

PRELIMINARY TEXT

THE PRELIMINARY TEXT OF THE PROPOSED RULE IS:

**64-4.209 Low-THC and Medical Marijuana Solvent Based Extraction and Related Products**

(1) The following definitions are applicable to this rule:

(a) “Closed Loop System” means an extraction system sealed during operation and designed to recover all Solvents used during the extraction process through a feedback loop.

(b) “Hydrocarbon Solvent” means N-butane, isobutane, propane, pentane, heptane, or any isomer or combination thereof.

(c) “Organic Solvent” means a carbon-based substance, that is liquid at room temperature, is capable of dissolving or dispersing one or more substances, and is identified as a class 3 Solvent by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, “Impurities: Guidelines for Residual Solvents Q3C(R6)” incorporated by reference herein and available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>.

(d) “Solvent” means any substance capable of dissolving or dispersing one or more other substances.

(2) Except as provided for in subsection (14), prior to processing with any Solvent, an MMTC must submit the following to the department via email to [OMMULicenseOperation@flhealth.gov](mailto:OMMULicenseOperation@flhealth.gov):

(a) A completed Form DHXXXX-OMMU-XX/2021, Request for Inspection, which is incorporated by reference and available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>;

(b) The certification from a licensed engineer required by paragraphs (6)(d) and (e), (7)(d) and (e), as applicable;

(c) Evidence from a local fire code official that the MMTC has passed the inspection required by subsection (9);  
and

(d) Standard operating procedures, including employee training plans, as required by subsection (12).

(3) An MMTC may not begin processing with any Solvent prior to receiving written notice of approval from the department.

(4) All Solvents used for extraction must be:

(a) A minimum purity of 99.5% with a certificate of analysis from the manufacturer to confirm purity;

(b) Free of odorants, bitterants, or other additives; and

(c) Stored, handled, and disposed of according to local, state, and federal regulations.

29 (5) Any Solvent based extraction must be conducted in an MMTC's department-approved processing facility that  
30 has passed a Food Safety Good Manufacturing Practices inspection in accordance with s. 381.986(8)(e)9., F.S.

31 (6) The following provisions are applicable to Hydrocarbon Solvent extraction.

32 (a) Extraction must be performed in a commercially manufactured Closed Loop System.

33 (b) Every vessel within the system must be rated to at least 125% of the maximum pressure specified in the  
34 manufactures maximum operational limits, not to exceed 10,000 psi.

35 (c) All vessels must be fitted with an emergency pressure release system vented to the atmosphere.

36 (d) An engineer, licensed pursuant to chapter 471, F.S., must certify that the system was commercially  
37 manufactured, safe for its intended use, and built to codes of recognized and generally accepted good engineering  
38 practices, such as American Society of Mechanical Engineers (ASME); American National Standards Institute  
39 (ANSI); Underwriters Laboratories (UL); or the American Society for Testing and Materials (ASTM).

40 (e) The certification must contain the signature and seal of the certifying engineer, the serial number of the  
41 extraction unit being certified, and the name of MMTC which will be using the extraction unit.

42 (f) All pressure vessels must be in compliance with section VIII, division 1 of the ASME Boiler and Pressure  
43 Vessel Code (BPVC) incorporated by reference herein. The department has determined that posting the incorporated  
44 material on the internet would constitute a violation of the federal copyright law. The materials incorporated herein  
45 have been deemed copyright protected and are available for inspection at the Department of Health, 2585 Merchants  
46 Row Boulevard, Tallahassee, Florida 32399-1710, or at the Department of State, R.A. Gray Building, 500 South  
47 Bronough Street, Tallahassee, Florida 32399-0250.

48 (g) All extraction facilities must be in compliance with National Fire Prevention Association (NFPA) 1, chapter  
49 38.6.2 and NFPA 55, which are both incorporated by reference herein. The department has determined that posting  
50 the incorporated material on the internet would constitute a violation of the federal copyright law. The materials  
51 incorporated herein have been deemed copyright protected and are available for inspection at the Department of  
52 Health, 2585 Merchants Row Boulevard, Tallahassee, Florida 32399-1710, or at the Department of State, R.A. Gray  
53 Building, 500 South Bronough Street, Tallahassee, Florida 32399-0250.

54 (7) The following provisions are applicable to liquid and supercritical carbon dioxide extraction.

55 (a) Extraction must be performed in a commercially manufactured Closed Loop System.

56 (b) Every vessel within the system must be rated to at least 125% of the maximum pressure specified in the  
57 manufactures maximum operational limits, not to exceed 10,000 psi.

58 (c) All vessels must be fitted with an emergency pressure release system vented to the atmosphere.

59 (d) An engineer, licensed pursuant to chapter 471, F.S., must certify that the system was commercially  
60 manufactured, safe for its intended use, and built to codes of recognized and generally accepted good engineering  
61 practices, such as American Society of Mechanical Engineers (ASME); American National Standards Institute  
62 (ANSI); Underwriters Laboratories (UL); or the American Society for Testing and Materials (ASTM).

63 (e) The certification must contain the signature and seal of a professional engineer, the serial number of the  
64 extraction unit being certified, and the name of the MMTC which will be using the extraction unit.

65 (f) All pressure vessels must be in compliance with section VIII, division 1 of the ASME BPVC.

66 (g) All extraction facilities must be in compliance with NFPA 1, chapter 38.6.4, which is incorporated by  
67 reference herein. The department has determined that posting the incorporated material on the internet would  
68 constitute a violation of the federal copyright law. The materials incorporated herein have been deemed copyright  
69 protected and are available for inspection at the Department of Health, 2585 Merchants Row Boulevard, Tallahassee,  
70 Florida 32399-1710, or at the Department of State, R.A. Gray Building, 500 South Bronough Street, Tallahassee,  
71 Florida 32399-0250.

72 (8) The following provisions are applicable to Organic Solvent extraction.

73 (a) Extraction must be performed in a commercially manufactured Closed Loop System under a maximum  
74 operational pressure of 15 psi.

75 (b) All extraction facilities must be in compliance with NFPA 1, chapter 38.6.3 and NFPA 30, which are both  
76 incorporated by reference herein. The department has determined that posting the incorporated material on the internet  
77 would constitute a violation of the federal copyright law. The materials incorporated herein have been deemed  
78 copyright protected and are available for inspection at the Department of Health, 2585 Merchants Row Boulevard,  
79 Tallahassee, Florida 32399-1710, or at the Department of State, R.A. Gray Building, 500 South Bronough Street,  
80 Tallahassee, Florida 32399-0250.

81 (9) The processing facilities and all equipment used for Solvent-based extractions, must be approved for their  
82 use and inspected prior to department approval, and at a minimum biennially thereafter, by local fire code official and  
83 meet any required fire, safety, and building code requirements specified in the Florida Fire Prevention Code (FFPC),

84 NFPA 1 Fire Code, and other applicable standards, including any applicable fire, safety, and building codes in the  
85 processing, handling, and storage of Solvents.

86 (9) The storage, handling, and disposal of any Solvent, or other liquid chemical used in processing or on the  
87 approved premises must comply with NFPA 30.

88 (10) The storage, handling, and disposal of any gas or liquified gas used in processing or on the licensed premises  
89 must comply with NFPA 55.

90 (11) The disposal of all marijuana waste must comply with Rule 64-4.207, F.A.C. Nothing herein is intended to  
91 relieve an MMTC of its obligation to comply with applicable federal and state laws and regulations for solid and liquid  
92 wastes, as required by s. 381.986(8)(e), F.S.

93 (12) An MMTC must create and maintain written detailed standard operating procedures for the safety and  
94 operation of all extraction equipment within manufacture equipment safety specifications. All employees performing  
95 any extraction must be trained on these standard operating procedures prior to performing extractions.

96 (13) An MMTC may not alter any commercially manufactured extraction equipment. Any alterations to extraction  
97 equipment must be performed by the equipment manufacturer.

98 (a) Any alteration must be inspected by an engineer, licensed pursuant to chapter 471, F.S., and certified as built  
99 to codes of recognized and generally accepted good engineering practices, such as American Society of Mechanical  
100 Engineers (ASME); American National Standards Institute (ANSI); Underwriters Laboratories (UL); or the American  
101 Society for Testing and Materials (ASTM).

102 (b) The certification must contain the signature and seal of a professional engineer, the serial number of the  
103 extraction unit being certified, and the name of the MMTC which will be using the extraction unit.

104 (14) MMTCs that are currently using carbon dioxide or Organic Solvents for extractions have 6 months from the  
105 effective date of this rule to comply with the applicable requirements herein.

106 (15) Prior to December 31, 2026, the department shall review this rule and amend, modify or repeal the rule if it  
107 is determined to create barriers to entry for private business competition, is duplicative, outdated, obsolete, overly  
108 burdensome, or imposes excessive costs. In the event the department fails to complete this rule review, the department  
109 shall begin the rule repeal process in accordance with chapter 120, F.S.

110 Rulemaking Authority 381.986(8)(e)11. b., 381.986(8)(k), FS. Law Implemented 381.986(8)(e)11. b., FS. History –  
111 New.