting that enforcing the award could necessarily violate the U.S. Federal Aviation Administration's (FAA's) regulations, which prohibit pilots from operating an aircraft while impaired by alcohol (Drummonds 2013).

In a number of court cases, litigation results regarding employment grievances could potentially interfere with workers' compliance with workplace drug and alcohol regulations for safety- and security-sensitive industries. In *Exelon Generation Company LLC vs. Local 15, International Brotherhood of Electrical Workers, AFL-CIO* (2015), the central contention was whether, when adopting and implementing its SAE's recommendations following fitness determinations, Exelon had just cause for imposing a total alcohol abstinence requirement on some of its employees as a condition of continued access to Exelon's nuclear power plants. Exelon argued that the

[25] The Steelworkers Trilogy referred to the three cases involving the United Steelworkers: the *United Steelworkers v. American Manufacturing Co*., 363 U.S. 564 (1960); *United Steelworkers v. Enterprise Wheel & Car Corp*., 363 U.S. 593 (1960); and *United Steelworkers v. Warrior & Gulf Navigation Co*., 363 U.S. 574 (1960).

dispute resolution procedure in the CBA provides no grounds for Local 15 to seek arbitration for the grievances in question, and that, if granted, an award to rescind the SAE's recommendation would be impermissible under NRC regulations. The district court decided that the arbitration clause in the CBA is sufficiently broad to allow the arbitral review of the arbitrability of the dispute itself, and thus granted Local 15's motion to compel arbitration. In prior cases involving Local 15, the court similarly ruled that third-party arbitrators had the power per the CBA to review or potentially revoke a licensee's denial of unescorted access authorization (*Exelon Generation Company LLC v. Local 15, International Brotherhood of Electrical Workers* [2008, 2012]). The NRC has developed a number of papers to address the need for clarifying the role of arbitrators in access authorization and FFD determinations (e.g., SECY-15-0149, NRC 2015, 2016a). In June 2016, the NRC decided to proceed with the rulemaking process to evaluate its policy on the role of third-party arbitrations in access authorization and FFD determinations at nuclear power plants (NRC 2016b).[26]

5.4 Procedural Due Process Protection

NRC has a strong commitment to protecting individual rights, including due process. For drug and alcohol testing outside the purview of 10 CFR Part 26 (e.g., treatment programs), it is unclear whether or not procedural due process protection is made available for individuals undergoing such testing. Established by the Fifth and Fourteenth Amendments, the due process clause requires that proper procedures be followed when the government deprives a person's life, liberty, or property (Chemerinsky 1999).[27] It provides a fair decision-making process for determining whether an individual has violated a law, rule, or regulation (Sperry 1999). The basic elements of procedural due process are notice of proposed action and opportunity to rebut charges against the individual (Ford et al. 2000; Jones 2008; Wasserman 2004). More specifically, procedural due process requires providing notice of the charges against an individual, demonstrating violation of an articulated standard of conduct, providing an opportunity to submit evidence and rebut charges against an individual, providing substantial and credible evidence supporting the charges, and providing justification for adverse findings (Linder 2016). This section summarizes areas where Part 26 reveals specific commitments to providing due process and highlights where there may be potential due process protection gaps for EtG testing occurring within the context of a treatment program.

Protection of individual rights is an important goal of the NRC's 2008 Fitness for Duty Programs Final Rule, which sought to "… protect the privacy rights and other rights (including due process) of individuals who are subject to 10 CFR Part 26" (NRC 2008). The rule requires FFD programs to provide written FFD policies and procedures that are "… clear, concise, and readily available, in its most current form, to all individuals who are subject to the policy" (§26.27). Regarding procedures for reviewing policy violation determinations, the rule also states that licensees and other entities shall establish procedures to provide an objective and impartial review of facts related to violation charges and "… the review procedure must provide notice to the individual of the grounds for the determination that the individual has violated the FFD policy, and must provide an opportunity for the individual to respond and submit additional relevant information" (§26.39 (a)-(b)). To ensure impartiality, the rule requires that the individual

[26] The docket for this rulemaking is NRC-2016-0145.

[27] Due process has two dimensions: substantive due process and procedural due process. The former addresses whether the government "has a sufficient substantive justification" for depriving a person's life, liberty, or property, and the latter focuses on whether proper procedures are followed when the government takes away a person's life, liberty, or property (Chemerinsky 1999).

conducting the review must not be associated with the administration of the FFD program (26.39 (c)).

Specific procedural due process protection pertinent to alcohol testing afforded by Part 26 includes the following:

- Providing a clear standard of conduct and purpose for testing all individuals subject to the FFD rule (§26.23)
- Specifying types of testing and conditions necessitating testing (§26.31(d))
- Providing reliable and objective evidence concerning testing and impartial justification for policy violation determination:
  - Ensuring reliable testing procedures are followed (§26.81–§26.103)
  - Specifying requirements for collection sites (§26.87), acceptable test devices (§26.91 (a)-(c)), quality assurance of test devices (§26.91 (d) and (e)), types of specimens acceptable for testing (§26.95–§26.97), and alternative evaluation processes to accommodate donors' medical conditions (§26.31 (5))
  - Specifying specimen security requirements and those for chain of custody and specimen preservation (§26.129)
  - Ensuring testing is performed by qualified and objective personnel: personnel (e.g., MROs, specimen collectors) conducting specimen collection, testing, and review and interpretation of test results must be adequately trained, knowledgeable about FFD policy, have appropriate credentials, and be free of conflict of interest with the licensee and the individuals subject to testing (§ 26.183, §26.85, §26.29, §26.31)
  - Providing unambiguous criteria across FFD programs for determining a positive test result based on the initial test (§26.31(4), §26.95, §26.97)
  - Requiring specimen collectors to show donors the displayed or printed alcohol test results (§ 26.95 (b)(4))
  - Providing unambiguous criteria for determining the need for confirmatory testing and interpreting confirmatory test results (§26.99–§26.103)
  - Prohibiting collected specimens from being tested for any purpose not specified in Part 26 without the donor's written permission (§26.31(d))
  - Requiring reporting of drug and alcohol-testing errors and FFD programmatic weaknesses to the NRC (26.791(d)) to monitor program effectiveness and test accuracy
- Providing opportunities and time for donors to respond before a policy violation is determined:
  - Determination of policy violation is made by the MRO who conducts an objective review and interpretation of test results and provides opportunities to discuss with donors about positive, adulterated, substituted, dilute, or invalid test results (§26.185 (a) and (c)).
  - The MRO may determine a positive, adulterated, substituted, dilute, or invalid test result as an FFD policy violation without discussing it directly with a donor if the donor expressly declines such an opportunity; does not respond after being successfully contacted by the MRO, MRO staff, or a licensee representative; or if the donor cannot be contacted after the MRO has made at least three attempts reasonably spaced over a 24-hour period (§26.185(d)).

- Providing additional opportunity for discussion with donors after the notification of MRO determination:
  - Within 30 days of the notification of MRO determination, the donor may present to the MRO information about the circumstances (e.g., serious illness or injury) that prevented the donor from responding to the MRO in a timely manner.
  - The MRO may modify the initial determination based on an evaluation of the information provided by the donor (26.185(e)).
- Providing clear articulation about management actions and sanctions to be imposed on an individual following a policy violation determination (§26.75)
- Protecting individuals' confidentiality and privacy
  - The MRO or MRO staff may not report initial laboratory test results that are positive, adulterated, substituted, dilute, or invalid to the licensee or other entity (§26.185(d)).
  - Donor records and other information must be maintained confidential by the MRO staff and should be only disclosed to individuals and entities consistent with the provision of the rule (§26.183 (d)).
  - An initial positive test result may not result in the termination of an individual's authorization and the individual may not be subject to other administrative actions except when initial test results are positive for marijuana or cocaine metabolites (26.75(h)).
  - Licensees and other entities may not disclose the temporary administrative action against an individual whose initial drug test result is not subsequently confirmed by the MRO as a violation of the FFD policy (§26.75(4)).
  - If the policy violation determination outcome favors the individual, the favorable outcome should be updated in the relevant records and all information deemed inaccurate should be deleted or corrected (§26.39 (d)).
- Ensuring accuracy of donor information and recordkeeping requirements
  - Ensuring accuracy of the information collected about individuals and providing opportunities for individuals to review and correct inaccurate information (§26.711(c)).
  - Records pertaining to policy violation determination, management action, access authorization termination and other information should be maintained by the licensee or other entity as required by any legal proceedings (§26.713).
  - Individuals must be anonymized when their drug and alcohol-testing data are tracked and trended by licensees or other entities (§26.719(d)).

The procedural due process protection afforded by 10 CFR Part 26 protects individuals who are subject to the rule from wrongful determination of policy violation and loss of access authorization, provides them with meaningful opportunities to submit evidence to dispute policy violation charges, and puts in place safeguards for protecting the privacy and confidentiality of their information and records. All licensees and other entities within the scope of the rule (§26.3) must implement these requirements and make them available to all individuals subject to the rule (§26.4). For drug and alcohol testing outside the purview of 10 CFR Part 26, on an individual's own initiative (e.g., substance abuse treatment programs) and in the absence of any legal mandate (e.g., 49 CFR Part 40), it remains unclear whether or not procedural due process protection is made available for individuals undergoing such testing. In particular, how information regarding noncompliance with required treatment programs under 10 CFR 26.69

(access authorization with potentially disqualifying information) is handled remains unclear (see Section 4.1.4).

5.5 Summary

Under the ADA and ADAAA, AUD is a covered disability and qualified individuals may be protected against employment discrimination on the basis of their disabilities. The ADA requires employers, upon employees' request, to make reasonable accommodations for employees with disabilities unless doing so will result in an undue hardship. However, an employee who has a disability can still be disciplined or denied employment if his or her alcohol use or alcohol addiction adversely affects job performance or violates professional conduct of the workplace. In addition, the ADA and ADAAA do not prohibit employers from conducting workplace drug and alcohol testing. Employers are free to comply with workplace drug and alcohol regulations of the NRC and DOT. Moreover, the ADA prohibits employers from using qualification standards to screen out individuals or a class of individuals with disabilities without demonstrating that the direct threat cannot be eliminated by reasonable accommodation, and the qualification standards are job-related and are consistent with business necessity.

Similarly, the FMLA protects the rights of employees to take unpaid leave for serious health conditions that may include AUD. However, the FMLA does not preclude an employer from terminating an employee who is on FMLA leave if the cause of termination is legitimate and nondiscriminatory (e.g., poor performance).

Employees who have AUDs may resort to litigation or arbitration to dispute employment grievances through unions in accordance with their CBAs. A number of recent court decisions have highlighted the need for regulatory agencies to clarify whether or not third-party arbitration disputing issues directly affecting compliance with these agencies' regulations is permissible.

Individuals subject to NRC FFD drug and alcohol testing are afforded procedural due process protection through 10 CFR Part 26, which provides notice of proposed action (e.g., policy violation-based sanctions) against the individuals and enables them to have a fair opportunity to submit evidence and to rebut policy violation charges. Such protection serves to prevent these individuals from wrongful determination of policy violations concerning substance use. However, it is unclear how compliance monitoring information is used in the context of access authorization and whether the same procedural due process protection is implemented to protect the rights of individuals.

6.0 Discussion and Conclusion

In this study, the project team reviewed and synthesized research on the scientific, clinical, regulatory, and legal factors surrounding alcohol use and AUDs and how these factors interface with workplace drug- and alcohol-testing requirements and implementing programs. Our research leads to the observations discussed below regarding workplace drug- and alcohol-testing policies and relevant requirements applicable to employment in safety- and security-sensitive industries and professions.

6.1 Discussion

The research questions posed in Section 1.2 are reiterated below along with a response to and a discussion of each.

1. **What is the "gold standard" in AUD treatment? Is total abstinence a reasonable treatment goal for patients performing jobs that are important for public health and safety?**

Response: The experts interviewed by the project team believe that total abstinence as a treatment option for AUD should be based on an individualized assessment using well-established diagnostic tools such as the DSM-5. Given the inherent risk in safety- and security-sensitive industries, total abstinence as a treatment option for AUD is not an unreasonable treatment recommendation for employees who have AUDs.

Discussion: Eleven experts specializing in substance abuse treatment were interviewed to gain an understanding of whether total abstinence is a preferred treatment or treatment goal for AUDs compared to alternatives (e.g., controlled drinking or harm reduction). The interview results indicate that many experts believe treatment recommendations should be aligned with individualized assessment outcomes based on diagnostic standards such as the DSM-5 diagnostic criteria, which are important for screening AUDs and for providing the clinical basis for conducting additional evaluation to individualize treatment. Further, experts called attention to the need to understand patients' employment circumstances (e.g., safety- and security-sensitive jobs) that could necessitate the recommendation of total abstinence (e.g., impairment on the job). The experts believed that total abstinence is not an unreasonable requirement in a safety- and/or security-sensitive job if a person has been evaluated to have an AUD and has had alcohol-related performance issues or tested positive for alcohol on the job. While EtG testing is not an unusual testing method for monitoring total abstinence during the course of AUD treatment, a number of experts commented on the risk of misinterpreting EtG test results due to its sensitivity, and stated that the interpretation of EtG tests should be done by highly trained and knowledgeable professionals.

2. **Is EtG an appropriate biomarker for alcohol testing? Is its use scientifically defensible for alcohol abuse treatment and workplace alcohol-testing programs?**

Response: Researchers have clearly established and SAMHSA has concurred that EtG is a specific and sensitive metabolite of ethanol consumption or exposure. Thus it is an appropriate biomarker for alcohol testing. Because of EtG sensitivity, EtG test results should be interpreted with caution and account for incidental exposure, sample degradation, and low detection values (i.e., less than 500 ng/mL). EtG is appropriate for clinical monitoring for alcohol use in treatment programs, but given the potential for false positives and negatives and the fact that there is limited consensus on cutoff values, its potential for defensible use in forensic workplace alcohol-

testing use is questionable. If EtG is used for monitoring in treatment plans, it should not be the sole indicator of failing to meet a total abstinence requirement, particularly when an individual is required to be in compliance as a condition of continued employment.

Discussion: In the context of an alcohol abstinence goal under a treatment plan, understanding when an individual has had unintentional exposure to alcohol is important, particularly when such exposure may result in elevated EtG values. EtG can provide a good window into alcohol abstinence for the prior two days for light consumption and upward of 3 days for heavy consumption. EtG results should be interpreted with donor information about other possible exposures to alcohol and the individual's health conditions.

EtG immunoassay testing in urine is suitable for initial testing but confirmatory testing must use mass spectrometry-based test methods (e.g., GC-MS, LC-MS) to minimize false positives. To minimize potential false positives, a cutoff value of at least 500 ng/mL for positive detection should be applied. Detection at less than 500 ng/mL may indicate a need for counseling on interfering substances and follow-up testing. EtG testing is possible in matrices other than urine (e.g., oral fluids, hair), but is not as well understood and may not be suitable for abstinence monitoring.

EtG is subject to both false positives and negatives and a considerable amount of attention has been paid to the incidental exposures that may cause false positives and their potential repercussions. However, the problems stemming from sample degradation due to poor handling and common contaminants or, much less likely, individual health conditions and/or genetic variation in alcohol metabolism are equally real and well understood by the research community. When EtG testing is used, the sample handling protocols should include a requirement to store samples at or below 4°C (i.e., the temperature of an ice bath) to minimize false negatives from bacterial contamination and false positives for samples with elevated sugar (e.g., from diabetics) and bacterial and yeast contamination.

3. How do workplace drug- and alcohol-testing regulations (e.g., 10 CFR Part 26) apply to workplace total abstinence requirements and EtG testing?

Response: The drug- and alcohol-testing regulations are silent on workplace EtG testing and can require abstinence for individuals with potentially disqualifying information as a condition for gaining or maintaining access authorization. Program implementation mandates that an individual who has suspected alcohol use problems be evaluated by an SAE. The SAE may, based on professional judgment, evaluate individuals who have violated substance abuse provisions of the FFD policy, determine the best recommendation for assisting the individuals, and serve as a referral source to assist their entry into an education and/or treatment program. A treatment program could include total abstinence as a treatment goal and use EtG testing as a means of clinical monitoring of abstinence compliance. It is important to point out, however, workplace alcohol-testing regulations are clear regarding test methods (i.e., oral fluid and breath testing for alcohol) and cutoff levels and are independent of the requirements for treatment monitoring associated with an AUD treatment program. There is no regulatory basis for using test methods outside the current NRC regulations for FFD compliance.

Discussion: Regulations and policies governing the drug- and alcohol-testing programs of the NRC and DOT unequivocally require individuals to be free from the impairing influence of drugs and alcohol while on the job. These regulations have defined requirements for alcohol testing, conditions that trigger testing, and sanctions associated with positive test results. Pursuant to 10 CFR 26.31(c), conditions requiring alcohol testing are pre-employment, random, for-cause, post-accident, and follow-up. Alcohol-testing methods are limited to breath (initial and confirmatory) or oral fluids (initial only), using devices stipulated in 10 CFR 26.91. The use of

EtG testing is not included in the types of testing covered in the NRC's Fitness for Duty Programs (10 CFR Part 26).

After an individual violates the FFD program's alcohol policy, the licensee must ensure the individual meets requirements for maintaining the individual's access authorization (the regulations for these are outlined in Table 4-4). These requirements have common elements including determination of fitness, development and implementation of plans for treatment and follow-up testing when warranted, and compliance with treatment and follow-up testing where applicable. The requirements do not specify how the licensee's SAE should "… protect public health and safety and the common defense and security by professionally evaluating the individual and recommending appropriate education/treatment, follow-up tests, and aftercare." Thus, the rule allows SAEs to exercise their professional judgment when determining fitness for duty and making recommendations concerning education, treatment, return to duty, follow-up drug and alcohol testing, and aftercare. The recommended treatment program testing is outside the purview of 10 CFR Part 26 and may rely on EtG testing to monitor treatment progress and success. FFD policy requires that individuals must be determined to be fit for duty for access authorization to be granted, maintained, or reinstated. For individuals receiving AUD treatment to be determined to be fit for duty, it is plausible that their compliance with AUD treatment program testing requirements and their success with the treatment programs could be relevant or even form the basis for fitness determinations under 10 CFR Part 26.

4. What are the rights and responsibilities of licensees and personnel addressing employment conditions and disputes associated with alcohol-related problems in the workplace?

Response: Both employers and employees have rights and responsibilities for ensuring compliance with NRC's FFD Program. The ADA recognizes the need to balance the interests of individuals who have disabilities against the legitimate interests of employers in maintaining a safe workplace (EEOC 2008). Potential problems might arise when the employers' authorities and employees' responsibilities are poorly defined. Within the workplace, employers must consider making reasonable accommodations for employees who have AUDs, while ensuring compliance with workplace drug and alcohol policies. Employees can be held to the same employment performance and conduct standards as other similarly situated employees regardless of AUD status; that is, an employee who has a disability can be disciplined or denied employment if his or her alcohol use or alcohol addiction adversely affects job performance or violates professional conduct in the workplace. The current regulatory and legal landscape has some ambiguity relative to whether or not policy violation-related employment grievances can be arbitrated. As of June 2016, the NRC has proceeded with rulemaking to evaluate its policy regarding the role of third-party arbitration in access authorization and FFD determinations at nuclear power plants to further protect public safety and health (NRC 2016b).[28] In addition, procedural due process protection is provided for individuals who are subject to drug and alcohol testing in accordance with 10 CFR Part 26 to prevent these individuals from wrongful determination of policy violations concerning substance use. For alcohol testing performed outside Part 26 or other legal mandates (e.g., DOT regulations), it remains unclear what procedural due process is followed for individuals undertaking such testing.

Discussion: Civil rights laws such as the ADA and ADAAA or pertinent Federal laws such as the FMLA do not interfere with requirements for employers to comply with workplace drug- and alcohol-testing regulations and policies. Individuals who have AUDs who are subject to workplace drug and alcohol regulations are required to remain unimpaired on the job.

[28] The docket for this rulemaking is NRC-2016-0145.

Under the ADA, AUD is a covered disability and qualified individuals who have AUD may be protected from employment discrimination and have the right to request employers to make reasonable accommodation, provided their disability does not result in job performance issues or misconduct. By the same token, the FMLA protects the rights of employees to take unpaid leave to treat AUD, but it does not preclude employers from discharging an employee who has an AUD while on FMLA leave due to poor performance associated with substance use.

Conflict between employers and employees as well as labor unions might arise when employers impose drug- and alcohol-related requirements that are not specifically stipulated in the current workplace drug and alcohol regulations but can potentially impact conditions of employment for employees. The central question, then, is whether an employer has just cause and grounds for imposing requirements on employment conditions not explicitly based in applicable laws or regulations. Consideration should be given to the boundaries of workplace drug- and alcohol-testing regulations, workplace policies, terms of CBAs, and the applicability of other pertinent laws. For example, the EEOC discussed whether imposing a total abstinence requirement by an employer (i.e., a commercial nuclear power plant) on employees who tested positive for alcohol as a condition of continued employment constitutes an ADA violation (EEOC 2014a). In an informal opinion letter, the EEOC argued that the requirement would serve as a qualification standard designed to screen out employees who have AUDs and the qualification standard was based on speculation regarding a risk that individuals who have AUDs might pose to others at work and to the public, rather than individualized assessment of risk, and hence might not be consistent with employment provisions of the ADA.

Another arena for conflict between employers and employees as well as labor unions might arise when the resolution of an employment grievance conflicts with employer compliance with workplace drug- and alcohol regulations. Through their unions and CBAs, employees have resorted to litigation and arbitration to resolve employment-related grievances. Outcomes from arbitration have resulted in reinstatement of access that was previously denied in accordance with NRC's regulations and, because individuals who were denied access due to prior policy violations, might have an adverse impact on public safety and security. Court decisions and arbitration awards like these highlight the need for regulatory agencies to clarify their positions regarding whether or not such arbitration is permissible and what options might be feasible to mitigate the impact of these arbitration and litigation outcomes.

6.2 Conclusion

Alcohol use is pervasive and abuse is common in American society. Ensuring individuals' alcohol use does not negatively impact public health and safety requires consideration of a host of factors, including workplace drug- and alcohol-testing regulations and programs, civil rights laws and public laws, rights and responsibilities of individuals and their employers, and management-union relations.

In this report, the project team researched and evaluated issues surrounding alcohol use, abuse, and treatment; what is needed to monitor and test for alcohol; and the programmatic and legal requirements affecting implementation of FFD programs.

Understanding the science and best practices in AUD treatment, understanding the interplay among workplace alcohol regulations and policies, and clearly defining the roles, authorities, rights, and restrictions of all the stakeholders in workplace drug- and alcohol-testing programs will help clarify the "grey areas" regarding alcohol-related requirements in the workplace, and contribute to better protection of the nation's safety, security, and public health as well as the protection of individuals' rights and civil liberties.

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Appendix A

List of Substance Abuse Organizations Contacted

Appendix A

List of Substance Abuse Organizations Contacted

Substance Abuse Organizations Contacted	Organization's Mission
Federal Agencies 1. National Institute of Health (NIH) National Institute on Alcohol Abuse and Alcoholism (NIAAA)	NIAAA provides leadership in the national effort to reduce alcohol-related problems by • conducting and supporting alcohol-related research in a wide range of scientific areas including genetics, neuroscience, epidemiology, prevention, and treatment. • coordinating and collaborating with other research institutes and Federal Programs on alcohol-related issues. • collaborating with international, national, state, and local institutions, organizations, agencies, and programs engaged in alcohol-related work. • translating and disseminating research findings to health care providers, researchers, policymakers, and the public. (source: http://www.niaaa.nih.gov/about-niaaa/our-work/mission-statement).
2. Substance Abuse and Mental Health Services Administration (SAMHSA)-Health Resources and Services Administration (HRSA), Center for Integrated Health Solutions (CIHS) run by the National Council for Behavioral Health	The SAMHSA-HRSA CIHS promotes the development of integrated primary and behavioral health services to better address the needs of individuals with mental health and substance use conditions, whether seen in specialty behavioral health or primary care provider settings. CIHS is funded jointly by the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Health Resources and Services Administration (HRSA), and run by the National Council for Behavioral Health. CIHS provides training and technical assistance to community behavioral health organizations, community health centers, and other primary care and behavioral health organizations. (source: http://www.integration.samhsa.gov/about-us/about-cihs).
Professional Organizations 3. National Association of Alcoholism and Drug Abuse Counselors (NAADAC)	"NAADAC's mission is to lead, unify and empower addiction focused professionals to achieve excellence through education, advocacy, knowledge, standards of practice, ethics, professional development and research." Adopted 1998 (source https://www.naadac.org/about)
4. National Council on Alcoholism and Drug Dependence, Inc. (NCADD)	The NCADD and its Affiliate Network is a voluntary health organization dedicated to fighting the nation's #1 health problem—alcoholism, drug addiction, and the devastating consequences of alcohol and other drugs on individuals, families and communities. (Source: https://www.ncadd.org/about-ncadd/about-us/our-mission)

Substance Abuse Organizations Contacted	Organization's Mission
5. National Association of State Alcohol and Drug Abuse Directors (NASADAD)	The NASADAD is a private, not-for-profit educational, scientific, and informational organization. The Association was originally incorporated in 1971 to serve State Drug Agency Directors, and then in 1978 the membership was expanded to include State Alcoholism Agency Directors. NASADAD's basic purpose is to foster and support the development of effective alcohol and other drug abuse prevention and treatment programs throughout every State. The Board of Directors is composed of a President, First Vice President, Vice President for Treatment, Vice President for Internal Affairs, Vice President for Prevention, Past President, Secretary, and Treasurer, as well as 10 regional representatives elected by the Association members in the region. The Washington, D.C., office is headed by an Executive Director and includes divisions concerned with research and program applications, prevention services, and public policy. (source: http://nasadad.org/about-us/)
6. American Academy of Addiction Psychiatry (AAAP)	Mission Statement • Promote high-quality evidence-based screening, assessment and treatment for substance use disorders and co-occurring mental disorders. • Translate and disseminate evidence-based research to clinical practice and public policy. • Strengthen Addiction Psychiatry specialty training and foster careers in Addiction Psychiatry. • Provide evidence-based addiction education to healthcare trainees and health professionals to enhance patient care and promote recovery. • Educate the public and influence public policy for the safe and humane treatment of those with substance use disorders. • Promote prevention and enhance addiction treatment and recovery across the lifespan. • Promote research on the etiology, prevention, identification and treatment of substance use and related disorders. (source: http://www.aaap.org/about/mission-statement-2/)
7. Drug and Alcohol Testing Industry Association (DATIA)	• DATIA's mission includes: • To promote the highest possible standards of professionalism and quality control in the drug- and alcohol-testing industry, and develop and oversee education, certification, and accreditation programs for the drug- and alcohol-testing industry; • To serve as the coordinated voice for the industry on regulatory and legislative matters of drug- and alcohol-testing and collection issues as well as drug-free workplace regulatory issues; • To serve as a body for discussion and resolution of common problems and issues affecting the drug- and alcohol-testing industry;

Substance Abuse Organizations Contacted	Organization's Mission
	• To inform its members of issues affecting their businesses through newsletters, legislative alerts, and meetings; • To collect and disseminate information on drug and alcohol service and product providers through a national directory distributed to business and the general public; and, • To actively cooperate with other entities, organizations, and service providers involved with or affected by drug and alcohol testing on common interests and concerns, including, but not limited to, substance abuse professionals, substance abuse program administrators, employee assistance professionals, Medical Review Officers, testing laboratories and employer trade associations. (source: http://www.datia.org/about-datia/mission.html)
Certification Organizations 8. International Certification Reciprocity Consortium (IC&RC)	IC&RC promotes public protection by setting standards and developing exams for credentialing prevention, substance use treatment, and recovery professionals. Organized in 1981, it has a worldwide network of over 50,000 professionals. Quality and integrity are the foundation of IC&RC's work. IC&RC's products use the latest research on evidence-based practices, and they are updated every five years and subjected to an extensive process of peer review. IC&RC standards and exams are used exclusively by IC&RC Boards. Each Board is independently run and operated with their own jurisdictionally specific processes. (source: http://internationalcredentialing.org/)
9. National Board for Certified Counselors, Inc. and Affiliates (NBCC)	The National Board for Certified Counselors, Inc. and Affiliates (NBCC) is a not-for-profit, independent certification organization established in 1982. NBCC's original and primary purposes are to establish and monitor a national certification system, to identify those counselors who have voluntarily sought and obtained certification, and to maintain a register of those counselors. As NBCC has grown, its divisions and affiliates have taken on additional responsibilities to advance the counseling profession and enhance mental health worldwide. Today, there are more than 63,000 National Certified Counselors (NCCs) in more than 40 countries. NCCs have voluntarily met high national standards; these standards, which include passing an examination, have been set by the counseling profession and are based on research. (source: http://www.nbcc.org/About/)
10. American Academy of Healthcare Providers in the Addictive Disorders	Dedicated to advancing certification of treatment providers in the addictive disorders. (source: https://americanacademy.org/)

Substance Abuse Organizations Contacted	Organization's Mission
Research Organizations 11. Center for Substance Abuse Research	The Center for Substance Abuse Research (CESAR), at the University of Maryland at College Park, is dedicated to addressing the problems substance abuse creates for individuals, families, and communities. To this end, the mission of CESAR is to inform policymakers, practitioners, and the general public about substance abuse—its nature and extent, its prevention and treatment, and its relation to other problems. In pursuing its mission, CESAR conducts policy-relevant research and evaluation studies, disseminates statistical and other information, assists in training students in substance abuse research methods and policy analysis, and provides technical assistance to agencies and organizations working in substance abuse related fields (source: http://www.cesar.umd.edu/cesar/about.asp)
12. Pearson Center for Alcohol and Addiction Research (Scripps Institute)	The Pearson Center was established in 2003 through the generosity of a multi-million dollar gift. The Pearson Center combines the latest biomedical research with new clinical treatments to fight the devastating, costly, and deadly disease of alcohol and drug addiction. Alcoholism and addiction are diseases of the spirit, behavior, and the brain. Traditional treatment involves group therapy and other psychological counseling to empower the spirit and address destructive behaviors. The physiology of the brain is often ignored. The Pearson Center is complementing and reinforcing traditional treatments by focusing on the physiological changes in the brain that drive excessive drinking and drug use while creating vulnerability to relapse. Researchers are studying the viability of using novel medications, designed at TSRI and elsewhere, to modulate the neurological effects of alcohol and drugs of abuse, reduce excessive intake, and prevent relapse by normalizing the brain during recovery from alcoholism and addiction. The Scripps Research Institute in La Jolla, California and Jupiter, Florida, is a world leader in the biomedical science of alcoholism, addiction, and the brain. It provides a fertile environment for breakthroughs that will alleviate the suffering of addicted individuals and return them to their families and communities. (source: http://www.pearsoncenter.org/about-us/)
13. Alcohol Research Group (ARG)	ARG was established in 1959 to conduct and disseminate high-quality research in epidemiology of alcohol consumption and problems including AUDs, alcohol-related health services research, and analyses of alcohol policy and its impacts. ARG is home to the National Alcohol Research Center, one of 18

Substance Abuse Organizations Contacted	Organization's Mission
	such centers funded by the US National Institute on Alcohol Abuse and Alcoholism (NIAAA), and is the only one of its kind specializing in the epidemiology of alcohol use and problems. ARG's mission focuses on better understanding the public health implications of alcohol use patterns and associated problems. Additionally, it disseminates these findings, as well as trains future generations of public health researchers to become independent scientists in the field of alcohol studies (source: http://arg.org/about-us/mission-vision-values/).
14. Alcohol Research Center-Treatment and Implications	NIAAA has established a nationwide program of Alcohol Research Centers. The Alcohol Research Centers Program complements and is interrelated with all other research support mechanisms and scientific activities that investigate the causes, diagnosis, treatment, control, prevention, and consequences of alcohol abuse and alcoholism. The Alcohol Research Centers provide long-term support (typically 5 years) for interdisciplinary research that focuses on particular aspects of alcohol abuse, alcoholism, or other related problems. This program encourages outstanding scientists from many disciplines to provide a full range of expertise, approaches, and advanced technologies for developing knowledge in these areas. A primary goal of each NIAAA-funded Center is to become, through excellence in scientific research, a significant regional or national research resource. In addition, each Center affords research training opportunities for individuals from various disciplines and professions (source: http://niaaa.nih.gov/research/major-initiatives/niaaa-funded-research-centers).
15. Rutgers's Center of Alcohol Studies at Rutgers University	The Center of Alcohol Studies (CAS) is known nationally and internationally as a leader in alcohol research, education and training, and documentation and publication of alcohol literature. Marsha E. Bates, Distinguished Research Professor, is Acting Director of CAS. The Center is a multidisciplinary institute dedicated to the acquisition and dissemination of knowledge on psychoactive substance use with a special emphasis on alcohol use and consequences. Center faculty specialize in biochemistry, counseling, education, information sciences, neuropharmacology, neurosciences, physiology, psychology, sociology, and statistics (source http://alcoholstudies.rutgers.edu/).

Appendix B

Questions Regarding Alcohol Diagnosis, Treatment, and Total Abstinence

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Questions Regarding Alcohol Diagnosis, Treatment and Total Abstinence

1. Path into the Program

1.1. Are decisions about an individual's treatment affected by whether they are in a treatment program as a workplace requirement or self-selection? If so, can you point out these differences as we go through our questions?

1.2. Does your program/research deal with individuals in treatment/recovery programs because they violated a workplace alcohol use policy or failed a workplace alcohol test?

1.3. Does your program/research also deal with individuals who are voluntarily seeking help with an alcohol problem?

2. Initial Assessment/ [Diagnosis]

2.1. What approach/diagnostic method is used to assess/diagnose the nature of the problem an individual has with alcohol use? Has this changed recently?

> 2.1.1. What are the main diagnostic categories? What are the primary criteria for/or basis of the diagnostic categories (e.g., dependence vs abuse)? For example, does your program distinguish among individuals in a treatment program because of a one-time poor decision or because they have a well-established problem with alcohol.
>
> 2.1.2. Is there a commonly used/well-established diagnostic method or instrument? How reliable have you found the diagnostic process to be? Are you familiar with any empirical assessments of the diagnostic categories or instruments?

2.2. [In your program/guidelines/research,] how does (or should) the diagnosis regarding the nature or type of an individual's alcohol use disorder/problem affect the recommended or required treatment strategy? If it does, what are the main treatment strategies or programs?

2.3. Does the individual have a say in the goal/approach taken in the program? Do individuals have choices in what program they enter?

2.4. Do you have experience with employee assistance programs, and if so, what is their role in diagnosis and treatment?

3. Treatment

3.1. [In your program] [According to your research/guidelines] Under what circumstances would/should an individual be required (or recommended) to abstain completely from alcohol and for how long?

> 3.1.1. Should [does] abstinence requirements apply to everyone who enters the treatment program or to only to a subset? If a subset, which ones?

3.1.2. How stringent does an individual's alcohol avoidance need to be? Under what circumstances is it appropriate to require/recommend abstinence from the consumption of any product containing ethanol –i.e., beyond drinking of alcoholic beverages? For example, is avoidance of daily use products such as hand sanitizer included? Specialty foods such as desserts made with alcohol?

3.1.3. For how long is abstinence to be maintained?

3.1.4. What is the rationale for requiring abstinence?

3.1.5. Are there any legal or regulatory bases for requiring an individual to abstain completely from alcohol consumption?

3.2. Under what circumstances, if any, would/should/could abstinence not be required or recommended as part of a treatment program?

3.2.1. Are there laws that protect individuals from requirements to abstain from alcohol consumption (as a condition of employment) that affect treatment strategies/programs?

3.3. In your professional opinion, what are the advantages and disadvantages of requiring total abstinence in terms of treatment effectiveness?

3.3.1 Is lifetime total abstinence a goal of your treatment program? What about other programs?

3.3.2 Is success in maintaining total abstinence considered an appropriate measure of treatment effectiveness? What other measures are commonly used to measure treatment effectiveness?

3.3.3 Are there programs whose effectiveness is not predicated on total abstinence? Can you describe these programs and how they are viewed in the industry?

4. Testing: Do you have knowledge about or experience with testing individuals for compliance with a total abstinence from alcohol requirement?

4.1. Could you describe the testing regime?

4.1.1. Type of test (matrix, frequency, metabolite(s) tested for, etc.)

4.1.2. Positive detection cutoff levels

4.1.3. Additional information collected from/about the subject (consumption/activities etc.)

4.1.4. Interpretation of results

4.1.5. Sanctions

4.2. If the program tests for ethyl glucuronide (EtG) could you describe any problems or issues experienced? Is additional test data or other information used in evaluating results such as EtS detection data?

5. Post-Treatment

5.1. Does your program (guidelines/research) recommend that an individual maintain abstinence from alcohol following completion of the treatment program?

5.2. In your experience, are employers requiring individuals to demonstrate continued abstinence from alcohol once they return to work?

6. Professional Standards and Guidelines

6.1. Are there professional guidelines and who issues them? Is there specific guidance regarding total abstinence as a treatment? Is there an entity that sets the professional guidelines for substance abuse experts and treatment professionals?

6.2. Are you familiar with their position (or with professional guidelines) regarding total abstinence as a treatment or requirement for individuals with alcohol problems?

6.2.1. If so, could you tell us: What is the position (or what are the competing positions)? [Can you provide references to documents/guidelines?]

6.2.2. What is the position (or what are the competing positions)? [Can you provide references to documents/guidelines?]

6.3. In your professional opinion, how strong do you think the empirical evidence is supporting or refuting the effectiveness of programs that advocate or require complete abstinence from alcohol consumption:

6.3.1. In helping an individual recover control/change behavior?

6.3.2. In deterring an individual from performing safety-sensitive activities while impaired?

6.3.3. Does the evidence indicate when (or if) abstinence needs to be permanent?

7. Could you recommend others who are knowledgeable about alcohol treatment programs or testing for alcohol abstinence organizations who we could talk to?

Appendix C

Additional Information Regarding DOT Agencies' Alcohol-Testing Programs

Appendix C

Additional Information Regarding DOT Agencies' Alcohol-Testing Programs

Table C-1. DOT Individuals and Agencies Subject to 49 CFR Part 40

Applicable Agency	Applicable Industry	Applicable Safety-Sensitive Positions	Additional Agency Regulations
FAA	Aviation	Flight crew, flight attendants, flight instructors, air traffic controllers at facilities not operated by the FAA or under contract to the U.S. military, aircraft dispatchers, aircraft maintenance or preventative maintenance personnel, ground security coordinators and aviation screeners. Direct or contract employees of 14 CFR Part 121 or 135 certificate holders, Section 91.147 operators and air traffic control facilities not operated by the FAA or under contract to the US military.	Title 14: Aeronautics and Space Subchapter F – Air Traffic and General Operating Rules Part 91.147: Passenger carrying flights for compensation or hire Subchapter G- Air Carriers and Operators for Compensation or Hire: Certification and Operations Part 120: Drug and Alcohol Testing Program Part 121: Operating Requirements: Domestic, Flag, and Supplemental Part 135: Operating requirements: Commuter and on demand operations and rules governing person on board such aircraft
FMCSA	Commercial motor carriers	Commercial driver's license holders who operate commercial motor vehicles, 26,001 lb gross vehicle weight rating or greater, or operate a vehicle that carries 16 passengers or more including the driver, or required to display a DOT placard in the transportation of hazardous material.	Title 49: Transportation Part 382 Controlled Substance and Alcohol Use and Testing
USCG[(a)]	Maritime	Crew members operating a commercial vessel.	Title 46: Shipping Part 4: Marine casualties and investigations Part 16: Chemical testing
PHMSA	Pipeline	Operations, maintenance, and emergency response.	PHMSA regulations Title 49: Transportation Part 199: Drug and Alcohol Testing
FRA	Railroad	Hours of Service Act personnel, engine and train, signal service, or train dispatchers.	FRA regulations: Title 49: Transportation Part 219: Control Drug and Alcohol Use
FTA	Transit	Vehicle operators, controllers, mechanics, and armed security.	FTA regulations 49 CFR Part 655, Prevention of Alcohol Misuse and Prohibited Drug Use in Transit Operations.

(a) Unlike other agencies listed in this table, USCG is not a DOT agency. Only crew members operating commercial vessels are subject to DOT 49 CFR Part 40.

Source: Adapted from DOT (2009), What employees need to know about DOT drug & alcohol testing, p. 1.

Table C-2. Alcohol Test Results and Specific Employer Actions

BAC Level	Employer/Employee Action
BAC < 0.02	None
0.02 ≤ BAC ≤ 0.039	**FMCSA**: Driver not to perform safety-sensitive function until the start of the next regularly scheduled duty period but not less than 24 hours following administration of the test [49 CFR 382.505] **PHMSA**: Employee not to continue performing safety-sensitive function until the individual's BAC is below 0.02 or until the next regularly scheduled tour of duty but not less than 8 hours following administration of the test [49 CFR 199.237, 199.225 (d)] **FRA**: Employee not to continue performing safety-sensitive function until the individual's BAC is below 0.02 or until the next regularly scheduled tour of duty but not less than 8 hours following administration of the test [49 CFR 199.237] **FAA**: Employee must cease performing safety-sensitive function until the individual's BAC is below 0.02 or until the start of the individual's next regularly scheduled duty period, but not less than 8 hours following administration of the test. [14 CFR 120.221(f)] **FTA**: Employee must not to continue performing safety-sensitive function until the individual's BAC is below 0.02 or until the next regularly scheduled tour of duty but not less than 8 hours following administration of the test [49 CFR 655.35, 655.48]
BAC ≥ 0.04	Employer must immediately remove employee from duty or prohibit employee from reporting to duty; employee can return to duty only after successful completion of a return-to-duty evaluation process