THE U.S. NUCLEAR REGULATORY COMMISSION

STAFF TECHNICAL DISCUSSION IN RESPONSE TO NUCLEAR ENERGY INSTITUTE'S

FREQUENTLY ASKED QUESTION (SFAQ-18-01) REGARDING ALCOHOL REPORTABILITY

The Nuclear Energy Institute (NEI) requested (see Enclosure 1) United States (U.S.) Nuclear Regulatory Commission (NRC) staff clarification on what alcohol-related events must be reported to the NRC's Headquarters Operations Center (HOC). The NEI stated that this clarification is necessary because the reporting of such events/occurrences represents an "unnecessary regulatory burden and they are of low regulatory/safety/security significance."

Title 10 of the *Code of Federal Regulations* (10 CFR) Part 26, "Fitness for Duty [FFD] Programs," Section 26.719(b), "Significant FFD policy violations or programmatic failures," requires that the licensees and other entities identified in 10 CFR 26.709, "Applicability," must report to the NRC HOC significant FFD policy violations and programmatic failures by telephone within 24 hours after the licensee or other entity discovers the violation. Section 26.719(b)(1)-(2) requires the reporting of the following alcohol-related events:

(1) The … consumption or presence of alcohol within a protected area [PA].

(2) Any acts by any person licensed under 10 CFR part 55 to operate a power reactor, as well as any acts by SSNM transporters, FFD program personnel, or any supervisory personnel who are authorized under this part, if such acts . . . (iii) Involve the consumption of alcohol within a protected area or while performing the duties that require the individual to be subject to the FFD program.

The purpose of these reporting requirements is, in part, to inform the NRC of alcohol-related events indicative of significant FFD policy violations or programmatic failures such that the NRC may take regulatory action if needed. These 10 CFR 26.719(b) reporting criteria are indicators whether the licensee or other entity is meeting the Part 26 performance objectives in 10 CFR 26.23(a), (b), and (d), which require the FFD program to provide reasonable assurance of the following:

- Individuals are trustworthy and reliable as demonstrated by the avoidance of substance abuse;

- Individuals are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties; and,

- The workplaces subject to Part 26 are free from the presence and effects of illegal drugs and alcohol.

The NRC staff uses the information reported under 10 CFR 26.719, "Reporting requirements," to: monitor licensee program performance; assess events or occurrences that may have root or apparent cause attributed to human impairment; study potential generic safety problems; assess trends and patterns of operational experience; identify precursors to potential degradation in human performance and safety culture work environment; provide operational

experience to the industry; and inform the inspection process, NRC-issued guidance, and NRC decision making.

The NRC staff developed the below guidance to address NEI's request for clarification on what alcohol-related events should be reported to the NRC's HOC. The NEI question as provided in Enclosure 1, and the response and additional guidance below, will be placed on the NRC's public web site under the "Frequently Asked Questions" section of the NRC's FFD programs web page.[1]

Response to NEI Question

> For the purposes of reporting alcohol-related occurrences to the NRC's HOC pursuant to 10 CFR 26.719(b)(1) and (2)(iii):
>
> Licensees should report to the NRC HOC alcohol-related events when they involve a liquid having an alcohol concentration equal to or greater than 0.5 percent alcohol by volume (ABV), as measured by the licensee or other entity, or a container labeled pursuant to the United States Department of the Treasury, Alcohol and Tobacco Tax and Trade Bureau under 27 CFR Part 16, "Alcoholic Beverage Health Warning Label."

Additional Guidance

1. Alcohol is a substance intended for human consumption with a molecular formula of C_2H_5OH. Alcohol is typically in a liquid form and could be named as a liquor, malt, beer, or wine, or used as an ingredient in a marinade, sauce, extract, vinaigrette, seltzer, or sport drink. Alcohol can be infused into a solid (e.g., a cake or confectionery), converted to a powder form, vaporized, and in prescription and over-the-counter medications.

2. An empty can, bottle, box, etc., that has a label indicating that it once contained a consumable product containing at least 0.5 percent ABV and was identified in a PA should be reported to the HOC even if the container is empty. However, if the licensee or other entity determines that the consumable product was not recently used (for example, the container was covered with dust, cobwebs, etc.), the event should not be reported.

3. For consumable products, including over-the-counter and prescription medications, that list alcohol as an ingredient but do not have a Federal alcohol label, licensees and other entities should use their site's internal processes and procedures in determining whether to report these occurrences to the NRC HOC. For example:

    a) If the product container has marketing and labeling information indicating that a consumable product "may" contain alcohol, the event should not be reported to the HOC.

    b) If the product is a food product with a label that states that it does contain alcohol (e.g., mustards, barbeque sauces, salad dressings, red wine or balsamic vinegars) and it was identified in the PA, the event should not be reported to the HOC.

[1] The NRC's FFD programs FAQ web page is located at https://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/faqs.html.

c) Regardless of 3a and 3b above, if the licensee determines that the product contains alcohol and, through behavioral observation or alcohol testing, concludes that the product could or did cause impairment, the event should be reported to the HOC. Examples of these products include, but are not limited to: medications, extracts, alcohol-filled confectionaries, cooking wines, vitamin tonics, dietary supplements, home-made beer, and herbal cleanses.

d) If the alcohol is in a powder or vapor form and was identified, possessed, or used in a PA, the event should be reported to the HOC.

4. Products that use alcohol and are denatured, such as Listerine®, Purell® hand sanitizer, or cosmetics, are not alcohol under 10 CFR Part 26.

NRC Staff Finding and Justification

Summary

The NRC staff finds that reporting of FFD-related events involving alcohol concentrations of less than 0.5 percent ABV is not necessary because: (1) the Federal government considers 0.5 percent ABV to be the threshold associated with impairment as evidenced by the Federal government-required alcohol warning label; (2) events associated with the use or possession of consumable products containing less than 0.5 percent ABV are not safety or security significant; (3) the reporting of these events is not consistent with the safety, security, or regulatory significance of other NRC-required reporting (recording) requirements; (4) licensees and other entities are required to implement corrective actions and the NRC implements a graded regulatory response to site events and performance issues involving the use or possession of consumable products containing less than 0.5 percent ABV; and, (5) reporting of these events represents an unnecessary regulatory burden on the NRC, licensees, and other entities subject to Part 26.

The guidance provided is based on codified requirements established by other Federal agencies. Additionally, the issuance of guidance helps provide consistency in the reporting of alcohol-related events to the NRC HOC.

Basis for a 0.5 Percent Alcohol by Volume Reporting Threshold

The NRC's regulations and guidance do not define the term "alcohol." As a result, the NRC staff reviewed the regulations issued by other Federal agencies to inform its guidance on what constitutes alcohol for purposes of the Part 26 requirements.

The U.S. Food and Drug Administration, in Title 21, "Food and Drugs," of the CFR, Part 328, "Over-the-counter Drug Products Intended for Oral Ingestion that Contain Alcohol," Section 328.3, "Definitions," defines "alcohol" to mean "the substance known as ethanol, ethyl alcohol, or alcohol, [U.S. Pharmacopeia Convention]." Section 40.3, "What do the terms used in this part mean?" of the U.S. Department of Transportation's regulations in Title 49, "Transportation," of the CFR, Part 40, "Procedures for Transportation Workplace Drug and Alcohol Testing Programs," defines "alcohol" as "[t]he intoxicating agent in beverage alcohol, ethyl alcohol or other low molecular weight alcohols, including methyl and isopropyl alcohol." This section also states that "alcohol use" means "[t]he drinking or swallowing of any beverage, liquid mixture or preparation (including any medication), containing alcohol."

Consistent with these definitions, alcohol, as that term is used in Part 26, is ethyl alcohol, also called ethanol, grain, or drinking alcohol, with a linear formula of C_2H_5OH (including ethanol solutions of CH_3CH_2OH). But the NRC staff also noted that the amount of alcohol a product contains will determine how the Federal government treats that product. To determine how the NRC should treat these products, the staff began by looking at Congressional findings and requirements.

Title 27, "Intoxicating Liquors," of the United States Code (U.S.C.), Chapter 8, "Federal Alcohol Administration Act," Subchapter II, "Alcoholic Beverage Labeling," provides the Congressional authority for requiring warning labels on containers of alcoholic beverages. Section 213, "Declaration of policy and purpose," of Title 27 states that "Congress finds that the American public should be informed about the health hazards that may result from the consumption or abuse of alcoholic beverages" and "that requiring such [Federally-required labeling] on all containers of alcoholic beverages is appropriate and necessary in view of the substantial role of the Federal Government in promoting the health and safety of the Nation's population." Section 214, "Definitions," defines the following terms:

- "alcoholic beverage" includes any beverage in liquid form which contains not less than one-half of one percent of alcohol by volume and is intended for human consumption.

- "health" includes, but is not limited to, the prevention of accidents.

Section 215 requires that any container containing an alcoholic beverage must bear the following statement:

> GOVERNMENT WARNING:
> (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects.
> (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.

These provisions are reflected in the Alcohol and Tobacco Tax and Trade Bureau's regulations in 27 CFR Part 16 as:

- Section 16.10, "Meaning of terms." "Alcoholic beverage. Includes any beverage in liquid form which contains not less than one-half of one percent (.5%) of alcohol by volume and is intended for human consumption."

- Section 16.21, "Mandatory label information." "There shall be stated on the brand label or separate front label, or on a back or side label, separate and apart from all other information, the following statement:

> GOVERNMENT WARNING:
> (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects.
> (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems."

Based on the above Federal requirements, the NRC staff finds that the use of a 0.5 percent ABV reporting threshold is consistent with the Federal government concern regarding the consumption of alcohol beverages and its impairing effect on an individual's ability to drive a car, operate machinery, and, through its definition of "health," prevent accidents.

Safety and Security Significance

Events involving the identification or consumption of consumable products containing less than 0.5 percent ABV are of low safety and security significance. The principal reason for this conclusion is that, consistent with the Federal government's definition of "alcoholic beverage" and its threshold for requiring a warning label on a container containing an alcoholic beverage, the NRC does not consider the consumption of a product containing less than 0.5 percent ABV to raise impairment concerns. Furthermore, the NRC staff does not consider it reasonable to find that an individual who maintains unescorted access to NRC-licensed facilities will ingest consumer products containing less than 0.5 percent ABV to such an extent that: (1) the individual becomes impaired and (2) the individual causes a condition adverse to public health and safety or the common defense and security in a manner that warrants an immediate regulatory action that is comparable to the events listed in the section below titled "Relative Significance of Alcohol-related Reportable Events." This finding is supported by the relative lack of alcohol-related events causing significant safety or security concerns that had a root or contributing cause attributed to the possession or consumption of alcohol.[2]

On the other hand, an individual who is subject to Part 26 and is impaired or can become impaired because the product he or she is ingesting contains 0.5 percent ABV or more, raises safety and/or security significant concerns because impairment can result in a loss of motor skills or mental faculty leading to errors of omission or commission during facility operation, maintenance, surveillance, construction and quality controls. Such a situation also indicates that the individual is not trustworthy and reliable and therefore cannot be granted unescorted access to the facility, special nuclear materials, or sensitive information without treatment and a subsequent access authorization determination. Additionally, should the possession or consumption of alcohol become prevalent in the work force, this could be indicative of a human performance or safety culture concern at the site.

Relative Significance of Alcohol-related Reportable Events

The NRC's regulations contain many requirements directing licensees and other entities to report a safety and/or security significant condition or occurrence to the NRC. The NRC staff reviewed some of these other reporting requirements to inform its guidance on the reporting of events involving alcohol below 0.5 percent ABV to the NRC within 24 hours. Examples of reportable events can be found in the following requirements:

- Section 50.9(b) establishes a two working-day period for notifying the Administrator of the appropriate NRC Regional Office of information having a significant implication for public health and safety or common defense and security.

- Section 50.72 establishes an 8-hour reporting requirement for a principal safety barrier being degraded or nuclear power plant being in an unanalyzed condition that significantly degrades plant safety.

[2] See the NRC's annual FFD performance reports listed here: https://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/performance-reports.html.

- Section 20.2202 establishes a 24-hour reporting requirement regarding the loss of radioactive material that caused or threatened to cause a radiation exposure in excess of an NRC regulatory limit.

- Section 37.81(b) requires either a 4-hour or 24-hour report when a Category 2 quantity of radioactive material is identified as being lost or missing and remains lost or missing, respectively.

- Section Part 73, Appendix G, requires the licensee to record in its safeguards event log, within 24 hours, when a safeguards vulnerability allowed unauthorized or undetected access to a protected area, material access area, controlled access area, vital area, or during transport of special nuclear material.

When compared to the above reportable (recordable) events or a Part 26 programmatic failure (such as allowing individuals into the PA without being drug or alcohol tested or escorted), an event involving alcohol below 0.5 percent ABV is not a significant FFD policy violation or programmatic failure warranting a 24-hour report to the HOC. As explained in the "Safety and Security Significance" section above, the possession or consumption of a liquid (or food product) that contains less than 0.5% ABV does not, by itself, cause a safety or security concern. In contrast, the safety and/or security significance of the above-mentioned events warrants reporting or recording within 24 hours or notifying the NRC within two days, as applicable.

Licensee and Other Entity Corrective Actions and NRC Response to Alcohol-related Events

As described in the NRC's Inspection Manual Chapter 2201, "Security Inspection Program for Operating Commercial Nuclear Power Reactors," and other inspection manuals used for inspection at Category I fuel cycle facilities and commercial power reactors that are being constructed, the NRC implements a graded regulatory response to alcohol-related events that are reported to the HOC under 10 CFR 26.719(b). This response (typically inspection) is based on the safety or security significance of the information reported. For reportable events, licensees and other entities typically, and voluntarily, inform the onsite resident inspector. Also, NRC regional and headquarters personnel review the reported information and any past occurrences that are similar in nature that have occurred at the site. For events that appear relatively complex, recurrent, or significant, the resident inspector and/or the NRC inspectors may query the licensee to better understand the event and any corrective actions the licensee proposes to take or has taken, and then may review the event at the next scheduled FFD site inspection. For events involving NRC-licensed operators, NRC staff associated with the 10 CFR Part 55 licensed operator program assess any changes to the individual's Part 55 medical restrictions. For any event, the NRC retains authority to conduct an immediate and/or unannounced inspection of the facility.

Although licensees should not report FFD-related events involving alcohol concentrations of less than 0.5 percent ABV, these events can be captured in other ways. All licensees and other entities identified in 10 CFR 26.709 are required to document, trend, and correct non-reportable indicators of FFD performance weaknesses (10 CFR 26.719(d)); collect FFD program performance data, including management actions (10 CFR 26.717(b)(8)); and analyze FFD performance data and act to correct any identified program weakness (10 CFR 26.717(c)). Licensees and other entities are also required to act to remove individuals from assigned duties and responsibilities when they are in violation of the site's FFD policy or are impaired or not

trustworthy and reliable for reasons other than substance use or abuse (e.g., 10 CFR 26.69(f), 10 CFR 26.75 and 10 CFR 26.77). When supervisors or NRC-licensed operators are identified in violation of the FFD policy, it is also a matter of routine for the licensee or other entity to review the direction provided and/or work performed by the individual to ascertain whether recent activities were safe and secure. For example, this review could provide assurance that latent or apparent failures have not been introduced into a structure, system, or component.

Burden

The NRC staff has determined that that the approximate amount of time for a licensee to report an event involving alcohol at a concentration of less than 0.5 percent ABV to the HOC and the amount of time for the NRC staff to receive, record, and assess the provided information is not commensurate with the low safety or security significance of the event.

As indicated in Table 1 below, the licensee burden to report an alcohol-related event to the NRC HOC involving alcohol at a concentration of less than 0.5 percent ABV is approximately 330 minutes and the resulting burden on the NRC staff is about 105 minutes. This licensee reporting/recordkeeping burden is larger than the generic 240 minutes used in the NRC's triennial report to the U.S. Office of Management and Budget, which details the burden associated with 10 CFR Part 26 reporting and recordkeeping requirements. This occurs because the alcohol-related reportable event burden in column 3 of Table 1 accounts for licensee implementation of voluntary actions to communicate, administer, and process a reportable event. For example, licensees will often require multiple levels of review and concurrence, beyond any NRC requirements, to ensure the quality and accuracy of licensee-reported information.

TABLE 1: BURDEN ESTIMATE

NRC Staff 105 minutes	OMB Collection 240 minutes	Licensee 330 minutes
- -	Reportability Review 60 minutes Trade/1st level management review (2 persons, 30 minutes each) 60 minutes Divisional management review (2 persons, 30 minutes each) 30 minutes FFD program management (1 person, 15 minutes) 30 minutes Shift Technical Advisor, Reactor Operator, and Senior Reactor Operator reviews (total) 30 minutes Control Room paperwork	Reportability Review 60 minutes Trade/1st level management review (2 persons, 30 minutes each) 90 minutes Divisional management review (3 persons, 30 minutes each) 30 minutes FFD program management (2 persons, 15 minutes each) 30 minutes Shift Technical Advisor, Reactor Operator, and Senior Reactor Operator reviews (total) 30 minutes Control Room paperwork
Licensee informs NRC Inspectors 10 minutes Inform Resident Inspector 20 minutes Typically inform regional inspector	- -	Licensee informs NRC Inspectors 10 minutes Informs Resident Inspector 20 minutes Typically informs regional inspector
HOC receipt of Information 15 minutes Telephone call & documentation 5 minutes Peer review 5 minutes Notify Manager-on-Call	Notification to HOC 10 minutes Telephone call 20 minutes Paperwork closeout	Notification to HOC 10 minutes Telephone call 20 minutes Paperwork closeout
NRC Management Review 20 minutes Morning briefing/reading (20 persons, 1 min. each)	- -	Licensee Management Post-Report Actions 30 minutes Post-report actions
NRC Staff Time 15 minutes Entry into NRC database, and technical assessment 15 minutes Inter-Office coordination	- -	- -