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[Notices]
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DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[FRA Docket No. 2001-11212, Notice No. 1]
RIN 2130-AA81

Alcohol/Drug Regulations: Temporary Post-Accident Blood Testing Procedures

AGENCY: Federal Railroad Administration (FRA)

ACTION: Notice.

SUMMARY: Some of the existing FRA post-accident toxicology testing (PATT) kits contain blood tubes with expiration dates ranging from December 2001 to May 2002. These expiration dates refer only to the vacuum used in the tubes to draw blood. The replacement blood tubes that are currently available will also expire in a few months. For this reason, FRA will delay replacement of the expiring tubes until completely new lots of 18-24 month blood tubes become available in early 2002.

This notice explains the procedures to be followed until the replacement of these expiring blood tubes is complete. These temporary procedures will not compromise either the quality or integrity of any test results.

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Background

Since 1986, FRA has included Vacutainer brand 10 milliliter (mL) evacuated blood collection tubes, manufactured by Becton Dickinson (Becton), in its post-accident toxicology testing (post-accident) kits. Each of the three individual post-accident kits in a post-accident toxicology testing box contains two Vacutainer brand ``grey-top'' glass tubes. These tubes, which have no interior coating, contain silicone, a rubber stopper lubricant; sodium fluoride, an antibacterial agent and mild anticoagulant; and potassium oxalate, an anticoagulant. As explained below, grey-top tubes are the only commercial blood collection tubes generally available that contain sodium fluoride in the preferred concentration and are FRA's tubes of choice for FRA post-accident testing.

On each tube, Becton has printed an expiration date, the date until which it warrants that the tube has sufficient vacuum to draw blood. Becton normally releases its blood tubes in lots which expire within 18-24 months of manufacture.

Many of the post-accident kits that have been distributed to railroads contain blood tubes that will expire in the next few months from November 2001 to May 2002. The replacement blood tube lots that are now available have only a few months remaining before their warranted vacuum capability expires. FRA has therefore decided to delay tube replacement until newly prepared 18-24 month blood tubes become available in early 2002.

Interim Procedures

Until the current inventory of blood tubes in the field is replaced in early 2002, FRA authorizes railroads to instruct local medical personnel to replace the expired tubes with their own stock of unexpired 10 mL, preferably grey-top, tubes. Substituted tubes must be 10 mL, not the 5 mL type, to ensure sufficient blood for analysis. This action is requested, but not required, and need only be considered when expired tubes are discovered during an actual post-accident collection. Medical facilities maintain supplies of grey-top and other color top vacuum tubes for clinical purposes. Tube replacement is always preferred to using expired tubes, but, if tube replacement is not possible, railroads are authorized to complete the post-accident collection using the expired blood tubes.

This procedure will not lead to an employee being subject to venipuncture more than once during a post-accident collection procedure. To draw blood specimens, a phlebotomist uses a single needle system that permits filling of more than one tube from the same needle unit. Use of an older grey-top tube may result in collecting a smaller specimen amount in that particular tube, but only if the vacuum in the tube, which is the differential between the tube's internal pressure and the atmospheric pressure, has been significantly reduced. If this should happen, the blood collector will simply replace that blood tube with a new tube; no new puncture is necessary.

Scientific and Technical Issues

Although FRA's interim procedures require railroads to replace expired blood tubes with unexpired tubes if possible, the use of an expired blood tube will not adversely affect employee rights or impact the validity of post-accident test results. FRA's post-accident testing program incorporates testing and analysis protocols designed to protect employees from unwarranted accusations of alcohol or drug use.

Discussed below are the two primary scientific and technical issues concerning the use of expired tubes: (1) The integrity of the vacuum present in the tube to draw blood properly, and (2) the potency of the chemical additives.

Evacuated blood tubes that have recently expired (i.e., within the past several months) are not expected to show a dramatic decrease in tube vacuum. Until its expiration date, each grey-top blood tube is warranted by Becton to have 90% or more of its vacuum remaining at an estimated deterioration rate of no greater than 5% per year. This loss of vacuum would affect only the efficiency of the medical professional's ability to draw a blood specimen. If a particular tube draws inefficiently due to lack of vacuum, a medical professional would ordinarily discard it and use another grey-top (or other color top) tube.

Since they are inorganic compounds, the preservatives found in the tubes, sodium fluoride and potassium oxalate, oxidize very slowly and even in a vacuum-decreasing environment, are unlikely to deteriorate significantly for many years. More importantly, there is no possibility that a ``false positive'' for any drug or its metabolites could occur because of an expired blood tube either from vaccum problems or from deteriorated preservatives.

The presence or absence of the chemical additives contained in grey-top tubes does not affect the detection of any of the drugs tested for in FRA's post-accident testing panel, with the exception of parent cocaine. Sodium fluoride in the grey-top tube contributes to the detectability of parent cocaine in blood, by helping to stabilize the spontaneous conversion of the parent drug in vitro to cocaine metabolites. The concentration (or absence) of parent cocaine is helpful principally in detecting recency of use.

Grey-top tubes are also helpful in conducting the alcohol analysis. Sodium fluoride is widely established as an effective antimicrobial agent in retarding endogenous alcohol production. The production

of ethyl alcohol in the body is a well known phenomenon, especially in post-mortem samples. In the presence of certain contaminating microorganisms and extreme conditions, alcohol identical to that found in alcoholic beverages may be created by the body after death, causing alcohol to appear in certain body fluids and/or tissues without having been ingested. Obviously, endogenous production of alcohol is of concern in the post-accident alcohol testing of both surviving and deceased crew members.

In FRA's post-accident testing, there have been several cases where, given severe trauma and the correct environmental factors, alcohol was produced post-mortem in detectable amounts, even in the presence of fully potent sodium fluoride. Using grey-topped tubes helps in this determination, but FRA has taken and will continue to take whatever scientific and technical steps are necessary to protect post-accident specimen donors from an incorrect interpretation of a positive test result. Among the procedures used by FRA to rule out an alcohol positive on a deceased employee as coming from endogenous production are: examining other tissues or fluids (i.e. urine, brain, vitreous) which may have been protected from trauma or decomposition; determining that the distribution of alcohol in the various body fluids and tissues is inconsistent with that expected in a living person; detecting the presence of other volatiles or physiological byproducts which can sometimes also be present during post-mortem decomposition; repeating analyses of a specimen kept at room temperature to determine if the alcohol concentration is increasing; and determining the identity of any microorganisms present to assess whether they have alcohol-producing capability.

Authority: 49 U.S.C. 20103, 20107, 20111, 20112, 20113, 20140, 21301, 21304, and 49 CFR 1.49(m).

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