



Interim Audit Guideline

Interim Audit Guidelines are interpretive statements issued by the Department of Revenue under authority of RCW 34.05.230. These guidelines explain the Department's policy regarding how tax law applies to a specific issue or specific set of facts and are intended to communicate timely guidance of tax issues important to the public and agency staff where no published guidance exists. They are advisory for taxpayers; however, the Department is bound by these guidelines until superseded by Court action, Legislative action, rule adoption, or an amendment to or cancellation of the interim audit guideline.

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This interpretive statement has been cancelled effective June 30, 2005. The information has been incorporated in an Excise Tax Advisory.

Taxability of Reagents, Controls, and Calibrators

The Revised Code of Washington (RCW) 82.08.0281 exempts sales of "prescription drugs" from retail sales tax. (The corresponding use tax exemption is found under RCW 82.12.0275.) The statute provides in part, "The term 'prescription drugs' shall include any medicine, drug, prescription lens, or other substance other than food for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or other ailment in humans or for use for family planning purposes, including the prevention of conception" The retail sales tax exemption provided by the statute applies under certain conditions to materials, solutions, or other preparations used in conjunction with the test of patient specimens in a medical laboratory.

The Department adopted Washington Administrative Code (WAC) 458-20-18801 (Rule 18801) to implement the prescription drug exemption. It provides in subsection (1)(c), that "other substances" include diagnostic substances and reagents, including prepared slides, tubes and collection specimen devices which contain diagnostic substances and reagents at the time of purchase by a laboratory. However, plain glass slides, plain specimen collection devices, and similar items used in the laboratory are not entitled to the exemption."

Reagents and other Diagnostic Substances

Rule 18801(5)(c) states in part, "laboratory reagents and other diagnostic substances are exempt from retail sales tax when used as part of a test prescribed to diagnose disease in humans." The Department has interpreted the term, "laboratory reagents and other diagnostic substances" to mean substances employed to produce a chemical reaction in order to detect, measure, produce, etc., other substances. In order to be a diagnostic substance, the application of the substance to a specimen must result in the identification of the characteristics of a particular disease. Hence, the *function* of a substance determines its taxability.

Examples of the laboratory reagents and other diagnostic substances that qualify for the retail sales or use tax exemption:

- Stains, dyes, and decolorizers that react with and cause a change in a cellular tissue. These substances are often used to stain the cell tissues in a manner that will mark, or highlight, certain portions of cells.

- Fixatives, decalcifying solution, dehydrating solution, and clearing reagents that chemically react with the specimen.

Examples of the laboratory reagents and other diagnostic substances that qualify for the retail sales or use tax exemption (cont.):

- Test strips impregnated with a reagent which when applied to a patient's specimen test for indicators of a disease.
- Glass test tubes/cylinders with a vacuum containing reagents or medicines, and prepared media.

Some substances are used solely for the purpose of preparing specimens for examination and diagnosis or facilitating examination of a specimen. Such substances do not themselves produce a chemical reaction resulting in the detection, measurement, or production of another substance. They merely facilitate or enable specimen testing and are not exempt under RCW 82.08.0281 and/or Rule 18801.

The following items are not reagents because they are not substances that chemically react with the specimen.

- Paraffin that is extracted from a tissue specimen without having chemically altered the cells.
- Gelatin that is extracted out of the specimen before staining, and leaves the cell structures unaffected.
- Electrodes.
- Tissue cassettes.
- Freezing medium.
- Liquid agar when used to gel patient specimen.
- Glass test tubes/cylinders that do not contain a reagent.
- Plain slides and cover slips that do not or are not coated with a reagent.
- Mounting medium to adhere the cover slip to the slide.
- Acids and other solutions when used for cleaning purposes.

Certain substances may have multiple uses

- Alcohol, for example, can be used either as a reagent (e.g. to react with a cellular tissue) or to clean counters, furniture, etc. Alcohol, if used as a cleaning agent, is subject to sales or use tax.
- Ammonium Hydroxide, if used as a cleaning agent, is subject to sales or use tax.
- Periodic Acid, if used for cleaning purposes, is subject to sales or use tax.
- Ethyl Ether may or may not be subject to sales or use tax as a reagent depending on its use.

Such substances are exempt only to the extent they are used as part of a test prescribed to diagnose disease in humans.

Controls

“Control” means a material, solution, lyophilized (freeze-dried) preparation, or pool of collected serum designed to be used in the process of quality control. The concentrations of the substances of interest in the control are known within limits ascertained during its preparation or before routine use. Controls are generally used with each test of patient specimens to validate the accuracy of that particular test. The sales of controls are not subject to sales tax when used in laboratory machines as part of a test prescribed by a medical practitioner for diagnosis of disease in humans. They are exempt because a part of the control is used to verify the accuracy of the lab machine test for each patient specimen run with a test.

Calibrators

“Calibrator” means a material, solution, or lyophilized (freeze-dried) preparation designed to be used in calibration of medical laboratory machines. The values or concentrations of the substances of interest in the calibration material are known within limits ascertained during its preparation or before use. Calibrators are generally used at specified intervals such as every eight hours, at midnight, or at shift changes, in accordance with the machine manufacturer’s requirements or the requirements of administering agencies to verify the accuracy of the machine. The reagents for the calibration of equipment are exempt from retail sales or use tax if the equipment is calibrated as part of tests for a specific patient. Reagents used to calibrate equipment that is not part of a prescribed test for a patient are taxable.

Reagent Kits

A reagent kit may include various items/substances necessary for performing a particular test prescribed by a medical practitioner. It may contain items that qualify for the tax exemption as well as others that do not. To determine taxability:

- (1) Analyze the taxability of the kit’s components.
- (2) If the primary components are exempt, the entire kit is exempt from taxation.
- (3) If the primary components are taxable, the entire kit is subject to sales or use tax.

Standards

“Standard” means a reference material of fixed known chemical composition capable of being prepared in essentially pure form or any certified reference material generally accepted or officially recognized as the unique standard used to test and calibrate medical lab equipment. Standards are often used in the original setup of medical lab equipment. It is the Department’s policy that sales of standards are subject to sales tax even if used at the same time a test is performed on patient specimen.

Transport Media

Transport media are systems that are used to preserve the specimens while in transport to the lab. Such systems may contain prepared or culture medium to grow microorganisms from patient’s specimens. Rule 18801(5)(c) provides that “prepared media” are considered exempt as “other diagnostic substances” when used as part of a test prescribed to diagnose disease in humans. If the resulting culture grown on the medium were used in performing diagnostic tests prescribed for specific patients, then the transport systems would be exempt.
